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'Bait and Switch' Advertising Brings $16 Million Verdict

A recent $16 million verdict illustrates the risk faced by a hospital when its marketing promises too much and misleads patients.

The plaintiff was a woman who chose a hospital because it advertised more gentle and natural ways to give birth, but she ended up with a chronic injury after a nurse wrestled her into an unwanted position and used her hand to keep the baby's head from emerging until a doctor arrived.

The verdict included $5 million for punitive damages related to what the jury said was "reckless fraud" in advertising and claims by a physician.

Caroline Malatesta originally planned to give birth at St. Vincent's hospital in Birmingham, AL, where she had delivered three times previously with no complications. However, she was intrigued by the marketing campaign of Brookwood Medical Center, also in Birmingham, which was billing its new women's center as an alternative choice for women who preferred a more natural birth process that emphasized giving the mother choice in how she delivered. The marketing campaign included features on local television news and talk shows.

"THE HOSPITAL PUTS OUT ONE OFFER, THE OFFER INDUCES THE PATIENT TO COME IN, AND WHEN THEY GET THERE, THE OFFER IS NO GOOD."
— KATHLEEN JUNIPER, JD, BUCHALTER NEMER

The hospital promised supportive nurses and also advertised its unconventional options such as water births. Malatesta was particularly interested in Brookwood's wireless fetal monitoring, which allows the mother to walk during labor. St. Vincent's didn't have wireless fetal monitoring, and Malatesta knew from experience that staying in bed made her labor more difficult. She interviewed a Brookwood physician

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who, Malatesta says, assured her that the nurses were especially supportive of a mother's preferences. The physician said that she could choose her method of birth and deliver in any position and not necessarily on her back, according to Malatesta. He also said she could choose a water birth, but the lawsuit later revealed the hospital did not offer that option even though it had been promoted in the marketing campaign.

Malatesta had not been drawn to alternative childbirth options before, but she liked the overall idea of a hospital that gave the mother more freedom to choose how she wanted to deliver, she told the news site AL.com. "Brookwood's advertising is what first piqued my interest in natural birth," Malatesta said. "It added a layer of legitimacy. Natural birth wasn't just a trend; these were real medical decisions." *(The article can be accessed by readers online at http://bit.ly/2c8LUrz.)*

Not the Expected Care

Malatesta's experience turned out to be far from gentle, and her choices were not respected, according to information revealed in the trial. Even worse, she was left with an injury that she says has changed her life. A jury found that the injury was the result of Malatesta being forcibly put on her back instead of her preferred position. *(See stories included in this issue for details on Malatesta's experience and for more information on how the injury might have been avoided.)*

When she realized a few months later that she was not recovering properly, Malatesta sought help and was diagnosed with pudendal neuralgia, a painful, debilitating condition that Malatesta has been told most likely is permanent. She wondered if the condition was the result of her birth experience, and the patient advocate at Brookwood set up a meeting with Malatesta and the hospital's vice president. The vice president later canceled the meeting and hung up on her when she called, Malatesta says.

She filed suit in 2014. In August 2016, Malatesta won the $16 million verdict not just for medical malpractice but also for fraud. The damages were $10 million for the pudendal neuralgia injury, $1 million to the husband for loss of consortium, and $5 million in punitive damages related to the fraudulent marketing.

Kate Darden, vice president of marketing and communications for Brookwood, issued a statement saying the hospital "strives for excellence in patient care and

EXECUTIVE SUMMARY

A jury awarded a plaintiff $16 million in a malpractice case that involved the hospital's marketing. The woman alleged she was misled by the advertising when choosing where to deliver her baby.

- The hospital had advertised its women's center as providing a more natural and relaxing experience than those at other hospitals.
- The woman suffered an injury during what she says was violent, forceful treatment by the staff.
- Senior hospital administrators had not reviewed the marketing materials before they were published and aired.

satisfaction, and we respectfully disagree with the jury's verdict."

Marketing for hospital services always must be considered in terms of specifically what is being offered, notes **Kathleen Juniper**, JD, an attorney with the law firm of Buchalter Nemer in Los Angeles. She focuses her practice on the advertising and marketing of health services and frequently reviews ad copy and marketing materials for her clients.

Testimony at trial indicated the marketing campaign never was approved by a senior executive such as the risk manager, chief medical officer, or legal counsel. Juniper says that such an oversight is inexcusable, and she suspects an overly aggressive marketing department may have intentionally bypassed that approval process.

"This was almost like a bait and switch. It's a classic example of false advertising," Juniper says. "The hospital puts out one offer, the offer induces the patient to come in, and when they get there, the offer is no good. They can't get the product or service advertised."

The hospital should have a formal, mandatory process for the approval of any type of advertising or other marketing, Juniper says. All claims should be reviewed by an attorney who takes the time to investigate any statements that make an offer to patients. Often that step will involve reviewing the material with the chief medical officer or another senior clinician.

Hospital risk managers should not assume that the marketing department has proper oversight, says **Damian D. Capozzola**, JD, an attorney in Los Angeles. "This practice of not vetting policies, products, protocols, and procedures with the would-be users, before implementation, while unfortunately not uncommon in a healthcare organization, is one of the most frustrating and extremely high-risk situations healthcare providers face every day," he says.

New Avenue for Claims

The case could put a spotlight on hospital advertising and prompt more allegations of fraud, says **Joshua H. Haffner**, JD, an attorney with Haffner Law in Los Angeles. That spotlight could be particularly bright in states that have a cap on medical malpractice damages, where the plaintiff could sue additionally for fraud that would not be subject to the cap.

"For lawyers whose clients were brought to the doctor or hospital by advertising, this is a whole new avenue to pursue," Haffner says. "This is really an important case, and hospitals will have to look at what they are doing with their advertising."

Haffner notes that the nature of the services advertised — more natural childbirth and non-traditional options — did not drive the fraud allegations. The problem was that the hospital promised a service and did not deliver it, which could apply to the most conventional treatment.

"I see all these advertisements for cancer treatment centers, substance abuse programs, and they all need to be careful with what they're saying," Haffner says. "You have to be careful that your marketers are not puffing up the facts of what you actually can offer. That can get away from you really quick when the hospital is pushing the marketing department to be aggressive and get people in."

