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INSIDE

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'Dr. Death' Case Holds Lessons for Risk Managers, Hospitals

The extraordinary case of a neurosurgeon who was so poorly vetted by hospitals that he critically injured dozens of patients and was blamed for two deaths in a short time is receiving renewed attention in true crime podcasts and an upcoming TV series. Risk managers should take the opportunity to learn how to avoid a repeat of the tragic series of events.

Christopher Duntsch, MD, PhD, practiced medicine in Dallas for two years and operated on 37 patients. Thirty-three were injured, and some of the complications were almost unheard of for that type of procedure, explains **Michael P. Lyons**, JD, founding partner of Lyons & Simmons in Dallas. Lyons represented one of the injured patients.

> FUNDAMENTAL FAILURES OF THE VETTING PROCESS AND REPORTING CONCERNS ABOUT DUNTSCH'S PERFORMANCE OCCURRED.

At least two hospitals quietly ended Duntsch's privileges but did not report him to the National Practitioner Data Bank (NPDB), Lyons says.

Duntsch's string of failures came to the attention of local authorities, mostly through the efforts of plaintiffs' attorneys and other concerned physicians. He was charged with five counts of aggravated assault with a deadly weapon — his surgical tools — and one count of injury to an elderly individual. After his July 2015 arrest, the media dubbed him "Dr. Death."

The trial included extensive testimony and other evidence about Duntsch's incompetence as a neurosurgeon, with expert witnesses testifying that his performance failures were so extreme as to go beyond mere errors and indicate

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someone who was not qualified to perform surgery at all.

One surgeon was so bothered by what he saw that he took Duntsch's surgical tools from him in the middle of an operation. Duntsch did not appear to even understand regional anatomy, Lyons says. Some fellow surgeons worried that he was a complete imposter, not a doctor at all.

Eventually, Duntsch's medical license was revoked. Duntsch was convicted of the criminal count of injury to an elderly individual and became the first doctor in the United States to be sentenced to life in prison for his practice of medicine. He is currently imprisoned in Huntsville, TX, and will be eligible for parole in 2045 at age 74 years.

Many Fooled by Credentials

Duntsch seemed to possess impressive credentials when the first hospital privileged him in Dallas, Lyons explains. He came from a top spinal surgery fellowship program, recorded high scores on Healthgrades, and showed a sophisticated online presence.

Although Duntsch is responsible for misleading hospitals and his patients, fundamental failures of the vetting process and reporting concerns about his performance occurred.

"There are systemic failures here. There need to be laws in place that require reporting to the National Practitioner Data Bank, laws with some teeth in them. It's not enough to say 'We have an obligation and need to police ourselves,'" Lyons says. "There needs to be ramifications when people fail to do that. Otherwise, you could talk about Duntsch or any other case, and if there is no requirement to report and there's a penalty for failure to do so, who's going to do it?"

Hospitals avoid reporting because they do not want to get drawn into a legal squabble over removing a physician's credentials and making a report to the NPDB, Lyons says, so they find an easier way to make the problem go away. That usually involves an agreement between the hospital and physician to part ways with no report and no fuss. The Duntsch case shows the danger of that approach.

"There should be a qualified privilege that protects them in that decision but also a hammer that hits them if they fail to report. As a minimum, it ought to count against them in any audit or rating as a healthcare institution," Lyons says.

EXECUTIVE SUMMARY

The criminal conviction of Christopher Duntsch, MD, PhD, holds important lessons for risk managers. His case is receiving renewed attention in the media.

- Duntsch is the first physician sentenced to life in prison for his actions while practicing medicine.
- The case highlights the risks of allowing a troubled physician to move to another hospital without reporting concerns.
- Critics say hospitals should be required to report physician performance issues to the National Practitioner Data Bank.

"As it is right now, there is essentially no way to hold someone responsible for negligent credentialing."

Guilt by Association

Lyons notes remedying the problem would be good for hospitals because no matter the ultimate liability decided in any particular case, the healthcare institution will suffer from association. That is true especially if someone alleges the hospital passed off a bad doctor to another facility without reporting to the NPDB or otherwise making concerns known.

"Nobody wants to deal with this situation. I have no doubt that every hospital involved with this case suffered negative effects from having their name dragged out every time somebody talked about 'Dr. Death,'" Lyons says. "The hospital can find itself in a tough position. Are you more concerned about their reputation and the potential fallout from having a rogue physician, or are you more concerned about some lawyer filing a lawsuit claiming you disparaged or tortiously interfered with a physician's ability to move on to the next healthcare institution?"

Much of that is clearer in retrospect, Lyons acknowledges. The first hospitals involved in the Duntsch case had no way to know how bad his case would get, but that is why reports to the NPDB should be routine.

"Often what happens is Hospital A says, 'We would like you to leave. We're not going to revoke your privileges but if you stay, we will,'" Lyons explains.

Then, the physician moves on to Hospital B, and their credentialing committee calls Hospital A to inquire about the physician's history and status at the time of departure. Hospital A reports accurately the physician's credentials were never revoked.

"The frustrating thing is that all of that is privileged. The public can't see it, and plaintiffs' attorneys can't use it," Lyons laments. "The physicians are protected in that they can move from one institution to another, but the public is not protected, and the physician can still sue the hospital for reporting the truth."

Letter Shows the Process

The only reason the credentialing process and the communications between hospitals came to light is because Duntsch gave a letter to a news reporter, Lyons notes. After his performance was questioned at the first hospital, including a suspension for investigation of drug abuse, Duntsch requested a letter when he left.

Lyons says it is clear the hospital wanted him to leave, and the letter was part of their agreed peaceable parting of ways. It is unclear why Duntsch publicized the letter, but Lyons says Duntsch likely thought it worked in his favor and did not realize it would expose the way hospitals pass troubled physicians from one facility to another.

"Also, he's just delusional," Lyons adds.

The letter addressed to Duntsch stated: "All investigations with respect to any areas of concern regarding Christopher Duntsch, MD, have been closed ... As of this date, there have been no summary or administrative restrictions or suspensions of Dr. Duntsch's medical staff membership or clinical privileges during the time he has practiced" at the hospital.

The letter was signed by the director of medical staff services. Duntsch used the letter to obtain privileges at two other hospitals, Lyons says.

Surgeon Blames Greed

One of the key experts testifying in the Duntsch trial was **Martin L. Lazar**, MD, FACS, a neurosurgeon in Dallas. He says the root cause of the scandal was greed. Neurosurgeons generate a great deal of revenue for hospitals, he notes.

"The hospital administrator at [the first hospital], in my opinion, was guilty of profound greed," Lazar says. "She had neurosurgeons on staff from private practice, but that wasn't enough for her. She wanted to increase their revenue, but in Texas hospitals are not allowed to employ physicians. They worked out a method in which the neurosurgeons are employed by a separate group, but the hospital has great influence."

It was a workaround that all the major hospitals in Texas still use, Lazar says. It is a "front organization that is legal, but one wonders about the ethical manifestations," he says.

The underlying issue, in addition to the desire for more revenue, was inadequate vetting by the first hospital. "The hospital never did a really proper investigation of Duntsch. They were so eager to get him on staff that they never really looked at his record as a resident and so-called fellow," Lazar says. "For example, Duntsch reported he had participated in something like 76 cases. There is no neurosurgical resident who can do less than several thousand operations. Right from the beginning, there was a red flag, but they never investigated it."

Lazar points out that when Duntsch left the first hospital and used the letter to obtain privileges at

other hospitals, one hospital administrator in Dallas held him to a higher standard. She was an administrator in charge of credentialing.

