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INSIDE

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'I'm Sorry' Legislation Not Showing Anticipated Results

The "I'm Sorry" movement has gained steam in the last few years. Risk managers have been encouraging physicians to show their regret and concern with patients after adverse events — not only because it is the right thing to do, but also in hopes of reducing potential liability.

Patients often sue because they think their doctors do not care about what happened to them. The reasoning was that a carefully worded apology would reduce the risk of a lawsuit and reduce the potential payout. Many state legislatures passed laws prohibiting plaintiffs from using a clinician's apology against them in a malpractice case.

> "MOST MEDICAL MALPRACTICE LAWSUITS ARE DRIVEN BY BAD OUTCOMES COUPLED WITH ZEALOUS PLAINTIFF'S LAWYERS, NOT WHETHER OR NOT THE PRACTITIONER OFFERED AN APOLOGY."

Thirty-six states passed apology laws, according to the Sorry Works! organization, which has promoted apologies after adverse events. The organization notes that disclosure still can be practiced effectively without apology legislation, saying that empathizing after an event — without admitting fault — will not land a physician in trouble. *(For more on Sorry Works! and the list of states with apology laws, visit: https://bit.ly/2YOk4IZ.)*

Do Apology Laws Work?

But after years of trying that approach, is it really working out that way?

Not necessarily, although that does

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AUTHOR: Greg Freeman
EDITOR: Jill Drachenberg
EDITOR: Jonathan Springston
EDITORIAL GROUP MANAGER: Leslie Coplin
ACCREDITATIONS MANAGER: Amy M. Johnson, MSN, RN, CPN

EDITORIAL QUESTIONS
Call Editor **Jill Drachenberg**, (404) 262-5508

not mean the apology approach is not worthwhile. A recent report in the *Stanford Law Review* from researchers at Vanderbilt University in Nashville, TN, questions the value of apology laws. The researchers used proprietary insurance data to assess the impact of I'm Sorry legislation, and found the results were not encouraging.

The researchers concluded that for surgeons, whose patients are more aware of the risks than other types of patients, "apology laws do not have a substantial effect on the probability that a physician will face a claim or the average payment made to resolve a claim. For non-surgeons, we find that apology laws increase the probability of facing a lawsuit and increase the average payment made to resolve a claim, a finding which is consistent with the presence of asymmetric information. Overall, our findings indicate that on balance, apology laws increase rather than limit medical malpractice liability risk."

The authors theorized that surgical adverse events and errors can be more apparent to the patient, whereas non-surgical patients may not realize an error occurred until the physician apologizes, partly because the apology law encouraged him or her to do so. *(An abstract of the report is available online at: https://stanford.io/2XWWSLo.)*

Minimal Benefits Seen

Apology laws have minimally affected malpractice litigation, says **Alex J. Keoskey**, JD, an attorney with DeCotiis, FitzPatrick, Cole & Giblin in Teaneck, NJ.

"Legislation designed to make apologies of physicians inadmissible in subsequent civil malpractice suits have limited value," Keoskey says. "Most medical malpractice lawsuits are driven by bad outcomes coupled with zealous plaintiff's lawyers, not whether or not the practitioner offered an apology."

A more useful effort should focus on establishing guidelines regarding which adverse events should be accompanied by a clear admission of fault, such as surgery on the wrong limb or leaving surgical instruments in the body, and which should not, Keoskey says.

"While it is certainly true that physicians who demonstrate empathy, caring, and even sorrow for adverse outcomes can help heal any residual anger or shock on the part of a family member, a clear admission of fault where the medical quality of care may be defensible makes little sense from a risk management perspective," he says.

Keoskey says risk managers should not sell apology legislation as a cure-all for any liability that may derive from admitting fault relating

EXECUTIVE SUMMARY

The "I'm Sorry" movement may not be lowering the risk of malpractice claims. The approach may still be worthwhile for other reasons.

- The authors of a recent analysis found that state apology laws may not be having the desired effect.
- Non-surgical patients may be unaware of an error until someone apologizes.
- Know the details of the apology law in your state.

to adverse outcomes. It is helpful to educate clinical practitioners regarding how and when to show sympathy, remorse, or in some rare cases, even to apologize, he says.

"However, such guidelines should never be included in writing within policy and procedures of the healthcare facility," he cautions.

It is important to distinguish between expressing concern and admitting to error, Keoskey says. Saying, "I am so sorry" whenever an adverse outcome occurs is a normal and helpful response to anyone suffering grief or anguish over death or a debilitating event involving a loved one, he says. That should not be discouraged.

For example, "I just heard that your mom passed away. I'm so sorry," does not constitute an admission of fault, Keoskey says. Neither should any apology offered to family members after unsuccessful surgery or procedure. Stating, "Unfortunately, the surgery was unsuccessful. Your mom didn't make it. I am so sorry for your family's loss," is distinct from "I didn't monitor her blood loss like I should have. I made a mistake. I am so very sorry."

"Even if the admission is not admissible in court because of an apology law, the family member will never forget it. Such statements will render them more likely to file suit, not less," he says.

Laws Not Meant to Inhibit Lawsuits

In reviewing the effects of apology legislation on malpractice claims, it is important to remember that the laws were never meant to actually protect physicians from claims, says **Carol Michel**, JD, partner with Weinberg Wheeler law firm in Atlanta. The legislation was passed because physicians were so concerned about litigation and liability that they were reluctant to apologize or engage in a normal interaction in which they expressed sorrow over a patient's outcome, she says.

States passed laws prohibiting those conversations from being used against physicians in court, but they were not intended to inhibit any reasonable claims of malpractice, she explains. The laws have been successful if they allowed physicians to hold the candid conversations they wanted but feared, she says.

"EVEN IF THE ADMISSION IS NOT ADMISSIBLE IN COURT BECAUSE OF AN APOLOGY LAW, THE FAMILY MEMBER WILL NEVER FORGET IT. SUCH STATEMENTS WILL RENDER THEM MORE LIKELY TO FILE SUIT, NOT LESS."