The entire incident and judgment can be traced back to that lack of review, says **Jamie Terrence**, RN, president and founder of Healthcare Risk Services in Los Angeles. Terrence previously was the director of risk management at California Hospital Medical Center in Los Angeles.

"If the hospital, through the doctors and nurses as its agents, as well as the marketing department responsible for the fraudulent ads, had informed mothers of the actual requirements associated with natural births in the medical facility, the hospital would have been better positioned to defend the lawsuit and, perhaps, this tragedy could have been avoided entirely," Terrence says. ■

SOURCES

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Nurse Wrestles Mother into Position — Injury Results

Caroline Malatesta's birth experience at Brookwood Medical Center in Birmingham, AL, was the opposite of what she expected. She chose the hospital because it promised a gentler birth experience but, instead, ended up injured from a nurse forcing her into a delivery position that she did not want.

Brookwood emphasized in its marketing that it respected the

mother's choice in how she wanted to deliver, unlike other facilities where mothers were expected to comply with a standard protocol.

When she first entered the hospital in labor, Malatesta was assisted by a nurse she recalls as kind and supportive, and who allowed her to proceed with labor on her hands and knees, as she preferred. Subsequently, another took over and told Malatesta that she should use the bathroom because she might not be able to get out of bed for the rest of her labor. The nurse "made it clear that she was not supportive of [her] decision to have a natural birth," she said. When the time came for her to give birth, she was not given the freedom of movement promised to her by the advertisement, she claimed in her lawsuit.

Malatesta was on her hands and knees when she felt a large contraction and said the baby was coming. The nurse ordered the mother to turn on her back, and Malatesta protested that she couldn't deliver that way. Her husband said he could see the baby's head. The nurse forcibly flipped Malatesta onto her back by grabbing her wrists and pulling her hands out from under her, the mother said. Malatesta's lawsuit said she tried to resist and struggled with the nurse.

Malatesta protested that her doctor had assured her that she could labor in whatever position she wanted, and the nurse responded, "Well, your doctor isn't on call tonight," according to the lawsuit.

She attempted to reduce the pain by raising her hips and trying to return to her hands and knees, but Malatesta claimed that the nurses held her down. During the final contraction, Malatesta says a nurse forced her left knee toward her chest, which put her legs in an asymmetrical position.

As the baby's head was crowning, a nurse pressed the baby's head back into her vagina and held it in for about six minutes while they waited for a doctor, she says. Malatesta said she was screaming at the nurses to stop and let the baby deliver. The baby was born a minute after the doctor arrived, the lawsuit said. ■

Nurse's Actions Called 'Obstetrical Violence'

In addition to the advertising fraud that led to a $16 million verdict against Brookwood Medical Center in Birmingham, AL, the physical interaction by the nurse is troubling, says **Kathleen Juniper**, JD, an attorney with the law firm of Buchalter Nemer in Los Angeles.

"You could call it obstetrical violence," Juniper says. "The facts of the case are pretty horrendous."

The rough handling by the nurse might have been avoided with a better handoff between the first nurse, whom the patient saw as respectful, and the second nurse, says **Damian D. Capozzola**, JD, an attorney in Los Angeles. The first nurse should have reviewed the patient's stated preferences at the handoff, and if the second nurse did not want to comply with them, she should have addressed that issue then.

"Ideally this takes place at the bedside so that the off-going nurse can introduce the patient to the oncoming nurse. At the same time, the plan of care is discussed between the patient and both nurses," Capozzola says. "Had this occurred, the oncoming nurse would have had the opportunity to discuss her concerns with her charge nurse or supervisor, and her patient assignment could have been changed."

The behavior of the nurse in this case was abnormal, especially considering the "Well, your doctor isn't on call tonight" comment, says **Jamie Terrence**, RN, president and founder of Healthcare Risk Services in Los Angeles. Terrence previously was the director of risk management at California Hospital Medical Center in Los Angeles. The nurse may have had some objection to the mother's choices, but her behavior demonstrates the need for effective internal communication, Terrence says.

"If the mother's first doctor had adequately communicated the mother's desire to have a natural birth, then the experience would have been better all around. Perhaps the nurse could have opted out if she so desired," Terrence says. "The bottom line is that there needed to be better internal mechanisms supporting both mothers who wish to give birth naturally and staff members, regardless of whether they advocate for natural births or not."

Terrence notes that regardless of hospital policies, patients have the right to make decisions about their care. This patient's rights were violated on many levels, she says.

"Patients are not prisoners without freedom of choice. If their choices are dangerous to them or to their unborn child, the hospital has the responsibility to educate the patient about any danger their choices may involve," Terrence says. "Caregivers may also refuse to participate in that care. But resorting to physical mishandling can be viewed as assault and, in certain circumstances, can even give rise to criminal charges." ■

In Unusual Settlement, Hospital Works with Plaintiff to Improve Safety

The malpractice case brought against Overlake Hospital Medical Center in Bellevue, WA, by **August de los Reyes** involved a tragic outcome but, in other ways, seemed familiar until the parties reached an unusual settlement. In addition to paying $20 million, the hospital agreed to involve de los Reyes in ongoing safety improvement efforts in a way that goes beyond the patient safety councils found at some facilities.

De los Reyes, a former design head for Microsoft's Xbox and now with Pinterest, broke his back and nearly severed his spinal cord in 2013 after a series of missteps at Overlake. The errors left de los Reyes paralyzed from the chest down at age 42, and the injury is thought to be permanent. *(See the story enclosed in this issue for more information on the sequence of medical errors.)*

De los Reyes says his professional interests and experience led him to see his injury as an opportunity for improving the healthcare process. "When we develop software, mistakes often happen, and we look at how the mistakes came about," he says. "I've been fortunate to work in organizations that have the best talent and resources, so when you have a situation where talent and resources aren't the issue, there is something else that allowed the problem to happen. Overlake is a modern hospital with the latest and greatest technology, and the doctors I met with were very capable, yet something happened that caused this situation to occur."

Once the injury occurred, his natural reaction was to analyze the problem the same way he would with a computer issue and learn from shortcomings, de los Reyes says. His primary motivation was to prevent the same injury from happening to anyone else, he says.