"She was the heroine in this case because she noticed that Duntsch was not providing adequate information. He would call and threaten her, but she didn't blink," Lazar says. "She told him that if he did not provide adequate information, his application would not go forward. In this case, an administrative individual acted ethically, morally, responsibly."

Duntsch did not receive privileges at that hospital. Lazar says many crippling injuries to Duntsch's patients could have been avoided if other hospital leaders had acted responsibly.

"Duntsch was the perfect storm of failures at every level in the healthcare system," Lazar says. "He was allowed to complete a training program when the people who trained him knew he was probably inadequate as a surgeon and had not done enough cases."

The trial revealed a conflict of interest involving Duntsch's mentors, Lazar notes. Duntsch researched the development of a method for growing spinal intervertebral disc material. Two people who trained Duntsch invested in his business. Those physicians vouched for him even though they had a financial interest in his surgical career.

"In my opinion, that was pure, unadulterated greed. They also were afraid to fire him from the program because they knew he would sue them," Lazar says. "They packed him up and sent him off to Dallas, and when he gets to Dallas they vouch for him on his application for staff privileges without explaining — because they were never asked — the details of his training. What kind of vetting procedure at a hospital, for a new physician, does not vet their training program?"

Particularly in neurosurgery, it is important to confirm the technical competence of the surgeon. The potential for life-threatening or life-changing complications is so great in the specialty that hospitals must exhaust all options for confirming the competency of a surgeon before granting privileges.

"They let him on staff, he killed and crippled, they found out that he was a drug abuser, and they did not adequately investigate his drug abuse," Lazar says. "They gave him back his surgical privileges, and of course he continued to cripple. Finally, they told him they were going to terminate him. They ended up giving him the letter, he didn't sue them, and he went to other hospitals."

Those other hospitals were eager to hire a neurosurgeon who could bring in great revenue. They did not adequately vet Duntsch, and he continued to cripple and kill patients, Lazar says.

"He was stopped because several physicians and a couple plaintiffs' attorneys repetitively got after the Texas Medical Board. I was the expert for the Texas Medical Board and insisted that they withdraw his license," Lazar says. "I had been doing that for a year and a half before they finally did it, and there were other physicians pushing for it before they finally revoked his license."

Unfortunately, Lazar says he does not see the medical community learning from the Duntsch case. Hospital leaders and their legal representatives still lean heavily on avoiding any risk of legal action from physicians who are terminated or reported to the NPDB. Lazar strongly favors making reports to the NPDB mandatory.

"The method by which hospitals dispatch unwanted physicians is unchanged. Hospitals don't want to get sued by a physician who's being threatened with termination, so they have this escape mechanism to avoid lawsuits," Lazar says. "The escape mechanism is saying 'If you leave voluntarily, we will give you a letter saying nothing happened.'" ■

SOURCES

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Healthcare Entities Protected from Vaccine Liability, but Risks Remain

Healthcare organizations are afforded substantial protection from liability related to administering the COVID-19 vaccines, but there are ways to void that protection and create vulnerability for plaintiffs' attorneys.

With more than 100 million people fully vaccinated in the United States, it is inevitable some will try to claim damages and sue the organization that administered the vaccine, says **James R. Embrey, Jr.**, JD, partner with Hall Booth Smith in Nashville, TN.

"Any time you're looking at those kinds of numbers, there have to be liability claims from some enterprising plaintiff's lawyer," he says. "If you have big damages, often a plaintiff will make a claim even if there is no real liability. They harp on the damages and hope that is dramatic enough to get some sort of settlement."

The good news is that organizations providing the vaccines are largely shielded from liability by the Public Readiness and Emergency Preparedness (PREP) Act, which provides tort liability immunity to certain individuals and entities during a pandemic. On March 10, 2020, the Department of Health and Human Services (HHS) invoked the protections of the PREP Act for COVID-19. It has been used to protect healthcare organizations during outbreaks of avian flu, H1N1, and Ebola.

"The act provides immunity from legal liability for any type of claim or loss related to a number of things — development, testing, manufacturing, distribution, administration, or use of a countermeasure, which includes vaccine administration," Embrey explains.

Vaccine administration is a "covered countermeasure," but the PREP Act requires it to be administered by a "covered person," Embrey says. A covered person includes a "qualified person," as defined in the act.

A qualified person includes a licensed health professional and other individuals "authorized to prescribe, administer, or dispense vaccine," according to the PREP Act. *(More information is available at this link: https://bit.ly/3uDcFfz.)*

Some Loopholes

Immunity from the PREP Act is broad and provides strong legal backing, but there are ways a hospital or other healthcare entity could be exposed to liability. "There are some cracks here, loopholes that could put you at risk," Embrey says. "There is a seventh amendment to the PREP Act that lists the individuals who are qualified to administer vaccines. Risk managers need to be sure that the individuals administering the vaccine are on this list."

The list includes nontraditional licensed or certified health professionals such as dentists, pharmacists, pharmacy technicians, podiatrists, paramedics, medical students, and veterinarians. The individual's state certification must be up to date or active within the last five years. *(The amendment is available online at: https://bit.ly/2SFiCuh.)*

"You want to make sure that whoever is sticking the syringe in someone's arm fits in that CDC box of approved people. This includes most clinicians of all sorts, even recently retired clinicians whose licenses expired within the last five years," Embrey says. "It does not include administrative employees. You want to make sure the individual giving the vaccine is authorized by the state in whatever capacity that makes them eligible to administer the vaccine."

Embrey stresses the importance of documenting individuals' eligibility to administer the vaccine. The PREP Act immunity could be lost if a plaintiff challenges the person's qualifications and there is no evidence the employer verified it.

Willful Misconduct Not Protected

The PREP Act makes an exception for willful misconduct, Embrey notes. If the person administering

EXECUTIVE SUMMARY

Federal legislation largely protects healthcare organizations administering COVID-19 vaccines. The immunity can be voided by failing to comply with requirements.

- The Public Readiness and Emergency Preparedness Act shields healthcare entities from most lawsuits.
- Many types of licensed or certified employees may administer vaccines.
- Carefully document compliance with vaccine storage and handling rules.

the vaccine intentionally harms the patient, the immunity will not apply to the individual or the employer. But a plaintiff would be challenged to prove such a claim.

"If the person acted intentionally to achieve a wrongful purpose, the PREP Act is not going to help you. That's a very tough thing to prove," Embrey says. "It has to result in a serious injury or death to lose the immunity, so that's also a high bar. This has to be proven by clear and convincing evidence — another high bar."

Willful misconduct could be claimed if, for instance, the person administering the vaccine reused a syringe or intentionally administered too much vaccine to one person, Embrey says.

Show Government Approval

Another way to jeopardize PREP Act immunity is by failing to properly coordinate vaccine administration with federal, state, or local officials.

"They have to have government authorization and coordination. They have to have the fingerprint of the government on their administration of the vaccine," Embrey says. "They should have that in writing, but it doesn't have to be anything extravagant. It can be a letter from the state health department, the mayor, the governor discussing what the vaccine administrators are doing to further the state's interest in vaccinating their citizens."

The letter may be as simple as a statement from the city stating the healthcare organization can use a public space for vaccine administration.

Improper storage is another potential liability risk. Embrey says this might be the most common claim brought against healthcare organizations related to the COVID-19 vaccine in coming months.

"The claim will be that the vaccine was delivered to you, and you stored improperly at the wrong temperature, or you stacked it too close to the side of the freezer, or the freezer breaks down," he explains. "Or, maybe the temperature indicator on the box is broken and your employee uses the vaccine anyway. As an attorney, I can see an argument there because storage isn't really addressed very well in the PREP Act."