"In my own experience, I certainly have the fact of early, candid conversations with patients and their family helping to either address a potential claim before the claim was actually made, or creating an environment of trust so that when a claim was made there wasn't the hostility and anger," Michel says. "We were able to, pre-lawsuit, negotiate the claim on a much better footing."

Physicians believe they should hold those conversations but in years past were dissuaded by risk managers who told them to say nothing after a bad outcome, or established rigid prohibitions on certain comments, including "I'm sorry." The I'm Sorry movement and the legislation in some states changed that attitude, but Michel says the true aim of the laws was to simply let doctors speak honestly to their patients.

"The laws are just evidentiary privileges rather than any immunity from claims or litigation," Michel says. "If you have a conversation with the patient or family, there are parameters on what they can get into evidence afterward. The legislation doesn't impede the plaintiff's rights to pursue a malpractice case in any other way."

Risk managers should continue to encourage open and honest conversations with patients and family members, Michel says, but also remind physicians to do so carefully. For instance, do not rush to start that conversation before all facts are known.

"The consensus now is that it is OK to empathize with the patients and family, to acknowledge their concerns, to look into the incident further, and provide them with the information you can," she says. "You just don't want to start out the conversation with 'Oh my god, we completely screwed up and everything is our fault.' The goal has always been to show sympathy and provide the information you have, but don't go beyond the factual information you have."

Michel notes that she often sees plaintiffs' attorneys filing motions to keep physician apologies out of the

case, rather than trying to get them admitted as evidence.

"Generally, it's because the plaintiffs' bar don't want the physician coming across as compassionate and caring," Michel says. "They don't want anyone to know that the physician showed concern and regret, that he or she didn't just walk away without any thought for the patient."

Effects Differ by State

The research into the effect of state laws found differences from state to state, notes **Elizabeth L.B. Greene**, JD, partner with the Mirick O'Connell law firm in Worcester, MA. That likely is because the laws are written differently, with some covering only the apology itself and others covering additional statements and explanations.

"I think that affects the effectiveness of the laws, but there's also the human impact to consider," Greene says. "It may be that the laws have had greater impact on human factor side, the effect on patients and physicians when they are allowed to have that conversation, than any real impact on malpractice litigation."

Risk managers should understand the apology laws in their own states and explain the specific allowances and limitations, Greene says.

For example, Massachusetts law states that "all statements, affirmations, gestures, activities, conduct expressing benevolence, regret, apology, sympathy, commiseration, condolence, compassion, mistake, error, or general sense of concern" will be inadmissible unless the speaker or a defense expert witness makes a contradictory or inconsistent statement as to material facts or opinion that was previously stated.

That means that if there is a contradictory statement, all the protected information is admissible, Greene says. Physicians in that state must be careful not to make statements that later prove untrue, she says.

"Risk managers who are counseling physicians dealing with adverse outcomes should have an understanding of the law in your state on apology and/or disclosure, because they are not the same. The specific advice you provide in any situation may be dependent on the details of that law," she says.

Avoid Taking Responsibility Too Early

Providers should be mindful that their involvement in the case may not have determined the outcome, so they should avoid rushing to take blame, Greene says. Physicians may be devastated by an adverse outcome and feel great guilt, but in many cases an investigation will reveal that they were not the cause, she says.

Physicians should be counseled not to jump to conclusions and make statements to the patient or family that suggest an error by the physician is to blame, or direct the physician to take all responsibility as captain of the ship, Greene says. Physicians should tell patients and family that certain information is known but other information will become available later, she suggests. Avoid trying to fill in the blanks or make assumptions about what happened.

"It is a good idea to provide some training and guidance on how to handle adverse outcomes, a toolbox of skills that they can use when this happens," Greene says. "We also need to make counseling available to the physician in the moment when an incident occurs, and before they talk to the patient. Patients are hanging on to every word that is said and these conversations are very meaningful, so physicians can provide accurate and transparent information." ■

SOURCES

- Elizabeth L.B. Greene, JD, Partner, Mirick O'Connell, Worcester, MA. Phone: (508) 860-1514. Email: egreene@mirickoconnell.com.
- Alex J. Keoskey, JD, DeCotiis, FitzPatrick, Cole & Giblin, Teaneck, NJ. Phone: (201) 347-2107. Email: akeoskey@decotislaw.com.
- Carol Michel, JD, Partner, Weinberg Wheeler, Atlanta. Phone: (404) 832-9510. Email: cmichel@wwhgd.com.

Counselors and Therapists Face Special Liability Risks

Counselors face substantial liability risks that may not receive as much attention as other healthcare professionals, and the exposure may be increasing.

The authors of a closed claim report published jointly by the Healthcare Providers Service Organization (HPSO), a division of Aon Affinity, and the insurer CNA, with the support of the American Counseling Association, found that $7.8 million was paid for counselor malpractice claims over a five-year period. The Counselor Liability 2019 Claim Report found that $8 million was paid during the previous 10 years.

The average total cost of malpractice claims was $113,642. Reports of sexual or romantic relationships accounted for 43.9% of malpractice allegations. The average license defense cost was $5,454, up from $3,727 in the 2014 report. There was a sharp increase in deposition assistance and record request matters, up 456% from the 2014 report. *(The report is available online at: https://aon.io/30y7td9.)*

The allegations of improper sexual or romantic relationships continue to be a primary concern with this group of professionals, notes **Jennifer Flynn**, CPHRM, manager in healthcare risk management with Aon in Fort Washington, PA. These allegations also were a leading cause of claims in 2014, and there is no indication that the profession is better addressing the problem, she says.

Because it is an ongoing problem, Aon published a guide to help counselors establish boundaries with patients. *(The guide is available online at: https://bit.ly/2O4oJpp.)*

> REPORTS OF SEXUAL OR ROMANTIC RELATIONSHIPS ACCOUNTED FOR 43.9% OF MALPRACTICE ALLEGATIONS.