"I didn't have animosity toward the hospital or the doctors, and I assumed that everyone involved would want to keep this from happening again," he says. "I opened that up as a channel of discussion in the settlement talks. Naively, I didn't know that this was breaking new ground. To me, it just seemed like common sense."

Direct Involvement

The settlement agreement with de los Reyes specifies that the hospital will work collaboratively with de los Reyes to understand what happened to him and to use that information for improving healthcare at the hospital, says **David Knoepfler**, MD, FACP, FHM, chief medical officer at Overlake. Exactly how the parties would collaborate was left open in the agreement, but Knoepfler says they agreed that de los Reyes would be involved in a significant way to learn more about his case and to design safety improvements.

The hospital has invited de los Reyes to its patient advisory council, but he moved to a different city after the injury and cannot regularly participate. His agreement with the hospital calls for him to work directly with hospital leaders and outside experts.

This type of collaboration requires a plaintiff and attorney who are oriented to improving the process rather than focusing on only one error, Knoepfler says. "August is a gentleman who is very forward-thinking, very systems- and design-oriented," he says. "As much as this was a catastrophic event, August clearly wants to turn this into something positive. We came to this through August being very practical minded and wanting to make sure his experience could be used to positively impact the hospital and its systems."

The settlement with de los Reyes meshes well with the hospital's recent efforts to embrace transparency and patient safety, Knoepfler says. At the first meeting with de los Reyes, his attorney, Knoepfler, and other hospital leaders, the group mapped out the goals for the collaboration. The first and primary goal for de los Reyes was to learn exactly what led to his injury, beyond the medical reports and information available to him and his attorney. "He wanted to understand the nature of the event

EXECUTIVE SUMMARY

A hospital in Washington settled a malpractice lawsuit with an unusual stipulation. In addition to a monetary payout, the hospital agreed to include the plaintiff in future efforts to improve patient safety.

- Failure to diagnosis led to permanent paralysis.
- The plaintiff will be involved with the ongoing investigation of the medical errors during his care.
- The hospital is reviewing its original root cause analysis for opportunities to learn more.

at a very deep level," Knoepfler says. "We both had the goal of doing everything we could to effect positive changes at the hospital. August also wants to assemble leaders in the field of systems design and use his case to review existing designs and how to enact change."

Meeting With Leaders

Knoepfler also agreed to de los Reyes' suggestion that his attorney **Robert Gellatly**, JD, with the Luvera Law Firm in Seattle, meet with several department leaders at the hospital to review the case from a medico-legal perspective. The leaders came from all departments involved in de los Reyes' care, including the ED, radiology department, and the hospitalist program.

"That meeting is not about learning how to practice defensive medicine but to learn what is crucial in terms of documentation and communication, anything that can be improved to provide better care," Knoepfler says. "That effort to improve and provide the best care is primary, not just trying to avoid having a lawyer send you a letter."

Gellatly says this case is not the first time his firm has sought such cooperation in a malpractice settlement, and many plaintiffs are eager for such a resolution. When de los Reyes expressed his interest, Gellatly proposed the agreement as a term of the settlement, and he specified that hospital leaders at the highest level would cooperate with de los Reyes. The settlement requires that leaders, including Knoepfler and the hospital's chief executive officer, meet with de los Reyes to openly discuss ways the hospital's systems could be improved.

The settlement was achieved with the hospital, the independent emergency medicine group that treated de los Reyes in the ED, and the radiology group responsible for his testing. The $20 million was all of the insurance available to those defendants, Gellatly says.

"They agreed, at our insistence, that there would be no confidentiality at all," Gellatly says. "We let them know of that early in the process, because often the hospital's attorneys will try to add a confidentiality requirement late in the settlement progress, and many lawyers go along with that. We don't because we don't think it serves the public interest."

Seeking the Whole Story

Overlake leaders are reviewing their original root cause analysis (RCA) and seeking ways to expand or improve it, with the goal of having a detailed and thorough explanation of the adverse event at their next meeting with de los Reyes.

"My sense is that he's not sure he's gotten the whole truth because the legal process sometimes leads to obfuscation or not always a complete and comprehensive story," Knoepfler says. "We're revisiting the RCA to make sure we're giving August the most complete story that we can."

Once the sequence of events for de los Reyes' case is thoroughly understood, the next step will be using that information to address communication issues in healthcare, as well as any other potential improvements. Knoepfler encourages hospital leaders to pursue this type of arrangement when appropriate and to work cooperatively with an injured patient even after a lawsuit is filed. Overlake has worked with other patients after adverse events in similar ways, and he has invited them to speak to quality committees and make other contributions.

"Work with the patients and, in our experience, if you can help the patient feel like they're part of something bigger, that they're changing the quality and safety of healthcare, it goes a long way," Knoepfler says. "Everyone wants to contribute and make a difference." ■

SOURCES

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ED Doctor Waited Five Days to Enter Diagnosis

The sequence of events that led to **August de los Reyes** being paralyzed from the neck down at age 42 began innocuously with a simple fall from his bed at home in May 2013.

De los Reyes hurt his back, and he was immediately concerned because he had been diagnosed 10 years earlier with ankylosing spondylitis, an inflammatory disease that could make him more susceptible to serious spinal injuries. The condition can cause vertebrae to fuse together, which makes the spine less flexible and more prone to fractures. When he developed severe back and abdominal pain, he decided to go to the Overlake Medical Center ED right away.

The ED physician sent him home with pain medication, even though he diagnosed a probable lumbar or thoracic fracture. However, court

testimony later revealed that he did not enter that diagnosis into de los Reyes' medical record for five days. De los Reyes' condition did not improve, and he made four more visits to the Overlake ED in two weeks. Each time he explained his concern about his susceptibility to a spinal fracture, but each time he was told there was no fracture and provided more pain medication, de los Reyes says.

Once a lawsuit was filed, the physicians who had seen de los Reyes gave conflicting accounts of information available to them and what they told de los Reyes. On the last visit to the ED, de los Reyes says he was in excruciating pain and had lost control of his bowels, a common symptom of spinal injury. He also had developed tingling in his waist and upper legs.

