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INSIDE

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Cybersecurity and Outsourcing Among Top Concerns for 2018

Hospitals and health systems in 2018 face a mix of risks from familiar issues and threats from new developments in the industry, analysts say. The best response for all risks is to be proactive and get ahead of the risk before it creates trouble in the organization.

Broad changes in the healthcare industry, most notably the push to value-based care, put pressure on hospitals to do more with less, says **Tim Feldman**, MM, vice president and general manager of healthcare compliance with Wolters Kluwer Legal & Regulatory U.S. in Boston. That creates potential risks.

Healthcare organizations are pushing their clinicians to practice at the highest end of their licensure, and while that can be safe and proper, it carries potential risks that should be monitored.

"Nurse practitioners and physician assistants are doing more and primary care physicians providing assessments and services that they might previously have pushed up to a specialist," he says. "Everyone is trying to do more as a way to contain costs and use the right setting for care, but that requires controls so that people are operating at the uppermost limits of their licensure and not beyond."

> HEALTHCARE ORGANIZATIONS ARE PUSHING THEIR CLINICIANS TO PRACTICE AT THE HIGHEST END OF THEIR LICENSURE, WHICH CARRIES POTENTIAL RISKS THAT SHOULD BE MONITORED.

Limits vary by state, so risk managers must ensure that clinicians are not pushed to operate beyond the scope of practice allowed in their particular states, he says.

Financial Disclosure: Author **Greg Freeman**, Editor **Jill Drachenberg**, Editor **Jonathan Springston**, Editorial Group Manager **Terrey L. Hatcher**, and Nurse Planner **Maureen Archambault** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. Consulting Editor **Arnold Mackles**, MD, MBA, LHRM, discloses that he is an author and advisory board member for The Sullivan Group and that he is owner, stockholder, presenter, author, and consultant for Innovative Healthcare Compliance Group.

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Cybersecurity increasingly is important for healthcare organizations, says **Darci L. Friedman,** JD, CHPC, CSPO, PMC-III, content strategy and author acquisitions manager with Wolters Kluwer Legal & Regulatory. Cyberthreats continue to threaten financial losses, damage to reputation, regulatory penalties, and even malpractice claims, she says.

"The number-one risk in 2018 is cybersecurity. Organizations need to be planning and be proactive. I would even go so far as to say that healthcare organizations should have a separate cybersecurity risk management program, taking all the precautions they can," she says. "A fundamental part of that program is not planning for an 'if' scenario, but planning for 'when' you have a cyber breach. That will have you teed up for when it happens, and you can execute your plan."

A good cybersecurity plan starts with proper budgeting, Friedman says. That is a challenge for many risk managers.

"Often in smaller organizations, cybersecurity is only a collateral piece of an IT professional's job. It needs to be a much more important part of a hospital or health system's operations and the budget has to reflect that," Friedman says. "It starts with the budgeting, because the risk manager can be eager to do all the right, proactive things to protect the institution, but unable to do those things without the necessary funds."

BYOD Can Be Risky

"Bring your own device," or BYOD, policies are a growing concern in cybersecurity, Friedman says. Some organizations have permitted or even encouraged staff and physicians to use their own electronic devices at work as a convenience or cost-savings measure, but that creates substantial risk by complicating the security measures that would otherwise be applied to in-house systems, she says.

"If you have BYOD, you need to have policies and procedures in place with appropriate training on how they use their own devices, the rules and limitations, and you need to provide encryption on the device," she says. "It also would be best to provide an app that allows you to remotely wipe the device if it is lost, but that is going to be a problem for a lot of people with their personal devices. Not having that ability to make the device safe when it is lost or stolen compromises your overall cybersecurity program."

Patient identity theft is a major concern, and the resulting liability could be shared by the healthcare organization that did not adequately secure the data, Friedman says. Patient data are among the most highly sought items on the black

EXECUTIVE SUMMARY

The coming year will see increased liability risks related to cybersecurity and cost-cutting measures, analysts say. Risk managers should take a proactive approach to preventing trouble on several fronts.

- Review monitoring and analytical processes to see if they are outdated.
- Look for ways to integrate risk management into existing processes.
- Watch for clinicians practicing beyond their scope of practice.

market, with law enforcement reporting that a full set of patient information sells for as much as $300, she notes.

Friedman points out that cyberliability usually is not covered by general liability insurance policies. Risk managers should understand whether their particular policy will cover cyber-related losses and, if not, consider obtaining cyberliability insurance, she says.

Outsourcing Brings Risks

Third-party vendor management is another major issue, Feldman says, as more services are outsourced.