Other allegations involved not practicing within boundaries of competence, sharing confidential information, and reporting to third parties.

"A lot of these claims involve the informed consent process, which we emphasize with the patient up front, discussing what will come out of the counseling process and what won't be addressed," Flynn says. "It also is important to address the policies and procedures of the counseling process so the patient has a good understanding of what he or she can get out of the relationship."

Complaints against a counselor's license were more frequent and severe in the latest research, Flynn notes. Counselors are spending $5,400 to defend a claim, she notes. Sexual indiscretion also was a top allegation with board complaints.

"It is important for counselors to defend themselves against board complaints," Flynn says. "Unlike the professional liability lawsuit, in which a court will compensate a plaintiff with a monetary award, the counselor in a license disciplinary event can face various sanctions ranging from continuing education sources all the way to license revocation. We emphasize the importance of defending yourself against these board complaints because the sanctions can be so severe."

Risk managers can remind counselors to be mindful of the laws and regulations that govern their interactions with patients, Flynn suggests. Those may include requirements for mandated reporting to third parties and the time frame in which those reports must be made.

"Documentation is always an important consideration," Flynn says. "It provides the counselor with a defense when the client alleges something that could lead to a lawsuit. It comes down to 'he said, she said' a lot of times, and we depend on that documentation to show that the counselor took a particular action related to that client's course of care." ■

EXECUTIVE SUMMARY

Counselors and therapists face significant liability risks that are unique to their profession. Allegations of improper sexual or romantic relationships are a leading allegation in malpractice cases.

- Informed consent and documentation are important defensive tactics.
- It is important to defend against board complaints.
- Failing to report to third parties can create liability risks.

SOURCE

- **Jennifer Flynn**, CPHRM, Manager, Healthcare Risk Management, Aon, Fort Washington, PA. Email: jennifer.flynn@aon.com.

Slip and Fall Prevention Different for Employees Than Patients

Risk managers always address fall prevention with patients, but do employees get enough attention? Healthcare employees are at risk of falls every day, and the tactics that work best with patients may not be the most effective when preventing potential workers' compensation claims.

Falls, slips, and trips were the second most common event leading to workplace injuries and illnesses in hospitals, according to a 2017 report from the U.S. Bureau of Labor Statistics, accounting for 25% of all reported employee injuries. Overexertion and bodily reaction, including injuries from lifting or moving patients, was the most common type of injury. *(The report is available online at: https://bit.ly/2KWyXT0.)*

Addressing fall prevention with employees is different than with patients, says **Bette McNee**, RN, NHA, clinical risk management consultant at insurance broker Graham Company in Philadelphia. With patients, fall prevention focuses mostly on transfers from beds and wheelchairs, as well as environmental factors, she says, whereas preventing falls among employees is more a matter of how they work with such focus.

Employee slips and falls tend to be the top workers' compensation claim in both frequency and severity, McNee says.

Addressing employee fall prevention starts with the low-hanging fruit, like flooring materials, mats, footwear policies, and snow and ice removal, she says. Risk managers also should look at what makes the hospital environment dangerous for employees — including employees' dedication to their work.

"Healthcare employees typically are so focused on their work — nurses walking around, reading a medication label or looking at a patient chart — that they can lack the safety mindfulness you might hope for. Their attention on the one task keeps them from seeing everything going on around them," McNee says. "When they are focused so intently on the patient, they don't tend to see the cords at the bedside or the wheelchair legs that have been removed and left on the floor."

Risk managers can encourage employees to think of a 10-foot circle of safety around them, McNee says. They do not necessarily have to be aware of everything in the room, but they can keep an eye out for hazards within 10 feet. This encourages a situational awareness with a limited scope, which can be more realistic for someone highly focused and multitasking than simply telling them to watch for hazards, she explains.

"They are constantly told that everything is a top priority and they have to pay such close attention, so it can be hard to tell them to watch out for hazards on the floor, too. But if you keep it to that 10-foot circle of safety around them, that can be more attainable," she says. "You also build interdependence when your circle of safety overlaps with your co-workers'."

An aging workforce also increases fall risk, McNee says, as well as health issues such as obesity. Hospitals have addressed these issues successfully with wellness programs, she says.

Even in an organization in which patient falls are treated with the utmost seriousness and no excuse is acceptable, employee falls may be excused sometimes as just an isolated event, McNee says. If a nurse is rushing to a code call and trips on a trash can, supervisors may dismiss it as an unfortunate accident and say the trash can should not be in the way next time, she says.

"They tend to treat it as a very unfortunate one-off accident, treat her, and get her back to work," she says. "They don't look at the situation as something that happens because of the laser focus they have on their duties and how the environment should be tailored to accommodate that."

Hospitals can begin addressing employee falls by assessing fall reports to identify trends, says **Meaghan Crawley**, MSN, RN, CEN, trauma injury prevention/outreach coordinator at Spectrum Health Butterworth Hospital in Grand Rapids, MI. Are there any common environmental factors such as wet floors or obstructions? Are the falls

EXECUTIVE SUMMARY

Preventing falls among employees requires different methods than preventing patient falls.

- Employees can be so focused on their work that they overlook hazards.
- Hospitals sometimes dismiss employee falls without looking for ways to prevent them.
- Environmental factors are a leading cause of employee falls.

occurring on a particular hallway or in any one unit?

"It's a root cause analysis to find out why you have falls on this one hallway and with this one job code. You're finding out what the risk is and why it is occurring," Crawley says. "You may find that there is a broken pipe leaking water on the floor, in which case you can not only get the pipe fixed but also provide the staff a card that has a number for them to call if they see the leak again."

Employee safety is a top priority at Butterworth Hospital. Falls and other safety incidents are included in the daily reports to hospital leaders.

"The data is where you can find out what kind of problems you're having at your own hospital, and how much those falls are costing your organization," she says. "It all affects the care you provide to patients as well, because if employees are not healthy and don't feel safe when they come to work, they can't provide the best care possible."