On this visit, a physician ordered an MRI. As technicians positioned him for the scan, he remembers screaming in pain and then going limp. The technicians completed the MRI, and it showed the fracture in his spine. De los Reyes was transferred to Harborview Medical Center in Seattle, where it was confirmed that he had lost all neurological function below his eighth and ninth thoracic vertebrae. Doctors told him he would never walk again. ■

Safety Huddles Produce Results If They Are Controlled and Monitored

Leaders at Bassett Medical Center in Cooperstown, NY, worried in 2014 that its culture of safety could be improved, particularly the length of time it took to resolve known safety issues. When a review of data revealed a decline in staff reporting actual and near-miss events, the vice president for patient safety and performance improvement called for the development of a safety huddle policy.

After a year of regular safety huddles, reporting of incidents has increased 51%, and participants reported more than 1,500 issues of concern.

Safety huddles were known to the leaders and staff at Bassett, but they had a reputation as one of those ideas that caused people to get excited initially but then lose interest, says **Ronette Wiley**, RN, MHSA, CPPS, vice president of performance improvement at the hospital.

"We heard from a number of people that safety huddles were useful until they fizzled out," she says. "One of the things that made ours successful was that we developed monitoring and tracking tools to help hold people accountable. We also had a great champion for the safety huddles in our CEO, who tries to attend every safety huddle."

The team designed a daily leadership safety huddle to promote awareness of issues within the previous 24 hours plus any issues that may arise in the next 24 hours. Leaders from 31 departments meet at 8 a.m. each day, which means that they must round on their units or otherwise contact their staff to be aware of any developments or concerns. There was some initial concern about that requirement being too onerous, so Wiley asked members to commit to only a 30-day trial period with the possibility of altering the time or frequency.

At the end of the 30 days, huddle participants reported that the meeting was ingrained in their workdays and should remain unchanged. Some members did ask for a call-in number so they could attend by phone, but that request was denied.

"We felt that was detrimental to the important face-to-face connection," Wiley says. "We also wanted to resist our natural tendency to multitask as we're driving or looking at something better on the computer."

Six Rules for Huddles

Some departments were added to the original huddle team as the first year continued. The team leaders added the human resources and biomedical departments to the

EXECUTIVE SUMMARY

A hospital achieved significant safety improvements by instituting a system of safety huddles. Staff and physicians meet regularly to alert one another to issues that have arisen or may arise in the next 24 hours.

- Safety huddles increased incident and event reporting by 51% over baseline from previous years.
- The huddles are intended to convey information, not be an opportunity for discussion.
- Participants raised more than 1,500 issues in one year.

huddles when they realized that those departments often were copied or consulted on issues that arose.

Wiley says these are the key rules for making their safety huddles successful:

• Arrive on time.

• Plan ahead, and appoint a substitute if you cannot attend. Participants will sign in at each huddle so that attendance can be monitored.

• Give yourself enough time to meet with staff before the huddle so that you are well informed.

• Be prepared to present your information in a clear and concise way.

• Stick to the facts. If there is nothing to report, the participant will state that fact, and the huddle moves on to the next person.

• Do not discuss issues and potential solutions. The huddle is intended only to make others *aware* of issues; problem solving happens in a different venue.

In addition, Wiley says the success of the safety huddles can be attributed to the visibility of the CEO and senior administrative and medical staff at the daily huddles. It also is important to recognize participation, so each month Overlake presents each safety huddle participant with a small gift and a message of thanks. Anyone responsible for a "good catch" or providing outstanding care receives a signed certificate of appreciation.

Supervisors also bring staff members to the huddle to recognize them for doing something especially noteworthy.

Incident and event reporting increased 51% during the first year that huddles were implemented, and near-miss reports increased 86%. There were several concrete improvements from information reported at the safety huddles, Wiley says. *(See the stories enclosed in this issue for more information on the results of the safety huddles.)*

"One example is what we call 'code grays,' which is patient behavior escalating toward violence," she says. "Last year we had a significant uptick that we learned about in the safety huddles, and after instituting a more robust de-escalation program, we're now seeing a 60% reduction in those incidents." ■

SOURCE

- **Ronette Wiley**, RN, MHSA, CPPS, Vice President of Performance Improvement, Bassett Medical Center, Cooperstown, NY. Email: ronette.wiley@bassett.org.

Safety Huddles Raise 1,500 Issues in One Year

During 2015, the safety huddles implemented at Bassett Medical Center in Cooperstown, NY, has increased incident and event reporting by 51% over baseline from previous years, and the increased rate is continuing in 2016, says **Ronette Wiley**, RN, MHSA, CPPS, vice president of performance improvement at the hospital.

Near-miss reporting has increased by 86%, she says, and more than 1,500 issues were raised at safety huddles during 2015. These are some other results:

• On average, 20-30 of the issues identified each quarter resulted in systems changes.

• Turnaround time for analysis and action related to events has decreased from seven days to an average of 48 hours.

• 88% of huddle participants surveyed report that safety and quality issues are reported, investigated, and corrected more quickly since the inception of safety huddles.

• 89% of huddle participants surveyed report that it is considerably easier to connect face-to-face with colleagues about issues and events because of the huddles.

• 86% of huddle participants surveyed report that organizational teamwork has improved because of the huddles. ■

Huddles Produce Many Safety Improvements

Ronette Wiley, RN, MHSA, CPPS, vice president of performance improvement at Bassett Medical Center in Cooperstown, NY, offers these examples of safety improvements resulting from the safety huddles implemented in 2015:

• After an outpatient fall, the hospital conducted an environmental assessment of all health centers that resulted in a number of proactive corrective actions in several locations. These actions included painting curbs; increasing handicapped parking spaces, and putting a call box in a parking lot so patients can request assistance going to and from their cars.

• Members of a safety huddle heard the story of a nurse who was unfamiliar with a new medication and did not recognize an adverse reaction it caused in her patient. The patient was not harmed, but the nursing

education department developed a brief education module for all nurses about the new medication.