"That means you have commingling of IT systems and data, and you have people coming in and out of the hospital every day providing services from contract nursing to food services and cleaning," he says. "All of that exposes you to more risk in terms of privacy and cybersecurity, risks that you were able to control more tightly when you had a lot of those services in-house."

Even hospitals and health systems using software and processes to monitor and manage cyber risks should reassess whether they are up to date in 2018, Friedman says.

"Is it something older, or a more modern program? Things change rapidly in this field and something that was cutting-edge a few years ago probably isn't now," she says. "We've moved away from static, point-in-time data and are now in the era of dynamic, continuous, ongoing analysis."

These issues are in the news all the time, but healthcare organizations still can be slow to implement the proper safeguards, Feldman says. It can take an incident at their own facilities to wake them up.

"Too often, you have healthcare leaders following the strategy that ignorance is bliss. They say that if they don't look too hard, then they won't really know their vulnerabilities and they won't have to do anything about them," he says. "They wait until something happens and then they focus on remediation, whereas the much better approach is to focus on prevention. No longer is not knowing an acceptable excuse for failure to act."

> "THEY SAY THAT IF THEY DON'T LOOK TOO HARD, THEN THEY WON'T REALLY KNOW THEIR VULNERABILITIES AND THEY WON'T HAVE TO DO ANYTHING ABOUT THEM."

Feldman notes that government regulators do not treat healthcare organizations equally when there is a cyberbreach or other compliance failure. Efforts, or lack of efforts, to avoid that problem can determine how regulators respond, he says.

Document efforts carefully and be prepared to show your work to investigators, he advises. Don't assume that a cyberbreach or other issue means you failed and your precautions don't matter.

"If there are auditable logs showing you did your risk assessments, reviewed vendors, did background checks and credit checks, all those things you can and should do but the problem still occurred, they're not going to come at you the same way they would with someone that didn't bother," he says. "The government is not out to get someone who did all they could to avoid an issue. There will be much greater fines and punitive measures for those organizations that did not take a proactive approach."

Just as risk managers worked to make patient safety a regular topic and high priority at board meetings, they should do the same now with cybersecurity, Feldman says. Risk managers also should look for ways to integrate themselves and their priorities into other hospital departments, Friedman suggests.

"I see a lot of merging of risk management, compliance and regulatory, and internal auditing. They should be working together holistically to address cybersecurity and a lot of other issues like third-party vendors and telehealth, because a lot of these issues span across several departments," she says. "Risk managers need to think about integrating into existing business processes and not forcing an artificial risk management process onto a department or site. That's how you're going to get better adoption."

More Opioid Restrictions

The opioid crisis also will bring risks to healthcare organizations in 2018, says **John C. Ivins, Jr.**, JD, partner with the Hirschler Fleischer law firm in Richmond, VA. Many states are revising their prescribing guidelines to make them much stricter, thereby introducing liability risks for healthcare organizations, he says.

"They include things like physical exam information that must be in the chart, to communications you're supposed to have when prescribing an

opioid, and data that must be added to the chart at the point of refill," he says. "All of these things should prompt risk managers to have policies in place that govern compliance with these requirements, and programs to ensure that these new requirements are understood and acknowledged by any physician on staff or with privileges."

This may require bylaw changes for medical staff, and the risk manager may have to be the one suggesting those updates, Ivins says.

Key Trends Continue

Medical malpractice case filings will continue to decline or remain at the current low level in 2018, says **Bruce Klores**, JD, an attorney with the law firm of Stein Mitchell in Washington, DC. Those cases that are filed likely will be meritorious with serious damages, he says, but few will ever get to trial.

Malpractice premiums should decrease based on lower indemnity payments and the bull market, Klores says. *(See the stories on pages 6 and 7 for more on malpractice trends.)*

"The most common cases will remain against OB/GYNs, primarily because errors in that field result in the greatest damage. However, as the population ages, cases against primary care providers will likely increase for failure to treat serious conditions such as cardiovascular disease earlier — which then result in stroke, disability, or death," Klores says. "The aging population will also result in more filings in the nursing and rehabilitative facility settings."

Pharmacy cases, including those where physicians or prescribers are added, will increase for a variety of reasons, he says. In addition to opioid claims, personal or individualized medicine claims will slowly increase predominantly in drug/gene interaction, gene expression profiling, and predisposition genetic testing, he says.

Risk managers should consider the implications of certain National Practitioner Data Bank information becoming public and anticipate how that information may affect claims of negligent granting of privileges, he says.

Evidence-based guidelines also are receiving attention, he notes, which means healthcare providers will be held responsible for adhering to them.