> "IF THE PERSON ACTED INTENTIONALLY TO ACHIEVE A WRONGFUL PURPOSE, THE PREP ACT IS NOT GOING TO HELP YOU."

Activist judges might try to find such loopholes for an injured party to get through the motion phase of the litigation and before a jury.

"I think storage is a weak point. The CDC has a lot of information on vaccine storage and handling, so make sure you are adhering to that exactly," Embrey says. "Risk managers should develop a protocol that ensures proper storage, and document your adherence to that protocol."

Chain of custody also is important. When receiving vaccine deliveries, ensure the chain of custody is valid. Do not accept delivery if the shipping company cannot show the vaccines were handled properly.

"Check the packaging and look for any problems right away. Were there broken vials? Any indication the package was mishandled in any way?" he asks. "It's common sense-type stuff, but putting it in writing on a checklist or a protocol form gives you the extra confidence that you're doing the right thing to stay under that immunity umbrella."

Must Prove Serious Injury

For any claim regarding vaccine administration to have merit, the plaintiff must show he or she was seriously injured, meaning permanent impairment of a bodily function, permanent damage to a body structure, or requiring medical intervention to avoid permanency.

A woman recently told media outlets in Nashville that she could no longer walk after receiving the Pfizer vaccine, Embrey notes. She did not claim the administration of the vaccine caused the alleged injury — just that the vaccine itself was defective.

"But in litigation, the plaintiff's attorney will bring in the vaccine manufacturer, and probably just to be safe they will bring in whatever organization administered the vaccine to her, too," he says. "It's an uphill battle for the plaintiff, but we probably will see more of these cases. As everyone in risk management knows, just being involved in a case like this will cost you money and time."

Federal Program First to Assess

Such claims must first be presented to the Countermeasures Injury Compensation Program, a federal

program that examines the case, determines if there is enough evidence for liability and damages, and if so, awards a certain sum, Embrey explains. If the program rejects the claim, the plaintiff can file a lawsuit with the United States District Court for the District of Columbia.

"If that happens, you go out with both barrels. You move to dismiss, citing the PREP Act immunity," Embrey says. "If the court says no and wants discovery to occur first, then the vaccine administrator will have to show everything they did to comply with HHS guidelines, that you did comply with the CDC's vaccine storage and handling toolkit, the protocols you used, all the signatures. There are a lot of defenses available to the administrator if they check all the boxes to make sure they remain under that umbrella of immunity."

Embrey says he suspects most plaintiffs' attorneys will find such vaccine lawsuits too challenging, and there will not be a huge wave of litigation. But there always will be some attorneys who will accept the challenge.

"Unless the pot of gold at the end of the rainbow gets very tempting because of some unforeseen circumstance and very serious injuries, the hill is too steep for most plaintiffs' attorneys right now," Embrey says. "But you still have to be ready to defend yourself and show you did the right thing." ■

SOURCE

- **James R. Embrey, Jr.**, JD, Partner, Hall Booth Smith, Nashville, TN. Phone: (615) 313-9911.

Hospital Security Must Work Closely with Risk Management

A well-run security program is important for ensuring safety in any hospital or health system, whether security staff are employed by the facility or provided by an outside contractor. Close coordination with risk management is essential.

Workplace violence is more common in healthcare settings than most people would imagine. Hospitals often have a hard time balancing the need for security with a desire to be open and welcoming, says **Paul Baratta**, segment development manager for healthcare with Axis Communications, a Boston-based company that provides security technology to healthcare institutions. He spent 26 years in law enforcement, including service as chief of police for Beth Israel Deaconess Medical Center overseeing police, security, and emergency management.

During his tenure at Beth Israel, he transitioned the hospital's security program from an outside vendor to a fully employed staff of 120 people and 15 armed police officers.

"You can't have your hospital be like a prison, but because of the incidents that happen in hospitals, you have to have a high level of security," Baratta says. "It has to be nonintrusive, but there at a level that protects both patients and staff without interfering with their quality of care. It's an everyday balancing act for a security director in a hospital."

Hospital security departments typically are quite busy with calls for service, which range from escorts to patient watches and responding to violent incidents, Baratta says. Nearly everything hospital security officers do involves some potential for injury to someone, or allegations that harm should have been prevented. That means risk management should coordinate closely with the security department.

"Whoever is in charge of safety and security at the hospital should have a really good working relationship with the risk manager. You need to have a good partnership," Baratta explains. "I used to have near-daily meetings with the risk manager at our hospital."

Baratta and the risk manager would discuss daily events at the hospitals, including costly slip-and-fall incidents and the loss of patient property. A hospital can spend thousands of dollars per year on lost dentures and eyeglasses.

EXECUTIVE SUMMARY

Risk managers should work closely with hospital security directors to coordinate efforts to address workplace violence and other threats.

- Hospitals must balance security with welcoming the public and providing a pleasant atmosphere.
- A property checklist can help avoid claims of lost patient belongings.
- Body-worn cameras on clinicians can help defend against claims of abuse.

Baratta, who also is an EMT, realized many patients claiming lost dentures had arrived at the hospital intubated, their dentures removed in the ambulance. Similarly, eyeglasses were removed in the ambulance, and both items were easily lost when the ambulance was cleaned.

"One of the things I put in place with risk management was an easy checklist so that when a patient came in, the staff could indicate what property the patient came in with. One of the things on the list was to check for dentures and eyeglasses," he says. "By working together with risk management, we were able to save a lot of money for the hospital and address concerns from patients."

Baratta also suggests risk managers and hospital security directors work together to educate hospital leadership about the prevalence of workplace violence and the costs to the hospital. It also is important to remember that improving security is about more than just staffing officers in the building, or technology like cameras and key cards.

"You have to have people, process, and technology. All three," he says. "You can't put in a technology solution without ensuring that you have good policies, procedures, and guidelines around it, and people trained to use it. A risk manager needs to look at any security solution in terms of all three."

Cameras are becoming more prominent in hospital security programs, including body-worn cameras for security officers and those inside ambulances, Baratta notes. They are particularly important when transporting behavioral health patients. For instance, in Florida, a "Baker transport" refers to the law that allows an individual to be committed for an involuntary 72-hour mental health examination if they display certain violent or suicidal signs of mental illness. Liability exposure can be reduced by using cameras in those situations.

Some hospitals are beginning to adopt body cameras for doctors and nurses in the emergency department. Similar to how body cameras are used by police departments, the cameras worn by clinicians most at risk for workplace violence can be important evidence in prosecuting violent patients or defending staff members against claims of abuse, Baratta says.

Body cameras also can be a deterrent to violence. When a doctor points out the patient encounter is recorded, some patients are discouraged from acting out in a violent way.

Widespread use of security cameras in hallways and other common areas also is good practice, he says. They can be particularly helpful with slip-and-fall claims.

"Every trip is worth a thousand dollars. There are people who do that for a living, just going to different hospitals and trying to collect," Baratta says. "Have that video to document the incident and see if what the person says happened really happened. Risk managers should work with their security teams to make sure they have those common areas covered well with cameras."

Management of aggressive behavior, known as MOAB in security, is a growing issue for healthcare organizations, Baratta says. Hospitals should create a MOAB program that teaches security officers and clinicians who are most at risk how to de-escalate potentially violent situations and how to minimize harm when they occur.

After Baratta implemented a MOAB program at Beth Israel, incidents of assault decreased significantly.