• In several huddles, concerns were raised about ED patients being transferred to inpatient units without receiving needed care such as antibiotics and blood products. As a result, the hospital added a prompt to the transfer portion of the electronic medical record that requires nursing staff to verify that medications and treatments have been given. Since the addition, there have been no reports of the problem. ■

Protect Subpoenaed Data from Routine Deletions

Responding to a subpoena can require a risk manager's oversight of many functions in a healthcare organization, and one area is easy to overlook: the scheduled deletions of data from the computer system that happen in nearly every hospital and health system.

Failing to stop those routine deletions could bring legal trouble, cautions **Katherine Lemire**, JD, a former federal prosecutor and president of Lemire, a New York City-based compliance and risk management firm. The definition section of the subpoena spells out what information is being requested, and that data must be preserved until it is provided.

"You want to make sure that no one inadvertently destroys records," Lemire says. "For instance, you might get a subpoena that asks for email correspondence related to a particular patient. You want to make sure your IT people know about that fast so that they're backing up and not doing routine deletion of emails."

Organizations vary widely in how long they keep emails or other general documents, with many deleting the data after 30 days, Lemire notes. Risk managers also should carefully document all instructions regarding preservation of data so that, if information is accidentally erased, the risk manager can show that it was not intentional and that he or she did make a good faith effort to preserve it.

Risk managers also should stay involved with the subpoena fulfillment, even if it is sent to outside counsel, Lemire says.

"The risk manager should manage that outside lawyer, as a way of controlling costs and ensuring that the process is moving appropriately," Lemire says. "I've seen cases where hospitals just decided to farm it out to an outside lawyer and forget about it, but that can result in oversights that hurt the hospital much more than the lawyer. Some supervision and monitoring is always warranted, even if they are experts in the subject matter." *(For more on responding to a subpoena, see "You Must Respond Carefully When You Are Served With a Subpoena,"* Healthcare Risk Management*, September 2016, at http://bit.ly/2c8fsqO.)* ■

SOURCE

- Katherine Lemire, JD, President, Lemire, New York City. Telephone: (646) 979-4100.

MACRA Would Grant Auditors HIPAA Access

A little-known feature of a proposed law adjusting physician reimbursement could create problems with HIPAA compliance, particularly if staff members are not informed.

Access to patient information is very broad under the Medicare Access and CHIP Reauthorization Act (MACRA), says **Dan Golder**, DDS, MBA, principal at Impact Advisors, a consulting group in Cody, WY. What could be a HIPAA violation in most circumstances might be allowed under MACRA, he says.

MACRA was enacted April 16, 2015, to eliminate the sustainable growth rate (SGR) formula that threatened every year to drastically cut physician compensation. MACRA limits aggregate Medicare physician payments to a 0.5% increase per year through 2019, and 4% of a physician's annual Medicare payments will be tied to one of two paths: the Merit-Based Incentive Payment System or participation in Alternative Payment Models. *(To access the rule, go online to http://bit.ly/1VCRVQn.)*

Hospitals with employed physicians and owned or affiliated physician practices will be affected by MACRA. The new system is effective Jan. 1, 2017, but CMS announced in September that it is providing options for physicians to enter more gradually and with fewer penalties.

The rule allows in-person audits of a physician's or facility's electronic health record (EHR) in a way that Golder says is unprecedented. "They might have gotten audited under Meaningful Use, but that meant getting a letter and sending some data in," Golder says. "These audits may be in-person audits with people coming in and looking at your EHR. That's a giant leap in terms of access."

As the proposed rule is written, the auditors would not be constrained by HIPAA, Golder says. "Government entities do have some access to patient data, but it seems that auditors looking at financial information should be covered under the HIPAA umbrella," Golder says. "There are no specifics about what the audits will be like, except for saying that auditors may come in, and they will have access to PHI [protected health information]. That's part of the legislation."

If the PHI access remains in the final rule, Golder advises risk managers to alert appropriate managers in the hospital or health system so they know the auditors can see PHI without any special permission. With hospital employees so well trained and sensitive about HIPAA compliance, it would be natural for them to resist the auditors, he says. "This will be inconsistent with everything they know about HIPAA and PHI, so there could be confrontations and delays if employees are not forewarned," he says. ■

Workplace Bullying Brings $1.08 Million Verdict

A nurse in Dallas has been awarded $1.08 million for what a jury found was workplace bullying by her boss, a urologist. However, the plaintiff settled for $440,000 just before the verdict was announced.

Patty Hahn, LVN, experienced three bullying incidents at North DFW Urology Associates in Grapevine, TX. A Dallas County jury recently found Scott Davidson, MD, and his clinic liable for sexual harassment, intentional infliction of emotional distress, and retaliation.

The $440,000 settlement was made shortly before the verdict was announced and cannot be appealed, says Hahn's attorney **Rogge Dunn**, JD, partner with the law firm of Clouse Dunn in Dallas. The $1.08 million jury verdict included $348,889 against the doctor individually for bullying, Dunn notes.

"A verdict such as this should serve as a warning and wake-up call to bosses everywhere that they cannot scream, demean, or otherwise bully their employees," Dunn says. "This is one of the few verdicts I'm aware of in the country awarding an employee damages against their boss individually for bullying."

Hahn described a threatening, hostile work environment, and she testified that, on three occasions, Davidson screamed, "Just shut up. Just shut up. I'm sick of you," with his hands raised and fists clenched. Hahn reported the behavior to the human resources department and filed a complaint. Soon after, Davidson called her into an office after business hours and gave her a "demonstration" of what screaming was, to prove that he had not screamed. ■

SOURCE

- **Rogge Dunn**, JD, Clouse Dunn, Dallas. Telephone: (214) 220-3888. Email: rogge@trialtested.com.

Court Says Reading Test Results Are Not 'Treatment'

Reading test results does not constitute "treatment" as defined in medical malpractice law, and neither does transmitting the report, according to a Pennsylvania Superior Court common pleas judge.