"Risk managers can prepare by understanding the trends facing them. Education, standards, and monitoring opioid prescriptions are essential," Klores says. "Patient screening, drug choice, and adherence monitoring of opioids will all be under the microscope." ■

SOURCES

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More Fraud Investigations Likely to Come

Federal prosecutors are pursuing healthcare fraud with no indication of letting up, so risk managers should redouble their efforts to find and eliminate anyone taking advantage of the system.

The government has taken a tough stance on healthcare fraud in recent years and will continue, says **Megan Cunniff Church**, JD, formerly a federal prosecutor and now a partner in the Chicago office of the law firm MoloLamken. She notes that the Chicago U.S. Attorney's Office recently launched a healthcare fraud unit.

"There is going to continue to be an uptick in healthcare fraud prosecutions and investigations. The Department of Justice has made it quite clear with its ongoing prosecutions of doctors and other healthcare providers that this is an area ripe for more investigations," she says. "In Chicago, they are putting prosecutors with a lot of experience and expertise on this fraud unit and pursuing these healthcare cases aggressively."

A government watchdog agency report recently concluded that, while the Department of Health and Human Services (HHS) has been effective in addressing Medicare and Medicaid fraud, it still can improve its efforts. The General Accounting Office (GAO) report concludes that the Centers for Medicare & Medicaid Services

(CMS) should more fully align its efforts with the GAO's Framework for Managing Fraud Risks in Federal Programs, which describes best practices in preventing and detecting healthcare fraud.

The GAO report notes that CMS does not require fraud awareness training on a regular basis for employees, which it says could help create "a culture of integrity and compliance." *(The report is available online at: http://bit.ly/2Be22rc.)*

"CMS is well positioned to leverage its fraud risk management efforts — such as demonstrated leadership for combating fraud, existing control activities, and stakeholder relationships — to provide additional antifraud training, as well as to develop an antifraud strategy based on fraud risk assessments for Medicare and Medicaid," according to the report. "We recognize that the effort may be challenging, given the size and complexity of Medicare and Medicaid, and the need to balance antifraud activities with CMS's other mission priorities. However, by not employing the actions identified in the Fraud Risk Framework and incorporating them in its approach to managing fraud risks, CMS is missing a significant opportunity to better ensure employee vigilance against fraud, and to organize and focus its many antifraud and program integrity activities and related resources into a comprehensive strategy."

Less Reliance on Whistleblowers

Some investigations will involve whistleblowers as many healthcare fraud cases have in the past, Church says, but there also will be more use of affirmative data analytics. Federal agencies are improving their abilities to use data analytics to discover fraud in real time so that they don't need rely as much on whistleblowers coming forward, Church says.

Prosecutors also will be pursuing more criminal charges against individuals, using traditional law enforcement techniques, she says.

"It won't just be corporations and healthcare providers paying fines and working on compliance issues. It will be more individuals facing criminal charges for what they personally have done as part of healthcare fraud," she says. "So, you'll see more use of undercover investigations, confidential informants, wiretaps, a lot of the things you wouldn't expect to see in white-collar cases. They will be using these tools to make sure the charges stick against physicians and other individuals involved in these crimes."

Formalize Compliance Training

Risk managers should look carefully at billing practices of physicians and other professionals, Church says. Watch for billing patterns that seem unusual or revenue that seems too good to be true.

"The organization should have robust policies and procedures on billing, and staff members should be trained to recognize discrepancies and bring them to the attention of the right people immediately," Church says. "Having policies and procedures is not enough if you allow retaliation against the people who sound the alarm. Those people should be rewarded for helping prevent bigger problems down the line."

Training in billing processes and compliance should be as regular and formalized as training patient safety and similar issues, she says.

Church also suggests educating staff and physicians about the potential consequences for not following policies and procedures, particularly the potential for individual criminal prosecution.

"Make sure everyone understands that they have to be truthful and ethical, even though that sounds very basic," she says. "That sounds like something you shouldn't have to say out loud to people, but apparently it needs to be said in the healthcare industry." ■

SOURCE

- **Megan Cunniff Church**, JD, Partner, MoloLamken, Chicago. Phone: (312) 450-6716. Email: mchurch@mololamken.com.

EXECUTIVE SUMMARY

Government enforcement in healthcare fraud cases is likely to be particularly active in the near future. Individual criminal prosecutions will be more common.

- The Department of Justice has indicated that healthcare fraud still is a top concern.
- Prosecutors will not rely on whistleblowers as much as in the past.
- Data analytics is becoming a key tool in identifying ongoing fraud.

Claims Frequency and Batch Claims Increasing

Healthcare systems in 2018 could see an increase in claim frequency for claims greater than $5 million, along with an increase in batch claims, according to a new report.