A common mistake is to implement fall prevention tactics without first looking at the data, says **Farheen S. Khan**, PhD, director of the Human Factors Division for the Rimkus Consulting Group in Atlanta. Hospital leaders often think they know where the falls are occurring and why, and implement prevention tactic without first consulting the data to determine if their assumptions are correct, she says.

Also, remember that solutions might not have to be facilitywide, she says. It is possible that environmental changes, such as new flooring, or policy changes, such as required footwear, might apply only to particular units. That can make implementation easier and less costly, Khan says.

"Falls among employees don't get written up as much in the literature because the focus of hospitals is medical care for employees, but it is a problem recognized by OSHA and the Bureau of Labor Statistics. There is literature available if risk managers are looking for resources," Khan says.

Hospitals can encourage the same kind of tailored fall prevention with nurses as with patients, suggests **Christine Ninchich**, clinical specialist with Medline in Northfield, IL.

Patient fall prevention techniques are designed for the patient's unique needs, and a similar approach can be used in nursing, Ninchich says. Nurses working in certain patient environments can be reminded that they face greater trip-and-fall hazards than in other areas and should exercise more care, she says.

"If I am working in a patient room that has dozens of cords and tubes, lots of equipment around, I need to be more aware of that and move more carefully," she says. "The nurse needs to be more deliberate about movement in that kind of environment, more so than might be necessary in a typical patient room or other area."

Video monitoring can help prevent employee injuries, and investigate the injuries afteward, notes **Paul Baratta**, business development manager for healthcare at Axis Communications, a company that provides security cameras. Hospitals often monitor employees as a way to identify causes of on-the-job injuries, and address a workers' compensation claim. It also can be used to determine whether employees are properly using best practices provided in safety training. ■

SOURCES

- Paul Baratta, Business Development Manager for Healthcare, Axis Communications, Chelmsford, MA.
- Meaghan Crawley, MSN, RN, CEN, Trauma Injury Prevention/Outreach Coordinator, Spectrum Health Butterworth Hospital, Grand Rapids, MI. Phone: (616) 391-8641. Email: meaghan.crawley@spectrumhealth.org.
- Farheen S. Khan, PhD, Director, Human Factors Division, Rimkus Consulting Group, Atlanta. Phone: (770) 436-9399.
- Bette McNee, RN, NHA, Clinical Risk Management Consultant, Graham Company, Philadelphia. Email: bmcnee@grahamco.com.
- Christine Ninchich, Clinical Specialist, Medline, Northfield, IL. Phone: (847) 949-2286.

Protect Metadata When Disclosing Information From Electronic Health Records

Information from electronic health records (EHRs) can contain metadata that are not immediately recognizable to the user, but could contain specific protected health information (PHI) about patients. Inadvertently providing this metadata could provide useful information to the opposition in a malpractice case, and could create other problems for the patient.

Metadata, in simple terms, are data that provide information about other data. The data often are embedded in a way that is not immediately visible, such as when a digital photo includes information about where the photo was taken, the date, exposure, and the shutter speed.

In healthcare, metadata can provide information such as medical conditions, treatments, and prescriptions. This PHI can inadvertently be included when providing information from the EHR for a legitimate purpose, such as responding to a subpoena. *(See the story on page 94 for more on risks from responding to subpoenas.)*

Metadata present yet another challenge for healthcare professionals to ensure they avoid unintentionally releasing confidential information, says **Frank Negro**, senior managing consultant with NTT Data Services in Plano, TX.

"One potential issue with the release of metadata could be physician scrutiny. For example, if a patient had two admissions for the same health concern and was treated by two different physicians, the metadata could show that one ordered a particular set of tests while the other did not," he says. "By analyzing this data, physician treatment patterns and related treatment quality conclusions could be derived."

It is incumbent on health systems to engage their risk and security teams before releasing PHI from EHRs, and those teams need to clearly understand what metadata are included, Negro says.

Inadvertent Release Can Damage Defense

The inadvertent release of metadata can potentially damage the defense in a malpractice case, says **Bill Fox**, JD, chief strategist for global healthcare, life sciences, and insurance at MarkLogic, a database company in San Carlos, CA.

"If, for instance, the information shows a certain result from a blood test, then it might be interesting if the metadata show when the doctor accessed the EHR or didn't access the EHR after that test result. What did the doctor know, and when, and was there a dereliction in duty in not accessing the data that were available?" Fox says. "If the doctor says he didn't know this information, the metadata might show that he actually did. That kind of information can be important in litigation."

But that kind of metadata disclosure should not happen if the data are properly safeguarded, Fox says. IT professionals should establish a data security plan that strictly controls access to metadata rather than including it with any EHR disclosure, he says.

Once metadata have been released, the healthcare organization is potentially liable for any damages. The data are no longer under the healthcare organization's control and are subject to the security of the party that possesses, says **Dominic Sartorio**, chief technology officer with Protegrity, a data security company based in Stamford, CT.

"There is a general concern whenever data must be shared: How can one be sure the third party has security controls as good as you do? Do lawyers, courts, and other counterparties have good data protection in place?" Sartorio says. "If metadata leak, harm could come to a person with pre-existing conditions, such as not being able to find employment, being unable to get insured, or the details can be used for identity theft. Secondarily, custodians of PHI are vulnerable to the financial and reputational consequences of not taking their data responsibilities seriously enough."

The best approach is to know

EXECUTIVE SUMMARY

Metadata can be released inadvertently when providing other data from electronic health records. There are ways to prevent this disclosure.

- Metadata can include privileged information.
- Plaintiffs may use metadata for an unfair advantage.
- Patients may be harmed and hold the healthcare organization responsible.

exactly what information is supposed to be released and ensure that only those data are included, Sartorio says. Granular protection can protect this sensitive data while still leaving case-relevant data in the clear, he says. Also, if sensitive data are what the courts need, then one can set up a system where these data are protected and only staff authorized on a "need-to-know" basis can see it unprotected, he says.