Judge **Arnold New**, JD, of the Philadelphia Court of Common Pleas, had ordered the transfer of a medical malpractice case from Philadelphia to Berks County because the plaintiff's allegations regarding an echocardiogram (ECG) allegedly improperly sent by a Philadelphia doctor were not enough to keep the case in the city. The plaintiffs challenged that order and said that reading the ECG constituted treatment, which would qualify, according to a report in *The Legal Intelligencer*. *(The report is available online at http://bit.ly/2c1G0Jz.)*

The case involved an infant who was treated in Berks County at Reading Hospital before he was taken to St. Christopher's Hospital in Philadelphia. The plaintiffs had argued their allegations that the baby may have suffered a broken rib at St. Christopher's Hospital and that a physician had interpreted and signed an ECG at St. Christopher's. They said these allegations were sufficient to keep the claim in Philadelphia. The judge disagreed and said that interpreting an ECG did not qualify as professional treatment sufficient to keep the claims in Philadelphia.

"The appellate courts have declined to extend the rules pertaining to venue in medical professional liability claims to encompass acts done within a county that do not rise to the level of rendering healthcare services. An untimely transmittal of an echocardiogram report does not rise to the level of rendering healthcare

services," New said, according to court documents obtained by *The Legal Intelligencer*. "Both asserted negligence directly stemming from the directives given regarding impending medical care, and both were insufficient to establish venue in a medical professional liability claim. Here, the appellants bring it down a notch by alleging an untimely transmittal of the report only."

The judge also determined that transmitting his report on the ECG to the hospital could not be considered treatment. "Transmittal of a report is an administrative function, not a function of providing medical care," he said. ■

Nurse Input Undervalued in Patient Safety

Nurses are an "underused resource" for improving patient safety, according to a recently published study.

Nurse researchers from the Karolinska Institutet in Stockholm conclude that nurses have a unique perspective of the patient care experience and their input should be valued more in patient safety efforts. Nurses at many of the facilities studied were an "underutilized" resource for measuring quality and safety in hospital settings, the study says. *(An abstract of the study is available at http://bit.ly/2clLA9W.)*

The researchers studied relationships between registered nurse assessments of care quality and patient safety, and they compared them with 30-day inpatient mortality post-surgery in acute care hospitals. The data included more than 200,000 surgical procedures performed in 67 hospitals throughout Sweden and survey responses from more than 10,000 nurses.

Researchers Find Link

The researchers found that nurse assessments of excellent patient safety and quality of care were related to significantly reduced odds of patients dying in the hospital within 30 days of admission after general, vascular, or orthopedic surgery.

In hospitals ranking in the top third by percentage of nurses reporting excellent quality of care, patients had 23% lower odds of 30-day inpatient mortality when compared to patients cared for in hospitals in the lowest third.

"RN-assessed excellent patient safety and quality of care are related to significant reductions in odds of 30-day inpatient mortality, suggesting that positive RN reports of quality and safety can be valid indicators of these key variables," the researchers concluded. ■

Office of Civil Rights Gives Warning: Small Breaches Are Going To Be Investigated

The Office for Civil Rights announced recently that it will step up its investigations of HIPAA breaches affecting fewer than 500 people.

Noting that the root causes of breaches might indicate entity-wide and industry-wide noncompliance with HIPAA's regulations, the Office for Civil Rights sent electronic notification to providers alerting them that small-scale breaches will receive more attention than in the past. It also pointed out that investigation of breaches provides its office with an opportunity to evaluate an entity's compliance programs and obtain correction of any deficiencies.

In the past, the Office for Civil Rights focused on breaches involving 500 or more individuals, and it investigated smaller breaches as time and resources permitted. The Office for Civil Rights says regional offices still will retain discretion to prioritize which breaches to investigate.

The Office for Civil Rights cites the following determining factors:

- the size of the breach;
- whether the breach involved theft of or improper disposal of unencrypted protected health information (PHI), or hacking;
- the amount, nature, and sensitivity of the PHI;
- repeated breach reports from a covered entity or from a business associate. ■

COMING IN FUTURE MONTHS

- Making the most of handoffs
- How opioid epidemic creates risk
- Reducing obstetrics claims
- Should your facility forgo alarms to reduce falls?

HEALTHCARE RISK MANAGEMENT™

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CE/CME QUESTIONS

1. **In the $16 million verdict against Brookwood Medical Center in Birmingham, AL, what portion was punitive damages related to fraudulent advertising and claims by a physician?**

   a. $1.5 million
   b. $5 million
   c. $10.5 million

2. **How does Damian D. Capozzola, JD, an attorney, say a poor patient handoff contributed to the Brookwood Medical Center verdict?**

   a. Patient records were incomplete.
   b. Incorrect information was included in the records.
   c. The outgoing nurse did not convey the patient's wishes to the incoming nurse.

3. **What medical error led to the malpractice case involving Overlake Hospital Medical Center and August de los Reyes?**

   a. Failure to diagnose
   b. Medication overdose
   c. Patient misidentification
   d. Patient fall while hospitalized.

4. **What was one rule for the safety huddles implemented at Bassett Medical Center?**

   a. The huddle is not a forum for discussion or problem solving.
   b. Attendees should refrain from contacting others on their units before attending the huddle.
   c. Huddles are limited to no more than five participants.
   d. Huddles can be conducted only at the end of a shift.

CE/CME OBJECTIVES

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

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

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

Unnecessary Heart Surgery With Pacemaker Results In $21.3 Million Verdict Against Hospital and Doctor

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News: In 2010, a 39-year-old patient was told by a doctor that a catheterization showed a 60% blockage in an artery. He then was told that if he did not have a pacemaker implanted, he would die. That doctor implanted the pacemaker and then recommended a stent. The patient sought other opinions, and other doctors told him that he did not need the pacemaker. They also told him that it could not be removed. The patient filed suit against the doctor, who settled with him, and the hospital. The trial lasted seven days, and the jury found that the doctor exceeded the terms of ordinary care and failed to obtain informed consent. The jury also found that the hospital failed in its duty and conspired with the doctor in accomplishing a corrupt or unlawful act. The jury awarded the plaintiff $21.3 million.

Background: In early September 2010, a milk truck driver went to a doctor to have testing done. The doctor informed the patient that a catheterization showed a 60% blockage in an artery and that if he did not have a pacemaker implanted, he would die. After the surgery to implant the pacemaker, the doctor recommended a stent. The patient was suspicious about this recommendation, so he decided to obtain the opinions of additional doctors. They informed him that he actually had a 10% blockage. They also told him that the surgery to implant the pacemaker was unnecessary. Unfortunately for the patient, the pacemaker could not be removed. Because his surgery left him bedridden for weeks, he suffered shoulder problems. The patient also was forced to switch to a job that keeps him away from home more, which meant less family time.