Risk managers also should focus on sterilization issues and employee misconduct claims, says **Erik Johnson**, regional director and actuary with Aon Global Risk Consulting in Raleigh, NC. Those issues were associated with some of the larger claims figures in the Aon/ASHRM Hospital and Physician Professional Liability Benchmark report. *(The report can be purchased online at: http://aon.io/2ABhZXp.)*

The report includes the following findings:

• The projected loss rate for hospital professional liability is $2,750 per occupied bed equivalent (OBE) for events occurring in 2018. The frequency of claims is projected to be $1.61 per 100 OBE and the severity of claims is expected to be $171,000 per claim.

• The projected loss rate for obstetrics claims occurring in 2018 is $172 per birth, and ED is $5.78 per visit.

• The projected loss rate for physician professional liability is $5,710 per internal medicine physician for events occurring in 2018. The frequency of claims is projected to be 3.50 per 100 internal medicine physicians, and the severity of these claims is expected to be $163,000 per claim.

• Projected loss rate for hospital general liability is $130 per OBE; the average general liability claim is expected to be $42,000 for claims occurring in 2018.

• Labor and delivery- (L&D) related issues, with an average value more than $350,000, continue to be significantly more severe than claims related to other allegations. The costliest L&D-related issue was delay in delivery, with an average cost of more than $1.1 million.

• Projected hospital professional liability and PPL loss rates are increasing at a 2% annual rate.

"The frequency and severity of the most typical medical malpractice claims are very stable, as they have been for more than 10 years. But we see a trend developing in the most severe type of claims, those costing more than $5 million," Johnson says.

> "WE SEE A TREND DEVELOPING IN THE MOST SEVERE TYPE OF CLAIMS, THOSE COSTING MORE THAN $5 MILLION."

"That is alarming because that kind of claim drives so many dollars for both the insurance industry and the hospitals."

The expected increase in batch claims is tied to sterilization issues and employee misconduct, both receiving more attention from the media and the plaintiffs' bar, Johnson says. Those are now among the most common batch claims.

"Risk managers have to expect those types of batch claims but also look to the possibility of other types that we haven't seen as much of yet," he says. "This is tricky because you have to try to imagine batch claims that might come up and then look to the wording and specifications in your liability coverage to determine if and how they would be covered."

Johnson advises meeting with the chief medical officer and chief financial officer to brainstorm about potential batch claims.

"Challenge the chief medical officer to think about circumstances that could affect multiple people. What kind of problem could you have that could result in many patients being harmed and bring claims?" Johnson asks. "On the other side, try to understand how insurers have reacted to batch claims in the past and how they might react to the type of batch claims you're thinking about."

Vicarious liability is another emerging risk, associated with physicians who are not employed by the hospital, Johnson says. The law on vicarious liability varies by state, but there have been successful cases recently in some states regarding a hospital's liability for doctors practicing in the facility but not employed, he says.

Tort reform also may affect some healthcare organizations in 2018, Johnson says.

"In 2017, we saw tort reform in Florida with the overturning of the cap on economic damages. That will be a big issue for healthcare organizations in Florida determining how it affects their claims and their premiums," Johnson says. "It's possible we could see more of that kind of tort reform in other states." ■

SOURCE

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Nurse Practitioner Payouts Increasing; Opioids and Neonatal Top Concerns

Payouts from malpractice claims against nurse practitioners (NPs) continue to rise, and much of the increase can be tied to the prescribing and management of painkillers, according to new data from insurance companies.

An analysis by Nurses Service Organization (NSO), a nursing liability insurer based in Ft. Washington, PA, and CNA Healthcare, an insurer based in Chicago, found a 13% increase in medication-related allegations against NPs due in part to improper prescribing/managing of controlled drugs, such as opioids and other painkillers.

The average paid indemnity of liability claims against NPs whose specialty is neonatal was $630,411, making it the specialty with the highest average paid indemnity.

One-third of NP license defense claims resulted in some level of discipline, ranging from fines to probation. Thirty-six percent of claims against an NP originated from a physician office practice. *(The full report is available online at: http://bit.ly/2Al3dW0.)*

One of the key findings of this analysis was that the average paid indemnity for closed claims with an indemnity payment of $10,000 or greater increased to $240,471 per claim, say the report's authors **Jennifer Flynn**, CPHRM, risk manager with NSO, and **Lynn Pierce**, BSN, RN, CPHRM, risk control director with CNA Healthcare. In the 2009 and 2012 CNA/NSO nurse practitioner claim analyses, which used the same criteria, the average paid indemnity is $186,282 and $221,852, respectively. This indicates an average annual paid indemnity growth rate of 6% between the 2009 and 2012 claim reports and a 2% annual growth rate between the 2012 and 2017 report periods, they note.