Metadata Can Give Advantage

When protected metadata are outside the scope of the subpoena, the healthcare organization may be providing information the other party should not see, says **Brian Hedgeman**, JD, a law clerk with admission pending at Epstein Becker Green in Washington, DC.

"Some information contained within the metadata might be privileged. Thus, your clients may be at risk of losing their dispute because opposing counsel has acquired information that bolsters their case. Additionally, client representatives may have disclosed something to opposing counsel that they were unaware of," he explains. "For instance, if metadata related to care and clinical decision guidelines were obtained, opposing counsel would have an opportunity to identify deviations from those standards, which may bolster his case."

However, some courts today generally require that parties who request metadata during litigation show "a particularized need for the metadata," as opposed to a generalized view of its importance, Hedgman says.

Also, proprietary or privileged information contained within the metadata would compromise the individual's economic or personal interests. Hedgeman notes these best practices for avoiding improper release of metadata:

- Converting a document into another format so that it does not preserve the original metadata;
- Transmitting the document via email or fax;
- Using scrubbing technology to remove metadata from various materials;
- Developing plans for disposing of metadata in the system when no longer needed;
- Restricting staff and third-party access to multiple systems where metadata can be accessed by allowing read-only permission levels.

However comprehensive the cybersecurity measures, there still is a need to transfer risk with cyberinsurance as a tool to manage exposure, as cyber is excluded on most current general liability policies, notes **Dan Hanson**, CPCU, senior vice president of management liability and client experience for Marsh & McLennan Agency in Minneapolis.

"Healthcare organizations are beginning to look to insurance or cyberrisk transfer programs as a way to shift the risks, not just as a solution for balance sheet protection but also for contractual evidence and compliance," Hanson says.

"Prompted by the wave of high-profile attacks and new data protection rules, annual gross written cyberinsurance premiums have grown by 34% per annum over the past seven years. The European Union Agency for Network and Information Security has also found a positive correlation between cyberinsurance take-up and the level of preparedness, and healthcare organizations are only beginning to recognize this."

Soon, organizations will find that legacy systems and the current way in which sensitive data are stored in the EHR are no longer sufficient for maintaining health data, Hanson says. Patients are likely to continuously integrate health devices, such as adding Fitbit information, downloading genetics information, and feeding additional personal data through wearable and implantable technologies.

"In the future, they could all make up a part of a medical record. It is also not likely to be just about health records on the server or cloud of a hospital, but also health data held on our private phones," he says. "The introduction of 5G networks will contribute to the high potential for compromise. Other emerging technologies will also lead the healthcare system to evolve into a more data- and analytics-driven one that can enable healthcare organizations to translate data into information that we can base decisions on." ■

SOURCES

- Bill Fox, JD, Chief Strategist for Global Healthcare, Life Sciences, and Insurance, MarkLogic, San Carlos, CA. Phone: (650) 655-2300.
- Dan Hanson, CPCU, Senior Vice President of Management Liability and Client Experience, Marsh & McLennan Agency, Minneapolis. Phone: (763) 548-8599. Email: dan.hanson@marshmma.com.
- Brian Hedgeman, JD, Epstein Becker Green, Washington, DC. Phone: (202) 861-1387. Email: bhedgeman@ebglaw.com.
- Frank Negro, Senior Managing Consultant, NTT Data Services, Plano, TX. Phone: (800) 745-3263.
- Dominic Sartorio, Chief Technology Officer, Protegrity, Stamford, CT. Phone: (203) 326-7200.

Address Metadata With Protocol for Subpoenas

A strict protocol for responding to subpoenas can reduce the risks that come with inadvertently releasing too much information, or the wrong information says **Jill M. Steinberg**, JD, shareholder with Baker Donelson in Memphis, TN.

Steinberg has found that the best practice for responding to subpoenas or authorizations for production of medical records in legal cases is to set up a special department or designate an employee as the legal health information management (HIM) representative. All requests for records in a legal case would be funneled through a person or persons trained in the legal issues and with ready access to the legal department or outside legal counsel when questions arise, she says.

For example, when a subpoena is served, the HIM department needs to make sure that the subpoena is valid. Issues that the HIM representative should be familiar with include determining if notice to opposing counsel is required under the law and that the provision of notice is evident from the subpoena.

"When providing records pursuant to medical authorizations or court orders, the responding department must make sure that the person requesting records has authority to obtain the records. For example, if the records are requested for a deceased or incompetent person, the authority of the person must be clear on the face of the authorization. The death certificate or documents appointing the person as a representative of the estate or conservator of the person must be provided," Steinberg says. "If a department just allows anyone who receives a subpoena to prepare records for production without making sure that the subpoena is valid, liability could be invoked against the hospital or medical provider."

Policies and procedures for responding to subpoenas should include a protocol for evaluating the validity of the subpoena, a calendar system for making sure that the response is timely, and an internal definition for what is produced as a legal medical record, she says.

There also should be a procedure for how to produce a record electronically or on paper. Healthcare providers must decide if they are going to produce records that were prepared by an outside medical provider but have become a part of the medical record, Steinberg says.

For example, when a patient is admitted to labor and delivery, the patient's prenatal records often will be placed in the medical record, she says. Steinberg recommends a statement added to the medical records custodian affidavit such as the following:

"Please be advised that the records produced herein also contain documents that were not prepared by personnel of the hospital/physician/practice group/clinic or by persons acting under their control with respect to the preparation of records, in the ordinary course of business, at or near the time of the act, condition, or event reported therein. Any such documents produced herein are produced in compliance with statute and regulations defining 'medical records,' but no independent certification can be made with respect to the authentication of such documents."