"It trains them not only how to restrain a patient if they have to, but also issues of self-defense like making sure you have a door behind you, how to place yourself in the right position in the room," he says. "Every risk manager should make sure their hospital is using a MOAB program." ■

SOURCE

- **Paul Baratta**, Segment Development Manager for Healthcare, Axis Communications, Boston. Email: healthcare@axis.com.

Maternal Health and Safety Improving, but More Work Is Needed

The latest data on maternal health are encouraging, but there still is substantial room for improvement in some areas, says **Leah Binder**, president and CEO of The Leapfrog Group in Washington, DC.

The Leapfrog Group recently released its 2021 Maternity Care Report, which measures hospital maternity care performance against best practices in three high-risk areas: cesarean deliveries, episiotomies, and early elective deliveries. Data from Leapfrog's most recent hospital survey shows progress across all three measures. *(The report is available at: https://bit.ly/3hjLkv8.)*

Leapfrog provides this summary of the latest results:

• Modest progress has been made with nulliparous, term, singleton, vertex (NTSV) cesarean delivery rates. A record 51% of hospitals achieved Leapfrog's NTSV cesarean delivery standard of 23.9% or less. In 2019, less than 42% of hospitals achieved the standard.

• Substantial progress has been made with lowering early elective delivery rates. From a 17% starting point in 2010, the number decreased to 1.6% in 2020. Almost 92% of hospitals meet Leapfrog's standard of an early elective delivery rate of 5% or less.

• The average episiotomy rate among reporting hospitals decreased to 5.2% in 2020. In 2015, the rate was more than 10%. The 2020 rate of 5.2% is the lowest rate since Leapfrog began publicly reporting the measure. Leapfrog's target rate is only slightly lower at 5%.

> "THAT IS AN EXTRAORDINARY CREDIT TO THE HEALTHCARE SYSTEM FOR IDENTIFYING THIS PROBLEM AND ADDRESSING IT RAPIDLY."

"We're very enthusiastic about progress on early elective deliveries," Binder says. "We're seeing a very significant drop in early elective deliveries, and it is now at the rate it will always be, which is virtually zero. That is an extraordinary credit to the healthcare system for identifying this problem and addressing it rapidly."

The episiotomy rate also is good news, but there is room for improvement. "There obviously is some leadership behind that effort because we're seeing some good results overall, and even stronger results in some particular hospitals," she says. "We are not seeing that kind of progress with C-sections. That is concerning. We're not seeing the reduction in unnecessary C-sections that we need."

Binder says she is concerned about not just the lack of progress in reducing cesarean delivery rates, but also the variation in the rate among hospitals.

"The variation tells us that whatever effort there is to reduce C-sections is not getting enough traction. There's no sense of urgency revealed by these numbers," she says. "There is no pattern of efforts we are seeing when we look at those rates. With the other measures, we see a pattern that indicates a national effort to improve, but we don't see that with C-sections. That is concerning."

Variation exists in the three measures by state, Binder notes, but there is no pattern by type of hospital. There seems to be a lack of leadership on reducing cesarean deliveries.

"Hospital leaders should look at these data and see how you are doing on these rates compared to neighboring hospitals. If you are doing well, you should recognize that and celebrate it with your team," Binder says. "If you're not doing well, you should address that. When there is effort from the very top of leadership to set goals and meet them, it happens." ■

EXECUTIVE SUMMARY

The latest report on maternal health from The Leapfrog Group shows progress on all three health measures, but there is room for improvement, the CEO says.

- A record percentage of hospitals achieved Leapfrog's target for nulliparous, term, singleton, vertex cesarean delivery rates.
- Early elective deliveries have decreased dramatically.
- Episiotomy rates are the lowest Leapfrog has measured.

SOURCE

- **Leah Binder**, President and CEO, The Leapfrog Group, Washington, DC. Phone: (202) 292-6713.

Prepare for OSHA Facility Inspections

Healthcare risk managers should prepare for an inspection by the Occupational Safety and Health Administration (OSHA) because deficiencies can bring significant fines and administrative burden, says **Richard Best**, PhD, director of regulatory affairs with Stericycle, a company headquartered in Bannockburn, IL, that provides OSHA compliance training and other services to healthcare organizations.

OSHA requires healthcare employers to provide workers with a safe and healthful workplace, free from any known hazards that cause or are likely to cause injury or illness, Best says. OSHA has set forth guidelines to help healthcare facilities ensure their workforce remains healthy amid the COVID-19 pandemic.

While these guidelines are not regulatory requirements, employers should begin implementing them in their daily protocols to get a head start on compliance in preparation for a future OSHA move to issue these guidelines in the form of an Emergency Temporary Standard (as some states have done) that is applicable to COVID-19 or other infectious diseases.

"While OSHA requirements can vary by state, some common protocols related to COVID-19 include conducting risk assessments, creating preparedness and response plans, performing health screenings, and displaying workplace signage that communicates the necessary safety measures," Best says. "To ensure employers are compliant and adhering to regulations, OSHA can perform unannounced on-site inspections, and employers should expect closer scrutiny concerning providing protections against COVID-19."

More important than the potential for penalties, noncompliance with OSHA standards and regulations can jeopardize the safety and health of employees.

Upon arrival, the inspecting officer should provide his or her OSHA credentials, Best says. If this does not happen, ask for credentials to confirm the inspector's legitimacy. The inspection will begin with an opening conference during which the officer will state the reason for the visit.

From there, the inspection may consist of private interviews of employees and could even involve the collection of air samples, photographs, and video of the facility. The visit will conclude with a closing conference to discuss findings.

Preparing for an on-site OSHA visit and inspection can help your facility achieve compliance with OSHA's requirements. Knowing the OSHA standards with which your facility must comply with is the first step in preparing for a site visit, Best says.

These standards depend to some extent on where the facility is located, as this determines whether it is covered under federal or state OSHA jurisdiction. State plans are required to be at least as strict as the federal standards, and they may carry additional requirements as well.

Aside from knowing which OSHA jurisdiction your facility falls under, there are specific steps that can help you prepare for an OSHA inspection, such as ensuring compliance with applicable standards for your specific workplace, Best says. For example, what about your written bloodborne pathogens exposure control plan (ECP)? The ECP is one of the first things an OSHA inspecting officer will ask to see in a facility.

Are safety data sheets readily accessible in the work area? Is the hazardous chemical inventory master list up to date? Have you considered organizing that list by assigning a number key to the safety data sheet for each hazardous chemical listed?

Such a method of organizing safety data sheets can help employees and associates readily access the safety data sheet they may be looking for, Best says.

EXECUTIVE SUMMARY

Occupational Safety and Health Administration (OSHA) inspections require preparation for the best results. Healthcare facilities must meet certain industry-specific requirements.

- Some states are covered by state OSHA plans.
- Bloodborne pathogen rules are frequently cited in OSHA healthcare inspections.
- Requirements for hazardous chemicals also are cited often.

Watch for Most Common Citations

While inspections should be thorough, OSHA does look for common violations known as "most frequently cited standards," Best explains. One of the most frequently

cited standards during healthcare facility inspections is the Bloodborne Pathogens Standard, which protects employees who are at risk of exposure to blood or other potentially infectious materials.

OSHA requires all healthcare facilities with such exposure potential to establish a written bloodborne pathogens ECP. An inspector likely will ask to see this plan early in the process.

OSHA's Hazard Communication Standard, which ensures safety when working with hazardous chemicals, is another commonly cited standard. It requires hazardous chemical inventory lists and safety data sheets to be consistently updated as they inform employees about chemical hazards in the workplace.

The four requirements for compliance include properly labeling chemicals, providing safety data sheets, training employees on all hazardous chemicals to which they may be exposed, and creating a written hazard communication program, Best notes.