> THE PATIENT SOUGHT OTHER OPINIONS, AND OTHER DOCTORS TOLD HIM THAT HE DID NOT NEED THE PACEMAKER.

The patient filed suit against the doctor and hospital in 2011. Almost 400 other plaintiffs also filed suit against the hospital and the group of cardiovascular specialists formerly known as "the heart doctors." This action was the first of the large pool of litigants to be prosecuted. In his complaint against the hospital, the patient alleged the hospital formed a joint venture with local cardiologists that provided incentives to boost the number of heart procedures, but it failed to put in safeguards to ensure that only necessary procedures were performed. Evidence was presented at trial that showed the hospital anticipated making $90 million over three years from heart procedures and that executives were given bonuses based on productivity and revenue. The same hospital agreed to pay the federal government $16 million in 2014 to dismiss civil claims against it for submitting false or fraudulent claims to the Medicare and Kentucky Medicaid programs for medically unnecessary heart procedures.

In his suit against the doctor, the patient claimed the doctor injured him by operating on him without justification and that he failed to obtain informed consent. The doctor settled with the patient before trial. That doctor

later was indicted on criminal fraud charges for implanting devices into patients without sufficient need or justification.

At the seven-day trial against the hospital, it was argued that the operation on the patient was medically necessary. The hospital also stated that the doctor acted independently of the hospital and said that doctors, not the hospital, make medical decisions. As to the alleged joint venture, the hospital said it was trying to strengthen cardiac care in a historically underserved region. Finally, the hospital stated it had no choice but to hire foreign doctors and because of a shortage of cardiologist specialists, it had to pay them incentives to get them to move to London, KY. The jury was unmoved by those arguments and rendered a verdict in favor of the patient for $21.3 million. The verdict included $20 million in punitive damages against the hospital on the basis that the hospital engaged in a conspiracy to profit off the people of Laurel County. The base $1.3 million was allocated 50/50 between the doctor and the hospital, but because the jury also found the existence of a joint venture, the hospital also was liable for the doctor's portion.

What this means to you: This case illustrates the need for hospitals to exercise care when hiring medical personnel. The screening process for hiring doctors, nurses, administrators, and other employees should be oriented toward preventing cases such as this one. Hospitals should put in review mechanisms to ensure ethical treatment of all patients. In a perfect world with a hospital that practiced morally, the test results received by the doctor in this case would have been reviewed by a supervisor to increase accountability and prevent tragedies such as this one.

All hospital employees are required by law to participate in compliance training. They learn about fraudulent billing, anti-kickback laws, and laws regarding bribes or excessive gifts for physicians. This training also covers the requirement to report noncompliance incidents to the compliance officer within the employees' organization. Hospitals also have case managers who follow assigned patients from admission through discharge and beyond. Their role is to evaluate whether the patients' needs are being met, the level of care is appropriate, and future care needs are addressed. In addition, a case manager has the responsibility to make sure that abnormal test results are acknowledged by attending physicians and medical plans of care are adjusted based on test results. Case managers are trained to identify fraud and abuse by healthcare providers and are mandated to report them. Had the employees of this hospital followed the required training, this practice should have been stopped before harm occurred.

> ... IT WAS ARGUED THAT THE OPERATION ON THE PATIENT WAS MEDICALLY NECESSARY.

Another lesson to be learned from this case is to seek multiple opinions on life-changing medical procedures. It is tragic that the plaintiff here learned too late that the procedure was unnecessary and irreversible and that the severity of the diagnoses should have prompted the plaintiff to seek a second opinion. Even medical professionals who have the best intentions misread tests and make other similar mistakes every day. Many such errors are harmless, but where one's livelihood or life is at stake, it would behoove patients to seek additional advice. This case also should encourage medical professionals to tell their patients to seek second opinions when appropriate.

This case also demonstrates the function of informed consent. When doctors have an interest in a certain procedure or treatment, it is imperative for them to fully inform their patients of that interest. That disclosure will permit the patient to decide whether they can attribute the recommendation of the procedure to the outside interest or their medical welfare. It also is important to let patients know what their options are so they can make an informed decision as to how to proceed with their medical care. Finally, it is equally important to tell patients the risks of medical procedures. Without that knowledge, a layperson is not in an informed position to make decisions regarding his or her health. It also is a good idea to document the process of explaining the options to the patient. Some physicians walk the patients through all possible options, from nothing at all to the most aggressive treatment, and explain the pros and cons of each. During this conversation, notes are made to reinforce the explanations, and then the pages used to explain the options can be saved in the patient's file. By taking this step, if there ever is a question about what was explained to the patient, there is contemporaneous evidence to fall back on. Such evidence can be tremendously helpful in defending a lawsuit, should that be necessary.

One argument the hospital made in its defense was that the shortage of cardiac specialists in the area forced it to hire foreign specialists. This argument leads to the point that training is essential for foreign professionals and locals alike. Because each culture is different, hospitals and staff members should be conscious of cultural differences and, equally important, be prepared to ensure that clashing cultural norms do not interfere with the administration of efficient and adequate healthcare. A hospital must not allow a misunderstanding stemming from cultural differences to have the appearance of corruption that this case contained. Also, ensure that all doctors can adequately articulate the risks, alternatives, and other factors concerning the procedures they intend to perform on patients.

Another factor here, and unfortunately not an uncommon one, is the tendency for administrations to offer physicians a "physician-friendly" environment. A hospital can't survive without patients, and patients go to hospitals where their physicians practice.

Keeping physicians happy, regardless of their ethnicity, specialty, or ethical conduct, can seem to be of paramount importance. It is much easier to look away than to confront a physician whose practice is in question. In many situations, even though "everyone knows," employees and administrators fear reprisals and fall silent. Hospitals should have communications mechanisms for reporting concerns without fear of reprisal.