An analysis of allegation categories revealed that diagnosis-related claims occurred most frequently, accounting for 32.8% of all closed claims, and with a higher-than-average paid indemnity of $283,263 per claim.

"Some of the more troubling trends that we noticed involved behavioral health and medication prescribing. Behavioral health accounts for 15.3% of the closed claims in the current report, compared with 6.5% in the 2012 report," Flynn says. "This included some high-severity claims involving improper prescribing of medications and failure to address a behavioral health condition in a timely manner."

The effects of the ongoing opioid crisis are manifesting in both malpractice lawsuits and license complaints filed against nurse practitioners, researchers found. Related to malpractice claims, frequency of allegations related to medication prescribing increased from 16.5% of closed claims in their 2012 analysis to 29.45% of claims in the 2017 analysis. Even more telling, they say, is the fact that claims related to a reported injury of addiction grew almost tenfold between 2012 and 2017, from 1% to 9.5% of all closed claims.

"We also saw the frequency of medication-related complaints filed with state boards of nursing. The frequency of these claims increased from 20.3% of closed claims in our 2012 analysis to 27.1% of closed claims in our 2017 analysis," Pierce says. "The majority of these complaints involved overprescribing of controlled substances as well as failure to explain potential drug side effects."

The report offers nurse practitioners, nursing leaders, and organizations greater insight into malpractice claims as well as licensing board actions brought against their colleagues and facilities, Flynn says. The closed claims analysis reveals that while there have been advances in clinical practice and patient safety, many claims continue to develop due to failure to diagnose or a delay in making a correct diagnosis, medication prescribing errors, and failure to provide proper treatment and care, she says.

"As the frequency and severity of claims facing nurse practitioners increases, risk managers will continue

EXECUTIVE SUMMARY

Malpractice claims against nurse practitioners are resulting in higher payouts. Improper prescribing or managing of controlled drugs is a main driver, along with neonatal care.

- Diagnosis claims have a higher-than-average indemnity.
- Behavioral health claims have risen sharply in five years.
- The data suggest a need to focus more on core competencies.

to play a critical role in helping to protect both nurse practitioners and patients from potential adverse outcomes," Flynn says. "Our hope is that nurse practitioners, risk managers, and organizations alike can review our recommendations and patient safety tools to understand their risks and areas of loss likely to impact their practice, and to help reduce their liability exposure while improving patient safety."

The findings demonstrate the need for a deliberative and focused effort addressing core competencies, collaboration, and communication among and between health professions, Pierce says. The data show that most claims develop from a failure involving core competencies such as diagnosis, medication prescribing, or treatment and care management.

"This suggests that a greater emphasis should be placed on reinforcing core competencies at every stage, from education all the way to daily documentation practices," Pierce says.

Diagnosis-related claims had the highest percentage of closed claims, with the specific allegation "failure to diagnose" representing 20.7% of all closed claims, Pierce notes. Within this subcategory, the analysis revealed the following three causes that accounted for more than half of failure to diagnose closed claims:

- failure to timely/properly establish and/or order appropriate treatment;
- failure to order appropriate tests to establish a diagnosis;
- delay in obtaining/addressing diagnostic test results or failure to do so.

"In order to reduce risk, increase patient satisfaction, and improve quality in this critical area, practices should draft a written practice policy that clarifies practitioner and staff responsibilities in regard to clinical tests, including ordering tests, reviewing results, and notifying patients of findings," Pierce says.

Another example comes from medication prescribing, the category of allegations with the second-highest frequency of claims. The increased frequency of medication-related allegations is due in part to the allegation of improper prescribing/managing of controlled drugs, including Schedule II and Schedule III opioids such as methadone, oxycodone, fentanyl, and hydrocodone, Pierce says. Many times, the patient had a history of drug or alcohol abuse and was currently using or abusing Schedule IV controlled substances.

"THIS SUGGESTS THAT A GREATER EMPHASIS SHOULD BE PLACED ON REINFORCING CORE COMPETENCIES AT EVERY STAGE, FROM EDUCATION ALL THE WAY TO DAILY DOCUMENTATION PRACTICES."

"Especially considering the high level of public concern regarding opioid overuse and abuse, it is more important than ever that nurse practitioners prescribe with care, document the rationale behind prescription decisions, monitor patients taking multiple medications, and cooperate with other healthcare providers in managing and tracking drug regimens," Pierce says.