Citations are not issued at the time of inspection, but only after further review by the OSHA area director or the equivalent in OSHA state plans.

"If your facility is issued a citation, it will arrive at your office by mail with the notice of any applicable penalties and an abatement or correction date. The notice of violation and citations must then be posted in an area where all impacted employees can view them," Best says. "If you feel you have been wrongfully issued a citation, you can appeal it to a formal OSHA review board that is separate from OSHA itself. However, overturned citations are not common." ■

SOURCE

- **Richard Best**, PhD, Director of Regulatory Affairs, Stericycle, Bannockburn, IL. Phone: (847) 367-5910.

'Total Breakdown in Communication' Led to Settlement of Advance Directive Case

By Stacey Kusterbeck

An 89-year-old New Jersey woman had put in place both "do not resuscitate" and "do not intubate" orders. Despite this, ED providers resuscitated and intubated her anyway.

Her daughter sued the hospital, the EP, and several nurses for disregarding the patient's wishes. The lawsuit alleged the providers either did not know about the advance directive or ignored it.

A superior court judge ruled the defendants violated the patient's "fundamental right to refuse unwanted medical care."[1] **Timothy L. Barnes**, Esq., represented the plaintiff, and says three issues led to a settlement for an undisclosed amount:

• Providers failed to carefully review the documentation about the advance directive in the medical chart. "The ED staff, both nurses and doctors, must read the entire chart and specifically familiarize themselves with any advance directives," says Barnes, an attorney with Morristown, NJ-based Porzio, Bromberg & Newman.

• The nurse failed to tell the resident about the advance directive, who failed to tell the attending in the ED, who failed to tell the hospitalist on the floor after admission. "There was a total breakdown in communication," Barnes says.

• No provider acted on the advance directive, despite the fact it was documented in multiple places. Instead, the providers relied on a brief version of the history taken by previous providers, without taking their own history, and without reading the documents in the chart. "Everyone was at fault, so they were all named in the suit. They all contributed to the settlement," Barnes reports.

EDs can learn a lot from this particular case about how to avoid litigation for disregarding advance directives. "We learned, through discovery, that the hospital revised many protocols as a result of the mishandling of this patient's DNR," Barnes says. ■

REFERENCE

1. *Koerner v. Bhatt*, N.J. Super. (Law Div. 2017).

COMING IN FUTURE MONTHS

- Risk manager burnout from COVID-19
- Responding to a fall claim
- Trends in nursing liability claims
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CME/CE QUESTIONS

1. **In the case of Christopher Duntsch, MD, PhD, what does Michael P. Lyons, JD, say is one reason Duntsch injured so many patients before he was stopped?**

   a. Hospitals did not report him to the National Practitioner Data Bank.
   b. Patients settled their cases with nondisclosure agreements.
   c. Hospitals did not cooperate with plaintiffs' attorneys.
   d. Patients were unaware his care was subpar.

2. **What does Martin L. Lazar, MD, FACS, say should have been a red flag regarding Duntsch?**

   a. He claimed to have performed only 76 procedures in his training.
   b. He claimed to have performed several thousand procedures in his training.
   c. His mentors would not endorse him when he applied for hospital privileges.
   d. His mentors expressed concern about his qualifications.

3. **What does James R. Embrey Jr., JD, say is important for preserving immunity from legal liability from lawsuits related to administering COVID-19 vaccines?**

   a. A "hold harmless" agreement from each person receiving the vaccine
   b. A statement from local, state, or federal governments endorsing your vaccine administration program
   c. An adequate rider to insurance coverage specifically covering vaccine administration
   d. A statement from the vaccine manufacturer indemnifying the institution from any legal liability.

4. **What does Paul Baratta say can reduce violent incidents in emergency departments?**

   a. Security officers armed with Tasers
   b. Audio recordings warning of the presence of security officers
   c. Signage indicating violent patients will be restrained
   d. Body cameras worn by clinicians

LEGAL REVIEW & COMMENTARY
EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

Damages Award Increased to Reflect Pain and Suffering from Feeding Tube

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Former Director of Risk Management Services (2004-2013)
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USC School of Law, 2016

News: A patient died in a New York VA hospital 118 days after an aortic aneurysm repair procedure resulted in occlusion of the patient's renal arteries. The patient's estate filed a wrongful death suit alleging the surgeons' negligence was the direct and proximate cause of the patient's death death. Plaintiffs were awarded $2.1 million, reflecting 58 days of pain and suffering the patient had affirmed.

The award was later modified to $3.9 million to reflect a more expansive view of pain and suffering, based on a calculation of the days in which the patient's circumstances could have reasonably indicated pain and suffering, despite the patient not indicating pain on those days. In effect, the court found the patient's inability to eat solid food and constant need of a feeding tube constituted pain and suffering, increasing the number of days the patient suffered from 58 to 118. A major factor in this analysis was the plaintiff's expert, who testified that pain and suffering can exist even when a patient does not affirmatively register it, but nevertheless experiences pain based on conditions the patient was subjected to because of negligence, such as inability to survive without constant use of a feeding tube.

IN EFFECT, THE COURT FOUND THE PATIENT'S INABILITY TO EAT SOLID FOOD AND CONSTANT NEED OF A FEEDING TUBE CONSTITUTED PAIN AND SUFFERING.

Background: A New York patient died in a Veterans Affairs (VA) hospital after an endovascular abdominal aortic aneurysm repair (EVAR) surgery, which resulted in the occlusion of the patient's renal arteries. Upon filing a wrongful death suit, the executor of the patient's estate alleged the occlusion was a result of operator negligence in the procedure, since the patient's kidneys were functioning before the EVAR. The suit alleged the doctors' failure to perform a confirming angiogram deviated from the standard of care in the community, such that the patient's death could not have occurred in the absence of negligence by one or more of the three physicians present during the surgery. A January 2018 bench trial established the doctors believed the patient was an excellent candidate for the closed procedure due to the anatomy of his aorta. They decided to use a Cook Zenith Flex AAA endovascular stent graft to perform the EVAR. However, the graft covered both of the patient's renal arteries, occluding blood flow. All three surgeons unsuccessfully attempted to re-establish blood flow to the kidneys. The patient required kidney dialysis and remained hospitalized in the VA until his death in July 2009, four months after the surgery.

In June 2020, the trial court ruled in the plaintiff's favor, awarding $2.1 million to the patient's estate, including $1.7 million for the patient's conscious pain and suffering, and $366,000 for his fear of impending death. This judgment originally excluded calculation of damages for days when the patient was recorded as alert and not indicating pain, and time the patient spent in palliative care. Although the patient spent 118 days in the VA hospital, the damages award

was based only on 58 of those days, at a rate of $30,000 per day. Believing these amounts to be too low and that both categories of excluded days should be counted toward the ultimate damages calculation, the patient's estate moved for a retrial or, alternatively, an adjustment of the verdict.

On March 31, 2021, a New York federal judge granted the estate's motion to adjust the verdict, accepting the estate's argument the patient endured pain and suffering for all 118 days he spent in the VA, rather than the 58 days the court originally counted. Despite the government's protests, the judge reasoned that although the patient did not outwardly express pain, other aspects of the patient's experience constituted proof of pain and suffering, such as his inability to eat solid food, thus requiring a feeding tube at all times, and the mental anguish of remaining a prisoner of his own body. The judge kept the same rate of damages ($30,000 per day), increasing the award for pain and suffering to $3.5 million. The damages to compensate for the patient's fear of impending death remained the same ($366,000) after the judge agreed with the court's original calculation of the earliest date the patient showed he was aware and anxious of his impending death. The total damages calculation after the estate's appeal amount to just over $3.9 million. The judge denied the bid for a new trial, noting the patient's estate was not introducing new evidence or testimony.