A second argument that the hospital made was that its payments to induce the influx of new cardiac specialists were made to help serve a historically underserved community. While this step would be an admirable action, except for the corruption, it brings to light an issue with offering incentives in the medical industry. Incentives sometimes give the impression of improper influence on a doctor's decisions. Therefore, hospitals must be wary of what they incentivize and pay careful attention to why they offer them, in addition to how they will affect the behavior of medical professionals.

The jury here made a decision that will help pave the way for the remaining hundreds of plaintiffs who will seek remedies for their unnecessary heart procedures. The hospital was projected to make $90 million from the heart procedures, and with only one case, has to pay out $21 million to only one plaintiff. When money gets put before the welfare of patients, everyone loses. ■

REFERENCE

Laurel County Circuit Court, Kentucky. Case Number: 12-ci-00090, Aug. 10, 2016.

Feeding Tube in Lung Results in Death And $5 Million Verdict From Jury

News: In 2008, a hospitalized 88-year-old man was given a feeding tube by a first-year resident at a hospital. An X-ray was ordered to confirm the placement of the feeding tube, but the radiologist incorrectly read the X-ray. The feeding tube was placed in the patient's lung rather than in his stomach. It later was discovered that the X-ray study used was not the proper study to confirm accurate placement of the feeding tube. Relying on the incorrect interpretation of the X-ray study, the patient was given feeding fluid for 12 to 14 hours into his lung. He was restrained to his bed due to a prior attempt to leave the bed. He exhibited symptoms of distress, which the healthcare providers failed to associate with an incorrectly inserted feeding tube. He died from suffocation. The jury awarded the patient's estate $5 million, and it attributed 25% of the liability to the hospital and 75% to the radiologist and her radiology group.

Background: In December 2008, a man was sent to the hospital to be treated for two episodes of syncope, or temporary losses of consciousness. He was transported to a local hospital and was given a feeding tube, which he pulled out. A second feeding tube was inserted, but it was removed after an X-ray indicated it was placed into the patient's left lung. The following day, a first-year resident inserted a third feeding tube into the patient. An X-ray technician X-rayed the patient's chest and abdomen, and the defendant radiologist reviewed the X-ray study. The radiologist incorrectly read the study as a correct placement of the tube, but once again the feeding tube had been inserted into the patient's left lung. The radiologist testified in her deposition that she incorrectly read the study and that she later learned that the X-ray that was taken was not the correct study to determine the placement of the tube.

Because the radiologist misread the X-ray study, the patient was given feeding fluid directly into his

lung. Because he previously tried to get out of his bed, the patient was in restraints and could not pull out the tube. As he began to drown from the fluid, he exhibited symptoms of distress, which the healthcare providers failed to recognize as being associated with an incorrectly placed feeding tube. The patient received the tube feeding fluid into his lung for 12 to 14 hours. Midway through the feeding, the patient's daughter called the hospital to speak to her father, but she was told that he was "sleeping comfortably" and tolerating his tube feedings well. The next morning the feeding tube was removed, and after failed attempts to resuscitate the patient, he was pronounced dead at 7:11 a.m. An hour later, another radiologist read a stat X-ray that had been taken of the patient's chest at 4:46 a.m. That radiologist noticed that the feeding tube was misplaced and told the ICU Critical Care Team, but the radiologist was informed that the patient already was dead.

The man's daughter filed a negligence action on his behalf against the hospital and the radiologist who read the initial X-ray. The complaint alleged that the defense was negligent for failing to have policies dictating the proper X-ray study to determine the correct placement of feeding tubes, administering the incorrect X-ray study, incorrectly reading the study, delivering feeding fluid into the patient's lungs, and failing to recognize the patient's symptoms as signs of respiratory distress. In an attempt to reduce damages, the defense pointed to the patient's old age, short life expectancy, and history of medical issues. Furthermore, and somewhat ignoring the horrifying circumstances surrounding the patient's death, the defense also argued that the distressed symptoms the patient exhibited, including elevated heart rate and increased blood pressure, were not unusual considering the patient's advanced age and medical problems. The use of the restraints preventing the patient from removing the feeding tube when he began to feel distressed was justified by the defense due to the patient's past removal of his feeding tube and attempt to leave his bed. The jury unanimously sided with the plaintiff after a three-hour deliberation. The jury awarded the patient's estate $5 million, attributing 25% of the liability to the hospital and 75% to the radiologist and her radiology group.

> THESE PLACEMENT TESTS ARE REQUIRED *EVERY FOUR HOURS* WHILE A FEEDING TUBE IS RUNNING ...

What this means to you: This case highlights the importance of proper X-ray and monitoring procedures for hospitals and doctors. The student doctor also should not have been permitted to place the tube without proctoring. Indeed, unfortunately, the standard procedure for placement of a feeding tube is well known to nurses but probably not well known to first-year residents.

Once the tube is placed and secured, there are two immediate steps to ensure correct placement, even without X-ray confirmation. The first involves withdrawing stomach contents with a large syringe. If stomach contents are seen, the tube is in the stomach. If air is withdrawn or nothing can be withdrawn, the tube may be in the lung or coiled in the back of the throat. In this case, the tube should be reinserted. A second method is to push a small amount of air through the syringe into the tube while listening with a stethoscope placed over the patient's stomach. If air is heard rushing into the stomach when the syringe is pressed, then the tube probably is in the stomach. These placement tests are required *every four hours* while a tube feeding is running because, even though the tube may be placed correctly, it can become dislodged at any time. Had these simple but important steps been taken by the nurses, this tragedy may have been avoided.

This case also illustrates the need for medical practitioners to pay close attention to a patient's symptoms. This man was drowning in fluid for no less than 12 hours. His heart rate was elevated. His blood pressure was high. A cardiologist believed he suffered from aspiration. The signs all seemed to point toward the patient suffering from a misplaced feeding tube, especially considering that an earlier X-ray showed a prior tube entered the patient's lung. The nurses never attempted to ascertain why the patient acted agitated. While patients with feeding tubes sometimes do require restraints, a patient in restraints requires very close monitoring, which includes the release of the restraint every few hours. The nurse who noticed an increase in the patient's heart rate failed to call a supervising doctor to check on the patient's symptoms. ■

REFERENCE

Montgomery County Court of Common Pleas. Case Number 2010-35494, May 13, 2016.