Flynn and Pierce recommend that all nursing leaders and organizations review their policies, procedures, and compliance programs on at least an annual basis and revise them as needed. Risk managers and nurse leaders also should establish a process for regular review and delineation of clinical privileges, they say.

Ensure nurse practitioners are provided with appropriate clinical support, in compliance with collaborative, supervisory, or employment agreements and confirm that everyone understands each party's role under the agreement. Communicate openly and swiftly about any questions or concerns that may arise, they advise.

Risk managers also should review job descriptions against the state's practice act to help reduce the likelihood of scope of practice-related allegations. Understand the current state scope of practice for nurse practitioners and support them within their scope of practice, they say.

Ensure nurse practitioner competency through ongoing peer review and professional performance evaluation, Flynn and Pierce suggest. Evaluations should focus on the nurse practitioner's clinical performance, documentation practices, and overall assessment and management of patients. ■

SOURCES

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Communication-and-resolution Programs Could Be Improved

Hospitals and health systems continue to embrace communication-and-resolution programs (CRPs) that provide structure for talking openly with patients and family members after an adverse event, and even initiating compensation, but there is room for improvement in many cases. Hospital leaders may be conducting their CRPs with the best intentions, but that doesn't necessarily mean CRPs are conducted in the best way.

The specific manner in which CRPs are conducted and the resulting effects were studied recently by **Jennifer Moore**, LLB, PhD, senior lecturer at the University of New South Wales in Sydney, Australia, and colleagues in the United States. They found that patients and family members sometimes report dissatisfaction with the discussions, even when the healthcare professionals thought they had conducted a by-the-book CRP.

Researchers interviewed patients, family members, and staff at three U.S. hospitals with CRPs and found that the CRP experience was positive overall for 18 of the 30 patients and family members. Satisfaction was highest when communications were empathetic and nonadversarial, they found.

"Patients and families expressed a strong need to be heard and expected the attending physician to listen without interrupting during conversations about the event. Thirty-five of the 40 respondents believed that including plaintiffs' attorneys in these discussions was helpful," the researchers reported. "Sixteen of the 30 patients and family members deemed their compensation to be adequate, but 17 reported that the offer was not sufficiently proactive. Patients and families strongly desired to know what the hospital did to prevent recurrences of the event, but 24 of 30 reported receiving no information about safety improvement efforts." *(An abstract of the report is available online at: http://bit.ly/2B5lV3M.)*

Consider How to Approach

Moore tells *Healthcare Risk Management* that their research suggests that there are four main ways to enhance CRPs. First, risk managers should spend time thinking about how to undertake the initial approach to the patient and family. The initial disclosure conversation should conclude with asking patients what form of communication they prefer in the future, such as email, telephone, or personal meetings.

"Risk managers should also consider asking the quality and patient safety office to make the initial approach. Consider involving a patient liaison or similar person to help the patient and family navigate," Moore says.

Second, structure the programs so that they attend to patients' and family members' emotional needs. For example, use appropriate terminology such as "reconciliation" instead of "resolution." Ensure that patient safety efforts are communicated to the patient and create space for the patient to be heard, Moore advises.

Third, ensure that the compensation discussions are nonadversarial, proactive, and occur early in the process. Fourth, structure ongoing contact opportunities into the process. For example, invite patients to provide feedback about the CRP. Seek feedback from patients and families about their CRP experiences a few months after completion, and contact patients on the anniversary of the event, she says.

"This research suggests that institutions should have the courage to reach out to patients," Moore says. "Indeed, deciding not to reach out to patients because of liability fears may increase the likelihood that the matter escalates."

Moore also identifies the key ways that CRPs typically fall short of their potential:

EXECUTIVE SUMMARY

Communication-and-resolution programs have been widely adopted, but the execution is uneven. Risk managers should review the actual performance of these programs.

- The risk manager should not make the first approach to the patient and family.
- Listening to the patient and family is important.
- Ensure compensation discussions are nonadversarial.

• not providing sufficient time for patients and families to be heard, particularly about matters that are important to them, but not clinically relevant;

• undertaking the compensation discussions in an adversarial style;

• not communicating patient safety efforts to patients and families;

• not notifying patients that they may consult an attorney;

• using an inappropriate form of communication and/or person when undertaking the initial approach.

CANDOR Offers Toolkit

CRPs can be optimized by using the Communications and Optimal Resolution Toolkit, or CANDOR, developed by the Agency for Healthcare Research and Quality, suggests **Victoria Rollins**, MHA, RN, CPHRM, CPTS, director of the patient safety program with The Doctors Company, a malpractice liability insurer in Napa, CA. The toolkit is available online at: http://bit.ly/2m9fch7.