In making these determinations, the court relied heavily on expert testimony provided by the patient's estate that the attending vascular surgeon was responsible for ensuring the C-arm and operating table are secured, and the failure to do so was a contributing factor to the outcome of the surgery. The estate's expert testified the stent graft was installed a few millimeters too high, covering the renal arteries and blocking blood flow, irreparably damaging the kidneys. The court disagreed with the government's argument the expert's testimony was flawed and could not identify with scientific certainty whether the occlusion occurred because of operator negligence or some other unknowable cause. They noted an expert who finds myriad causes but is unwilling to opine as to which might be the cause does not preclude the court from finding a cause if the evidence supports that result.

PAIN AND THE SUFFERING IT CAUSES IS SUBJECTIVE AND DOES NOT REQUIRE THE OBJECTIVE DATA OF A PULSE RATE OR BLOOD PRESSURE TO BE FACTUAL.

Although the government noted it was considering appealing this issue, it has not filed an appeal at the time of this article. As such, this newer, more expansive calculation of damages based on the patient's experience while hospitalized — rather than affirmative indications of pain and suffering — stands as valid law.

What this means to you: While it always is necessary to consult with local counsel (as damages analyses can vary by state), this case suggests an expansion of the traditional concept of how courts and experts calculate pain and suffering. The court used a rate of $30,000 per day as compensation for the deceased patient's suffering throughout the proceedings, but agreed with the plaintiff's expert's opinion the patient was suffering even when he did not affirmatively indicate pain, in large part due to the feeding tube the patient was forced to use for all 118 days he was hospitalized before his death. The court disagreed with the government's contention that damages should be calculated only on those days the patient affirmatively indicated pain.

This case opens the door to a more speculative calculation of pain and suffering damages, based not just on patient feedback, but also on a more holistic view of the circumstances a patient experiences while hospitalized — such as the constant need for a feeding tube. Although this case centered on the feeding tube, this type of damages calculation can be applied to any number of circumstantial factors, giving plaintiff's experts more leeway in calculating the number of days subject to the court's rate of damages.

Pain and the suffering it causes is subjective and does not require the objective data of a pulse rate or blood pressure to be factual. A patient's pain is whatever it is to the patient, not the observer. When a patient is asked to rate his or her pain on a scale from 1-10, the response, regardless of outward appearance or level of activity, is the patient's level of pain. It is not the duty of the healthcare provider to reinterpret pain to a level that fits some other scenario. Pain, suffering, discomfort, aggravation, stress, distress, depression, and frustration all are feelings an individual experiences at a level that only can be expressed by that individual. ■

REFERENCE

- Decided March 31, 2021, in the U.S. District Court for the Western District of New York, Case Number 1: 10-cv-00363.

Verdict Upheld in Medical Malpractice Trial Despite Juror Bias

News: A doctor misdiagnosed a patient's leg wounds and ulcers as venous rather than arterial, setting off a chain of events that led to a leg amputation and, ultimately, the patient's death. In the resulting medical malpractice trial, the trial judge allowed two jurors who expressed bias against medical malpractice plaintiffs to serve on the jury, despite not personally seeing the jurors' questioning regarding that bias. During the trial, an expert witness presented by the doctor testified to his conclusion that the doctor met the standard of care despite the misdiagnosis, but did not delve into the specifics of his analysis or the numerous factors he considered in coming to that conclusion.

The appeals court ultimately found neither of these facts required overturning the jury's verdict or ordering a new trial because the patient did not offer timely objections to the judge not personally overseeing the jury selection process, and because the expert identified the specifics of his analysis in his pretrial report and could have been cross-examined on those issues despite only testifying to his ultimate conclusions in front of the jury.

Background: A patient suffering from diabetes, kidney disease, and other ailments sought treatment from a Pennsylvania doctor for leg wounds and ulcers. The doctor misdiagnosed the leg wounds as venous rather than arterial. The patient later needed a leg amputation, which caused a series of complications ending in the patient's death. The patient's widow filed a malpractice suit against the doctor and the hospital.

Voir dire for the medical malpractice trial began in March 2018. The process was conducted by a court clerk, which was common practice in the county where the trial was held, although in many jurisdictions the trial judge conducts voir dire personally. The plaintiff made several motions to challenge three potential jurors for cause based on their affirmative answers to two juror questions regarding their feelings about medical malpractice lawsuits, admitting they held animosity toward medical malpractice plaintiffs and expressing support for caps on damages awarded to the deceased patient's estate. The judge ultimately granted one motion (preventing that juror from serving on the jury) but denied the other two motions.

Before the trial, the patient's executor also made a motion in limine to preclude an expert from testifying the doctor had provided "excellent care" and acted reasonably given the circumstances, arguing these were mere conclusions without any stated factual basis, and thus an impermissible expert opinion. The judge denied this motion, and later overruled an objection on the same grounds during the trial.

The jury ultimately found in favor of the doctor, determining the standard of care was met. The patient's executor appealed on both the voir dire issue (arguing that the judge did not witness the voir dire and thus improperly denied the for-cause challenges) and expert testimony issue. The appeals court initially sided with the patient's executor based on a recent, unrelated-but-similar case on appeal in the Pennsylvania Supreme Court. When that court considered the similar case, it found a patient's estate waived their objections to jury selection issues the judge did not personally witness by failing to file pretrial motions based specifically on a claim that error occurred because the judge did not personally observe the voir dire. Given this ruling, the appeal in the instant case also was dismissed for the same reasons — the executor's motions to dismiss the jurors for cause before trial made no mention of the fact the judge did not personally oversee voir dire; the first time the executor raised those issues was after trial concluded.

As for the expert witness testimony, the executor argued the expert witness discussed a "multifactor" analysis to be used to determine whether the patient's wounds were venous or arterial, but then concluded the doctor acted reasonably without actually discussing those factors and how they weighed in favor of the doctor. The executor also objected to the expert's reference to "literature" that supported his opinion, without actually specifying which literature or admitting any of the literature into evidence. The trial court applied the rule that expert testimony is allowable as long as it is limited to the "fair scope" of the expert's pretrial report. Under that rule, the trial court found the expert's testimony was fair (and admissible) in that it gave the executor enough grounds to prepare a meaningful response, and the expert's conclusory opinions did not constitute an unfair surprise. The appeals court agreed, noting that although the expert did not detail all the factors and how they affected his opinion, his pretrial report adequately discussed several factors in detail. The appeals court also ruled the expert's single, vague reference to "literature" was improper, but that it did not prejudice

the executor to the extent required to overturn the trial court's decision to allow that testimony.

Because the appeals court ruled in the doctor's favor on both issues, it affirmed the trial court's decision and denied the executor's bid for a new trial.

What this case means to you: This case provides two meaningful lessons about medical malpractice jury trials and related expert witness testimony. First, as to medical malpractice jury selection, there is a procedural takeaway and a substantive takeaway. Procedurally, this case affirms that a judge need not oversee the jury selection process personally. If either party to a litigation takes issue with that practice, it should object specifically on that basis before the trial begins, rather than waiting to make a motion on this basis after it loses the trial. Moreover, this practice was especially allowable given that it was common practice in the county in which the trial was held. The executor was not allowed to abide by this common practice without objection, only to blame the negative outcome of the trial on that practice after the jury found against her. Perhaps more importantly, jurors in medical malpractice cases need not be completely impartial or divorced of opinions on medical malpractice actions or plaintiffs. In this case, the trial court and the appeals court agreed two jurors could stay on the jury despite affirmatively registering disdain toward medical malpractice plaintiffs and expressing support for an absolute cap on recovery for successful medical malpractice plaintiffs, regardless of the harm suffered by the patient or the egregiousness of a doctor's negligence.