It also is a best practice to include a caveat in any production of a medical record that explains that not all metadata be produced in a printed or electronic medical record. The following is an example of possible language to consider:

"Some electronic data and metadata relating to the patient's clinical course, and which may fall within the parameters of the definition of 'hospital records' set forth in applicable statutes, cannot be reproduced through the mechanism of printing the records directly or scanning the patient's records onto a CD or jump drive for printing. The records produced in response to this authorization/subpoena consist of printable data reasonably accessible

for scanning and/or printing as of the date of the authorization/subpoena request as established by the third-party software vendor, and by information technology personnel within the hospital system, consistent with the necessity to maintain the electronic records functionality and speed for patient care."

One of the biggest challenges is the sheer volume of subpoenas and medical records requests that healthcare providers deal with, Steinberg says. Consider establishing a system in which risk managers are advised of medical record requests from any "red flag" attorney. Risk managers can review these records for any potential medical malpractice claim filed, she suggests.

"Every party to an automobile accident, disability claim, and/or medical malpractice action — even if the provider whose records are requested is not a party — will possibly seek to obtain medical records pursuant to subpoena or authorization," Steinberg says. "It is important for risk managers to have a robust communication system with HIM and to make sure that they are advised when there is a subpoena issued on a case against the medical provider or a request for records from an attorney who typically files suit against medical providers." ■

SOURCE

- **Jill M. Steinberg**, JD, Shareholder, Baker Donelson, Memphis, TN. Phone: (901) 577-2234. Email: jsteinberg@bakerdonelson.com.

Future for Risk Managers Will Require Flexibility, Learning

Risk managers seeking to improve their careers must evolve continually with the changing healthcare landscape, says **Ann Burke**, RN, CPHRM, CPPS, director of risk management with Coverys, a liability insurer based in Boston.

There are new technologies to consider, along with value-based reimbursement models, that are dependent on quality patient outcomes, she says. Healthcare delivery models continue to bring new and sometimes unfamiliar services and exposures to an organization, she says.

"The healthcare environment is not stagnant. To stay ahead of turns in the road, it is imperative that risk managers approach patient safety and risk proactively utilizing an enterprisewide lens," Burke says. "Data analytics is currently viewed as a key component of proactive risk management and will become even more vital to the risk management role. Risk managers should get ready for the ride and be prepared to wear their enterprise risk management hats to address operational, clinical/patient safety, strategic, financial, human capital, legal/regulatory, technology, and hazard exposures as the delivery of healthcare and patient needs and expectations evolve."

For risk managers to best position themselves for future career opportunities, it is essential to stay informed of not only current but evolving risk and patient safety issues, Burke says. Take advantage of what national, state, and regional professional risk management and patient safety societies may offer for education and training.

"A lot of insight into current challenges and solutions can be gained through networking with risk management and patient safety peers," she says. "Expanding knowledge to include enterprise risk management strategies will help position a risk manager for the future."

Burke notes that there are options for healthcare risk managers to work in a variety of settings. Opportunities exist in acute care hospitals, outpatient services, urgent care and retail clinics, and medical liability and healthcare insurance companies. Obtaining the proper education and credentials will allow risk managers more freedom to choose from the available options, she says.

"Regardless of the environment, risk management employment opportunities usually require several years of experience in the healthcare field, and many require RN licensure and varying college degrees. Some risk managers also hold their juris doctorate and may have worked as an attorney in the healthcare arena," Burke says.

"Holding the designation as a certified professional in healthcare risk management [CPHRM] is considered a premium certification for the risk management profession, and many employees either require or prefer certification as part of the hiring credentials," she explains. "Another designation that risk managers hold is that of a certified professional in patient safety — CPPS. The bearer of this certification is recognized as holding core patient safety knowledge." ■

HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **In the recent report in the *Stanford Law Review* from researchers at Vanderbilt University in Nashville, TN, what did they find was the effect of apology laws on non-surgeons?**

   a. Apology laws increase the probability of facing a lawsuit and increase the average payment made to resolve a claim.
   b. Apology laws decrease the probability of facing a lawsuit and decrease the average payment made to resolve a claim.
   c. Apology laws increase the probability of facing a lawsuit and decrease the average payment made to resolve a claim.
   d. Apology laws decrease the probability of facing a lawsuit and increase the average payment made to resolve a claim.

2. **Why does Carol Michel, JD, partner with the Weinberg Wheeler law firm in Atlanta, say plaintiff attorneys often try to exclude a physician's apology from evidence?**

   a. They do not want to complicate the case with discussion of apology laws.
   b. They do not want the physician to come across as compassionate and caring.
   c. They do not want to have to include conversation, such as the patient's comments.
   d. They do not want the jury to consider facts divulged in the physician's apology.

3. **In the Counselor Liability 2019 Claim Report, allegations of sexual or romantic relationships were cited in what percentage of malpractice claims?**

   a. 23.9%
   b. 43.9%
   c. 63.9%
   d. 83.9%

4. **In the 2017 report from the U.S. Bureau of Labor Statistics, slips, trips, and falls accounted for what percentage of all reported employee injuries in hospitals?**

   a. 15%
   b. 25%
   c. 45%
   d. 65%

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

Patient Loses Eye to Improper Sterilization of Surgical Equipment; Awarded $3.5 Million

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

***Jamie Terrence**, RN*
President and Founder, Healthcare Risk Services
Former Director of Risk Management Services (2004-2013)
California Hospital Medical Center
Los Angeles

***Elena N. Sandell**, JD*
UCLA School of Law, 2018

News: An appeals court affirmed a $3.5 million verdict in favor of a patient whose left eye was removed following an infection caused by improper sterilization of surgical tools. The patient alleged that the surgical staff failed to follow proper sterilization procedures, introducing two species of bacteria to her eye. A jury found in favor of the patient and her husband and awarded $2.7 million to the patient and $470,000 to the patient's husband.

The hospital sought a new trial after the verdict, but the court found that the patient's expert sufficiently supported the finding of negligence. An appellate court affirmed the verdict and finding.