"This toolkit works best because it was created by healthcare professionals and calls for a prompt response and specific actions after an adverse event. CANDOR calls for actions to be taken by specially trained hospital staff within an hour of an event and calls for the hospital to complete a thorough investigation within two months, keeping patients and relatives fully informed along the way," Rollins says. "When the investigation is complete, the patient and family are provided with the findings and engaged in a discussion of how the healthcare organization will try to prevent similar adverse events in the future."

All CRPs should include a commitment to patient-centered quality and safety, Rollins says. For all parties involved, a good CRP can offer resolution without the stress, time, expense, and unknown outcomes of a lawsuit. Patients who are satisfied with their physician and believe their physician is as honest as possible are less likely to sue, she notes.

"Even when the matter cannot be resolved and goes to trial, the fact that the patient and doctor talked early on can make a huge difference in the outcome of the case," Rollins says. "Patients tend to pursue litigation with a vengeance when they think the doctor doesn't care, but they tend to be much more reasonable when they can see that the physician is a human being with emotions, regret, and sympathy for the patient."

> "EVEN WHEN THE MATTER CANNOT BE RESOLVED AND GOES TO TRIAL, THE FACT THAT THE PATIENT AND DOCTOR TALKED EARLY ON CAN MAKE A HUGE DIFFERENCE IN THE OUTCOME OF THE CASE."

A common mistake is to look at CRPs as a malpractice liability reduction strategy, says **David B. Mayer**, MD, vice president for quality and safety with MedStar Health in Columbia, MD.

"It is not a medical malpractice strategy, so if you think that, you're starting off on the wrong foot," he says. "Reducing claims and payouts are wonderful secondary benefits, but a good CRP is a comprehensive patient safety strategy that has been shown to reduce risks to future patients."

Mayer also recommends the CANDOR toolkit, which was piloted at eight MedStar hospitals. MedStar uses CANDOR in its 10 hospitals and 300 ambulatory sites. The health system uses a "Go Team" approach that is modeled after the National Transportation Safety Board's process for quickly dispatching professionals to the site of a transportation accident, with specific goals in mind.

MedStar dispatches teams of trained employees to particular tasks after an adverse event. The "discovery and learning" team investigates the facts, the "care for the caregiver" team helps clinicians involved in the incident, and the "patient and family communication" team initiates conversations with the patient and family.

"We activate teams right away. We don't wait weeks or a month until we've had an M&M conference," he says. "We immediately start conducting interviews to learn what happened, and that team is trained in how to do interviews correctly, as opposed to looking for someone to blame and punish. If we need to, we bring in experts like pharmacists who might understand the issue more deeply than our team members, so they can help us design better processes and fix the gaps in our program so this incident doesn't happen again."

The "care for the caregiver" team addresses part of the process that is overlooked: acknowledging the trauma and lasting emotional effects on the clinicians involved, Mayer says. This team also is activated for

situations other than medical errors, such as when clinicians lose a patient they have come to know during treatment.

"This is a comprehensive patient safety program that has been shown to reduce harm to future patients, and when you reduce harm to future patients then you see fewer claims and better care," he says. "Then you don't have to employ CANDOR as often. The aviation industry still has tragedies occasionally, but when you look at the progress they've made over the years it is remarkable how effective they have been in reducing harm. That's what we should be striving for in healthcare, as well."

Prompt Reporting Necessary

Mayer notes that good and prompt reporting of adverse events is critical to making CANDOR or any CRP work. If you don't hear about an incident for a week or until a claim is filed, you have lost much of the opportunity to investigate and interact with people in the most effective way possible.

MedStar teaches clinicians that the first thing they should do after stabilizing the patient is to contact the safety office at the hospital — but that requires a culture in which staff believe that the goal is to learn and not to punish, he says.

"Some hospitals and leadership think they're ready for this, but they're not. They may have individuals who believe in this and want to make it happen, but the culture has gaps so significant that they're not going to be successful with CANDOR until they address those issues," he says. "They have to be ready at all levels, from the physicians who have to get over the very legitimate fears they have about admitting errors up through the board and the C-suite."

That fear from physicians is not unfounded, notes **Dennis J. Alessi**, JD, co-chair of the healthcare law and employment law practices at Mandelbaum Salsburg law firm in Roseland, NJ. Thirty-two states have enacted "apology laws" protecting clinicians who express regret after an adverse outcome, but such laws do not offer unlimited protection, he explains.

Most statutes distinguish between an expression of sympathy and an admission that the care provided did not meet the standard of care, he says. The first generally is not admissible in court, but the second is.