As for the expert testimony issue, this case shows the importance of a testifying expert's pretrial report, the allowable scope of the expert's testimony, and conclusions regarding malpractice and whether the standard of care was met. The testifying expert in question essentially testified only as to his conclusions the doctor acted reasonably and met the standard of care, without delving into the detailed factors that affected his analysis. Rather, he relied on the identification of several of those factors in his pretrial report, and loosely discussed only a select few of those factors in his testimony.

The legal issue presented to the court focused on whether providing conclusory testimony to the jury was allowable given the more detailed expert report. In essence, the appeals court judged the parties' arguments on this issue as a matter of fairness, with the key question of whether the executor was fairly given notice of the testifying expert's theories of the case and the factors he used to apply his opinion to the specific facts. The appeals court agreed with the trial court, stating because the testifying doctor had outlined many such factors in his pretrial report, the executor could and should have been able to fairly cross examine the expert at trial, delving more deeply into those factors if her attorneys so chose. The expert did not unfairly surprise the executor by simply testifying to conclusions — or vaguely and cursorily referencing that "literature" supported his conclusions. The executor had free reign on cross-examination to steer the doctor toward a more detailed discussion of those factors.

Finally, from the factual and physiological perspectives, arterial and venous occlusions can both cause ulceration and wounds, especially on the lower extremities. Diagnostic ultrasound examinations of venous and arterial blood flow are relatively accurate in determining the location of the occlusion that is causing the problem. Although the appearances of the wounds are similar, the causes are different. An arterial ulcer occurs when the artery is blocked and blood cannot flow to the tissue. A venous ulcer, or stasis ulcer, occurs when the blood pools in the lower extremity and cannot flow back to the heart. These are much more common and sometimes can cause confusion during the initial evaluation. Confirmatory studies should be sought when any doubt exists. ■

REFERENCE

- Decided April 8, 2021, in the Superior Court of Pennsylvania, Case Number 1166 WDA 2018.

HIPAA REGULATORY ALERT

CUTTING-EDGE INFORMATION ON PRIVACY REGULATIONS

Right of Access Settlements Yield Lessons, Insight on OCR Approach

With nearly 20 settlements so far, the Office for Civil Rights (OCR) is showing its determination to protect patients' rights to obtain their medical records from healthcare entities.

OCR announced its Right of Access Initiative in 2019 and vowed to "vigorously enforce" patients' right to access their medical records. OCR continues investigating allegations of improper delays that potentially violated the HIPAA Privacy Rule's right of access requirements (45 C.F.R. § 164.524).

Former OCR Director Roger Severino said in November 2020, "We will continue to prioritize HIPAA Right of Access cases for enforcement until providers get the message." There have been seven more settlements since then.[1,2]

Lessons from Settlements

A key takeaway from the 18 Right of Access settlements is that providers cannot ignore OCR investigations, says **Elizabeth Litten**, JD, partner and chief HIPAA privacy & security officer with Fox Rothschild in Princeton, NJ.

"If a patient complains and OCR investigates, the provider must do whatever it can to provide the requested records to the patient as quickly as possible," Litten says. "Many of the settlements involve situations in which the provider failed to provide the complainant's records even after the OCR began an investigation and provided 'technical assistance' designed to facilitate the provider's compliance."

Risk managers and compliance officers can learn from the Right to Access settlements, says **Daniel Hernandez**, JD, partner with Shutts & Bowen in Tampa, FL. He notes all the settlements resulted from a consumer complaint, typically after months of the consumer trying to access records. Healthcare entities must respond in 30 days (or 60 days, if there is a reason to justify the extension).

"If you communicate with these patients when you're having difficulty locating the records or producing them in the format the patient has requested, I think most patients will understand and agree to a longer period," Hernandez says. "Most of the settlements come after not just one complaint but a second complaint. There is an initial complaint to OCR, OCR reaches out to the healthcare facility to say there is a complaint and let us help you facilitate the production of these records with technical guidance, but still the records are not produced, and there is a second complaint."

If OCR pursues a settlement after just one complaint, the lapse of time between the first request and the complaint has been significant.

"It's not as though the hurdles for complying are insurmountable. The healthcare facilities have these records, and the settlements are not coming as the result of technical violations of HIPAA, such as providing the records in an incorrect format, providing them to the incorrect person, or charging too many fees," Hernandez says. "These settlements come from just not producing the records on a timely basis. If healthcare facilities did that, they would not find themselves in this situation."

Create Policies, Train Employees

Healthcare organizations should make sure they maintain written policies on right of access and train employees on how to respond to records requests. Hospital leaders may have a firm grasp on what HIPAA requires in this regard, but frontline employees responding to

record requests may not understand the requirements or the potential consequences of not responding.

"They need to understand that when there is a complaint, they need to jump on it right away," Hernandez says. "They cannot ignore the patient's request or the complaint about a slow response. I think the problem is a lack of training in many facilities."

Often, hospitals have not created a good process for tracking records requests, so they become lost in a stack of other documents on some employee's desk. "It's not so much a matter of saying no to the request but rather the request gets lost in the system. If the patient doesn't follow up and make multiple requests, nothing happens," Hernandez says. "Sometimes, even when the patient does make repeated requests, nothing happens." Hernandez notes all the recent settlements include a corrective action plan, which brings continued scrutiny after the fine is imposed.

The requirements of the plans are straightforward and derived from HIPAA — the same procedures hospitals should have been following in the first place. A corrective action plan means OCR will be watching closer.

"The enforcement mechanisms available to OCR are unique and have significant teeth to them," Hernandez says. "I don't get the sense that the average person at a hospital who works in the front office has a good appreciation for the potential consequences of not giving a patient his or her records in 30 days. They think the only potential consequence is that the patient will get a little upset but eventually they'll get their records and everything will be fine."

Those employees should be educated on the size of the fine OCR could impose on the hospital, and the possibility that such a fine could result in termination for the responsible employee.

"With that knowledge, I think they would be more cognizant and more responsible," Hernandez says. "Educating staff on the seriousness of this rule and the potential consequences would address a lot of the problems you see here." ■

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2. HHS.gov. OCR news releases & bulletins. https://bit.ly/3nqLAJM

Busy Year for Right of Access Settlements in 2021

The Office for Civil Rights (OCR) announced its 18th settlement of an enforcement action in its HIPAA Right of Access Initiative on March 26.[1]

The settlement involved Village Plastic Surgery (VPS) in Ridgewood, NJ, which agreed to take corrective actions and pay $30,000 to settle a potential violation of the HIPAA Privacy Rule's right of access standard.

The case stemmed from a September 2019 complaint alleging VPS "failed to take timely action in response to a patient's records access request made in August 2019," HHS says. OCR's investigation determined VPS' alleged delay was a potential violation of the HIPAA Right of Access standard.

VPS sent the requested records to the patient after the OCR investigation.

In an earlier settlement announced Feb. 10, Renown Health, a private, not-for-profit health system in Reno, NV, agreed to take corrective actions and pay a $75,000 fine — for a single alleged violation.[2]

"In February 2019, OCR received a complaint alleging that Renown Health failed to timely respond to a patient's request that an electronic copy of her protected health information, including billing records, be sent to a third party," HHS reports. "OCR's investigation determined that Renown Health's failure to provide timely access to the requested records was a potential violation of the HIPAA right of access standard. As a result of OCR's investigation, Renown Health provided access to all of the requested records." In addition to the hefty fine, Renown Health agreed to two years of monitoring as part of a corrective action plan.