Background: A patient was diagnosed with a macular hole in her left eye, which caused her to suffer some vision impairment. In 2011, she underwent surgery to repair the eye; however, her eyesight worsened. The day after tsurgery, the patient could see only light with her left eye, although previously she could distinguish shapes and see clearly enough to count fingers. Testing revealed elevated blood pressure and a collection of white cells, referred to as hypopyon, in her eye. These white cells indicated that the patient was suffering from endophthalmitis. Although an antibiotic injection was administered directly into the woman's eye, her condition continued to worsen. As the infection progressed, the patient's eye sustained significant damage and was removed.

The patient and her husband sued the hospital, alleging that the hospital failed to adhere to proper sterilization procedures led to the patient's eye infection. During trial, the patient's expert witness testified as to the type of organisms that caused the infection, explaining that they were not "common" and should not be found in an operating room. This expert testimony supported the allegations that the hospital's staff had not followed procedure and had failed to adequately sterilize all surgical instruments. The patient argued that the sterile technique during the preparation, and use of a bottle of balanced salt solution (BSS), had not been followed adequately. This caused two bacteria species, *Pseudomonas aeruginosa* and *Serratia marcescens*, to enter the patient's eye and cause the infection. The hospital contended that it followed the proper procedures and argued that the patient had not shown sufficient evidence linking the physician's conduct to the patient's injury. The hospital specifically claimed that there was insufficient evidence and expert testimony pertaining to causation and that the trial court erred by permitting evidence about the bottle of BSS.

THE PATIENT ALLEGED THAT THE SURGICAL STAFF FAILED TO FOLLOW PROPER STERILIZATION PROCEDURES, INTRODUCING TWO SPECIES OF BACTERIA TO HER EYE.

A jury found in favor of the patient, awarding $2.7 million to the patient and $470,000 to the patient's husband. The defendant hospital challenged the jury's finding by bringing two different legal procedures: a

motion for judgment as a matter of law and a motion for a new trial. The trial court denied both and found that the patient's expert sufficiently supported the finding of negligence. The defendant hospital appealed the verdict and trial court's decisions. In its ruling, the appellate court explained that the expert's testimony was sufficient. The expert stated that it was his opinion, to a reasonable medical certainty, that the bacteria must have been introduced due to a breach of the surgical procedure because such bacteria do not live in eye drops or makeup and because the rate at which the infection progressed suggested that the bacteria had been introduced directly into the patient's eye during surgery. The appellate court did not find that the trial court abused its discretion or that its rulings were based on an erroneous legal standard.

What this means to you: The lessons from this case include the importance of proper sterilization, as well as the legal procedures and appeal options. In its decision, the appellate court detailed why the district court had reached the correct conclusion, how the evidence proffered by the patient was admissible, and why it constituted a sufficient factual basis for the patient's prima facie case. The appellate court noted that the hospital did not dispute the possibility that a breach in the sterilization process had occurred; instead, the hospital focused its challenge on the fact that the patient had not presented convincing evidence demonstrating that the breach in sterilization practices had caused the infection.

This was a rational decision by the hospital. Attempting to argue that it was impossible for the sterilization procedures to have been followed is unrealistic and would undermine the hospital's credible arguments. Maintaining sterility in surgical suites is a daunting task in every hospital and surgery center. The room itself, the surgical field, instruments, and personnel must be free of microorganisms. *Pseudomonas* often is the bacteria responsible for postoperative infections, especially if reusable surgical instruments are not sterilized properly. The problem frequently arises from the insufficient cleaning of the equipment in preparation for sterilization. Hospitals and other freestanding surgical facilities must ensure that staff are trained in proper techniques and that sterilization equipment is maintained and inspected frequently. Proper technique and attention is required by all persons involved.

Challenging causation in this case by arguing that the bacteria in this specific patient's eye could have been caused by the patient's makeup presented a better possibility for the defendant hospital. The patient allowed her makeup to be tested, and the analysis showed that the makeup was not contaminated. In response, the hospital attempted to undermine the analysis by arguing that the testing occurred five years after the incident, rendering the results unreliable.

One of the hospital's main challenges on appeal was that the trial court improperly admitted evidence about the makeup testing because the results were irrelevant and should have been excluded. The appellate court disagreed with this contention and found that the trial court correctly admitted the evidence because the hospital introduced the issue of contamination of the makeup and the evidence was indicative of the level of care the patient generally took of her makeup. In fact, the appellate court noted that because relevancy has a low threshold for admission, the disputed evidence satisfied the basic relevancy test in that it tended to make the existence of any fact of consequence more or less likely. Furthermore, the evidence was offered to rebut an allegation introduced by the hospital and, consequently, did not require an expert witness.

The parties also disputed evidence of a photograph showing the seals used on the BSS bottles. In particular, the patient claimed that the seals used on the bottles had been contaminated by a non-sterile sticker placed on the cap and that surgical staff relied on the sticker that indicated the seal was "sterile." During trial, evidence showed that the hospital changed the location of the sticker since the time of the incident. The hospital moved to introduce a photograph of the seals the hospital used at the time of trial, rather than a photograph of the seals used at the time of the incident. However, the trial court excluded the evidence because the packaging on the seals was different, and the photograph showed the seals in sterile packaging with the word "sterile" printed on the sticker. Because of the differences in the packaging, introducing the photograph would have been prejudicial. The district court correctly chose to exclude the evidence, according to the appellate court.

Many medical malpractice cases revolve around expert witnesses, their testimony, and their credibility. This case was no exception, as the patient's expert witness was crucial in obtaining a favorable jury verdict. As affirmed by the appellate court, the patient's expert provided critical, convincing testimony indicating that but for the hospital's negligence before and during surgery, the

infection-causing bacteria would not have entered the patient's eye. The expert also explained that such aggressive types of bacteria are not normally found in products such as makeup and eye drops.

The defendant hospital could not rebut this expert testimony or provide credible proof that a breach had not occurred. In fact, as highlighted by the court, the hospital did not appeal the element of breach; they did not present evidence indicating that a breach had not occurred. Rather, the hospital focused its defense on attempting to disprove causation, a necessary element for a plaintiff. Without the causal connection, the patient's case would have failed, regardless of the nature or extent of the patient's injury. Unfortunately for the hospital in this case, its defense argument was unsuccessful, and the jury's award of $3.5 million was affirmed. ■

REFERENCE

Decided May 28, 2019, in the Minnesota Court of Appeals, Case Number A18-1516.