On Feb. 12, OCR announced a settlement with Sharp HealthCare, which operates four acute care hospitals, three specialty hospitals, three affiliated medical groups, and a health plan in California. The settlement included a $70,000 fine and a corrective action plan with two years of monitoring.[3]

A patient claimed Sharp failed to respond in a timely fashion to request directing that an electronic copy of protected health information be sent to a third party.

"The OCR provided Sharp with technical assistance on its alleged failure to provide access to the records and requested that Sharp respond to the patient's request. In August 2019, the OCR received a second complaint from the same patient alleging that

Sharp still had not responded to the patient's records access request," HHS reports. "The OCR investigated the matter, and Sharp provided access to the requested records."

At press time, OCR had settled five Right of Access investigations so far in 2021, four of those since President Biden was sworn in to office on Jan. 20. ■

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Whistleblower Exception Allows Reporting HIPAA Violations with PHI

Healthcare professionals can find themselves in a quandary when they want to report fraud or other concerns within their organizations because doing so could require disclosure of protected health information (PHI). That could seem like a HIPAA violation; fortunately, there is a whistleblower exception that covers this scenario.

A major goal of the HIPAA Privacy Rule is to ensure an individual's health information is properly protected while still allowing the normal flow of health information needed to provide and promote high-quality care, says **Layna Cook Rush**, CIPP/US, CIPP/C, shareholder with Baker Donelson in Baton Rouge, LA.

Many provisions in the Privacy Rule are designed to strike a balance that permits important uses of information while still protecting patient privacy. The Whistleblower Exception is one of these provisions. This exception is intended to allow the disclosure of patient information to protect patients, healthcare workers, and even the public — but there are restrictions on its application.

The Whistleblower Exception states that a covered entity, such as a physician or hospital, is not considered to have violated the HIPAA Privacy Rule if a member of its workforce or a business associate discloses patient information. This, provided the workforce member or business associate believes in good faith the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards. Or, the care, service, or conditions provided by the covered entity potentially endanger patients, workers, or the public. *(Read more about the exception at this link: https://bit.ly/3dV2Fs9.)*

"Additionally, the disclosure must be to either a health oversight agency or public health authority authorized to investigate or to an attorney retained by the workforce member or business associate to determine the legal options of the workforce member or business associate," Rush says.

The Whistleblower Exception can be used by a workforce member, which can be an employee, volunteer, or even independent contractor, or by a business associate of a covered entity. The disclosure must be made to an oversight agency or to an attorney who is assisting the individual in determining his or her legal options.

The Whistleblower Exception allows an individual to disclose concerns about issues such as billing fraud or compliance issues by using PHI to make the case, says **Christina M. Kuta**, JD, an attorney with Roetzel & Andress in Chicago.

"They can disclose this to an accrediting body, an insurer, other enforcement agencies, or even an attorney they have hired to represent them if they have a good faith belief that there is an issue that needs to be explored," Kuta says. "Once you have that good faith belief, you are allowed to gather information that you wouldn't otherwise be able to gather from the covered entity or the business associate. This could mean printing out patient records or billing statements, things that otherwise you likely would not have a legitimate need to access and certainly wouldn't be allowed to share with third parties."

Under the Whistleblower Exception, the individual can provide that PHI to another party without fear that accessing and disclosing that information will be deemed a HIPAA violation, as long as the necessary requirements are met.

The biggest risk concerns the good faith belief, Kuta says, because there is no objective way of determining that. If a nurse overhears two coworkers talking about how they incorrectly billed a patient, is that enough to conclude they are overbilling many patients, obtain PHI that might prove

the allegation, and send it to the government or a lawyer?

Maybe not. The nurse might have overhead discussion of one error the coworkers were correcting. That might not constitute good faith belief. Accessing and distributing PHI on that alone could be a HIPAA violation not protected by the Whistleblower Exception.

Another pitfall is obtaining and distributing too much PHI to report a concern.

"If you have a concern that the facility or practice is upcoding for one particular procedure, you can't take all the records from the department or from that physician practice and give them to a lawyer," Kuta says. "A lot of patient information there has nothing to do with the fraud you're alleging. Disclosing that information is a HIPAA violation. It wouldn't qualify for the Whistleblower Exception because it is not related to what you're whistleblowing on."

If patient information is used to report a covered entity to an oversight agency, the "minimum necessary" rule still should be used.

"The minimum amount of information necessary to accomplish the intended purpose should be disclosed. For instance, if the patients' names and addresses are not necessary for the oversight agency's investigation and the names and addresses can be redacted from the records being disclosed, then they should be," Rush says. "If the data can be deidentified such that all patient identifiers are removed, then the data should be deidentified before it is disclosed."

There is a good faith requirement in the Whistleblower Exception. It cannot be invoked except when there is a legitimate belief the covered entity is engaging in activity that could be detrimental to patients, workers, or the public. It should not be used as retaliation or for personal gain. For example, an employee who has been terminated cannot take patient information to use in a wrongful termination lawsuit against the covered entity.

"Also, whistleblowers should be very careful about how they disclose patient information and how much they disclose. Courts have sanctioned whistleblowers who placed patient information in the court's public record without sealing or redacting the information," Rush says.

The Whistleblower Exception allows a whistleblower to share information with his or her attorney for the purpose of evaluating legal options. Someone contemplating disclosing patient information as a whistleblower should consult with his or her legal counsel to determine whether a covered entity has engaged in conduct that should be reported to an oversight agency, the amount of information that needs to be disclosed to allow the oversight agency to investigate, and the appropriate agency to which the disclosure should be made.

The Whistleblower Exception protects a covered entity from being considered to have committed a breach if the whistleblower is a member of the covered entity's workforce and is the victim of a crime, says **Arielle T. Miliambro**, JD, partner with Frier Levitt in Pine Brook, NJ. However, the PHI disclosed must be about the suspected perpetrator of the criminal act and is limited to the information necessary to identify and locate the perpetrator.

"For example, an employee who has been assaulted by a covered entity's patient may evaluate, and perhaps ultimately use, this exception to report the assault to appropriate authorities without violating the patient's privacy rights under HIPAA," Miliambro says. "Although the requirements of the Whistleblower Exception have certain flexibility based upon a good faith standard, the requirements must be met precisely as set forth."

Miliambro says it is important to note the covered entity remains, at all times, responsible for the use of PHI by its employees and business associates, even when those individuals attempt to disclose PHI pursuant to the Whistleblower Exception. Therefore, a covered entity may be in breach of HIPAA, and thus exposed to liability, if an employee or business associate impermissibly relies on the Whistleblower Exception to disclose PHI.

A concern for both employer and employee would be that the whistleblower would disclose PHI to either an individual or entity not covered under the Whistleblower Exception, says **Paul F. Schmeltzer**, JD, an attorney with Clark Hill in Los Angeles.

For example, if a whistleblower made an allegation that included PHI to the Equal Employment Opportunity Commission or a media outlet, their actions would not fall under the whistleblower exception.

"The most common scenario is a healthcare employee protected under the HIPAA whistleblower exception making allegations of fraudulent billing in the covered entity's medical practice," Schmeltzer says. "Healthcare employers would be wise to include information in their annual HIPAA trainings that discusses the limited nature of HIPAA's whistleblower exception and the consequences that could follow if the employee's disclosure does not meet the criteria of that rule." ■