Appellate Court Rejects Loss-of-Chance Argument for Patient Who Suffered Stroke

News: A patient exhibiting signs of a stroke was examined at a hospital by an emergency physician. However, the physician failed to properly diagnose the stroke, and did not timely administer tissue plasminogen activator (tPA) treatment. The patient subsequently sued, alleging that timely treatment would have lowered the risk of suffering neurological damage and diminished mobility.

The trial court found that state law does not recognize a negligence claim for the mere increase in risk of a serious disease and that the patient failed to provide sufficient evidence that the physician's negligence caused the patient's injury. An appellate court confirmed the ruling and stated that any change to the negligence law is the authority of the state legislature rather than the court.

Background: On Aug. 24, 2014, a patient with symptoms of a stroke was transported to a nearby hospital. She arrived at 2 a.m., within the critical three-hour window during which tPA should be administered. The treatment must be administered within three hours of the onset of a stroke (or 4.5 hours for certain eligible patients) for maximum effectiveness. In most cases, strokes cause neurological effects. With a timely administration of tPA, patients have a 40% chance of an improved neurological outcome.

An attending ED physician examined the patient. However, the physician failed to diagnose the patient's stroke and did not order the administration of tPA within the three-hour window. Furthermore, tPA was not available at the hospital where the patient was treated. A prompt diagnosis would have permitted the patient to be transported to a nearby facility for timely treatment.

The patient filed a medical malpractice action against the physician, alleging that the physician failed to diagnose the stroke, failed to timely treat her, and that these failures diminished her chance of an improved neurological outcome.

The defendant physician sought to defeat the patient's claim before trial by bringing a motion for summary judgment, a legal procedure that permits a party to seek judgment without a genuine dispute about material facts. The physician challenged the patient's allegations, claiming that the patient failed to show a likelihood that her injuries were caused by the physician's actions. The trial court granted summary judgment for the physician, and the patient appealed. The appellate court affirmed the trial court's decision, explaining that in the state, the loss of chance is not recognized as an independent cause of action. An injured patient must demonstrate sufficient causation between the physician's actions and the patient's injury. Thus, the court properly granted summary judgment in favor of defendant.

What this means to you: This case reveals a potent defense for physicians and care providers: A patient must prove causation when raising a malpractice allegation. A plaintiff must prove that the physician or care provider's conduct is a substantial factor in causing the harm, which means that it must be more than a remote or trivial factor. However, it does not have to be the only cause of the harm. If the harm would have occurred without the physician or care provider's conduct, then the conduct was not a substantial factor in causing harm.

In this case, in addition to proving a breach of care, the patient was required to prove that the failure to administer tPA caused the patient's injury. The patient was unable to prove that, arguing instead that the

failure to administer tPA increased her chance of suffering neurological damage. With the defendant physician's motion for summary judgment, the court reviewed the evidence in the light most favorable to the patient to ensure that she could present evidence to a jury.

However, even with this deferential standard, the court found that the patient could not recover based on the legal theory of "loss of chance" because the state does not recognize such a claim. The court explained that while it was clear that the patient's stroke caused her neurological injuries, according to the data presented on tPA administration her chances of an improved outcome would only have been 40% had the drug been promptly administered within the three-hour period. The court acknowledged that the physician was negligent in failing to diagnose the stroke, but that negligence was not the proximate cause of the patient's injury. Because the patient's chance of an improved outcome was only 40%, it was insufficient to reach the "more likely than not" threshold required under the traditional approach, which is 50% or higher. Had the success rate of tPA been found to be 50% or higher, the patient would have established sufficient proximate causation and the litigation would have proceeded to a jury.

This case also reveals the importance of properly evaluating a patient's needs and transferring patients who require greater needs than available at the care provider's facilities. Here, the patient likely would have been transported to a hospital where ED physicians were credentialed to administer tPA had the family called 911 for a paramedic response. Paramedics are trained to recognize the signs and symptoms of strokes and also are aware of which facilities in the area can provide the required level of care. Many people assume that all hospitals and EDs employ staff with the same levels of expertise and provide similar care, but services offered at locations may vary greatly. The physician's failure to timely diagnose prevented the appropriate transfer to a nearby facility that could have provided timely treatment with tPA. That failure may constitute negligence if a reasonable physician in the same or similar circumstances would not have made that error.

The appellate court affirmed that the physician acted negligently in not timely diagnosing the patient, and that tPA should have been administered promptly, but that the patient's neurological impediments were caused by the stroke. Because the chance of an improved outcome did not meet the 50% and above threshold, the trial court properly granted summary judgment for the physician. The plaintiff brought an additional argument that she had suffered a separate type of injury because of the physician's negligence: a loss of chance to a better neurological outcome. First, the court found that even if the cause of action of "loss of chance" were recognized in the state, by the same analysis for the patient's above, the patient would have only had a 40% chance of a better outcome, and the proximate causation element would not have been satisfied. In states that recognize the "loss of chance" theory, an injured patient may recover only in instances in which the chance of a better outcome is more than 50%. Under such circumstances, a patient would be entitled to recover the full value of the healthier outcome. However, when the chance of a better outcome is less than 50%, a patient is not entitled to any recovery. Thus, the patient in this case was unable to recover despite the physician's negligent conduct.

If named in a medical malpractice action, a physician, hospital, or care provider should explore all potential defenses, including challenging the applicable duty of care or arguing that the care provider's conduct was not the actual or proximate cause of the patient's injury. Care providers should work closely with counsel to evaluate the efficacy of such defenses, recognizing that laws may vary by state. ■

REFERENCE

Decided June 3, 2019, in the North Carolina Court of Appeals, Case Number COA18-888.