"You sometimes end up with the judge deciding whether it was a statement of sympathy or an admission that they performed below the standard of care, and it's not always clear. You have lawyers arguing that the doctor felt sorry only because he knew he made a mistake, so the statement should be admissible," Alessi says. "Doctors don't get a lot of protection from these statutes in some states, and 18 states don't have even that level of protection."

Risk managers must take those concerns into account when urging physicians to participate fully in a CRP, he says. To best protect clinicians against claims that they admitted guilt when talking to patients and family, Alessi says the clinician should always be accompanied by an uninvolved witness who could later verify the nature of the conversation. This could be a nurse not involved in the adverse event, for instance, but not someone like a physician from the same practice who would have a financial interest in the outcome of litigation.

"That visit should go in the clinical notes just like every other encounter with the patient. The nurse or other witness should sign off on the accuracy of those notes," Alessi says. "Those notes are admissible in court, and you have within those notes the signed statement by another person that those notes are accurate. That gives your attorney the opportunity to introduce those clinical records showing there was no admission, which can be persuasive even if the judge still allows testimony saying there was an admission." ■

SOURCES

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CE QUESTIONS

1. **According to Darci L. Friedman, JD, CHPC, CSPO, PMC-III, content strategy and author acquisitions manager with Wolters Kluwer, what is a main reason a "bring your own device" policy is potentially risky?**

   a. It is difficult to implement the same cybersecurity safeguards that you might use on a strictly in-house system.
   b. IT professionals must be proficient on different operating systems.
   c. The licensing agreements on different devices may not be sufficient for legal protection.
   d. The devices may not communicate well with the electronical medical record.

2. **What is one strategy Friedman recommends to make personal devices less risky in the healthcare workplace?**

   a. Limit areas of the hospital in which they can be used.
   b. Do not allow sharing of devices among staff and physicians.
   c. Allow only physicians to use their own devices.
   d. Use an app that allows remote wiping of the device if it is lost or stolen.

3. **According to the Aon/ASHRM Hospital and Physician Professional Liability Benchmark report, what is the projected loss rate for hospital professional liability per occupied bed equivalent for events occurring in 2018?**

   a. $2,750
   b. $4,750
   c. $6,750
   d. $8,750

4. **What nurse practitioner specialty had the highest average paid indemnity in the recent closed claim study by Nurses Service Organization and CNA Healthcare?**

   a. Surgical
   b. Pediatrics
   c. Neonatal
   d. Intensive care

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

Doctor Delays Delivery, Receives Phone Call, Resulting in Brain-damaged Infant

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News: A pregnant woman presented to a Miami hospital on an early December morning for the delivery of her son. Seven hours after her admission, the patient was started on Pitocin and she began pushing several hours thereafter. Several times during the delivery, the patient requested her physician perform a cesarean section, but the physician refused. After treating other patients, delivering another baby, and taking an eight-minute call from his stockbroker, the physician began a vacuum-assisted delivery.

AFTER TREATING OTHER PATIENTS, DELIVERING ANOTHER BABY, AND TAKING AN EIGHT-MINUTE CALL FROM HIS STOCKBROKER, THE PHYSICIAN BEGAN A VACUUM-ASSISTED DELIVERY.

The child suffered irreversible brain damage, and the child's parents initiated a medical malpractice claim against the physician, hospital, and other parties. After a bench trial, the couple, individually and on behalf of the minor child, was awarded more than $33 million.

Background: On Dec. 2, 2013, a pregnant woman was admitted to a Miami medical center at 2:40 a.m. for the delivery of her son. The patient signed a consent form for a cesarean section and any other surgical procedure required during delivery. The medical staff administered Pitocin from 9:46 a.m. until 1:30 p.m.

At approximately 12:27 p.m., fetal monitoring strips began to indicate intermittent decelerations. The patient's treating physician was present when she began pushing at 1:49 p.m. and Pitocin was restarted. Fetal monitoring showed a non-reassuring heart rate. Throughout the morning and the afternoon, the patient requested that a cesarean section be performed by the physician, who allegedly repeatedly refused the patient's requests.

The child was born at 3:21 p.m. with extensive hypoxic ischemic encephalopathy causing irreversible brain damage due to decreased blood flow to his brain and a large subgaleal hematoma caused by the prolonged use of a vacuum delivery system.

The patient claimed that after the baby's brain damage was apparent, the physician wrote in her chart that the patient refused the performance of a cesarean section. However, a labor and delivery nurse that was present during the delivery corroborated the patient's allegations that the physician refused a cesarean section and responded to her requests with direction to "keep pushing." The patient also claimed that the physician blamed her for not pushing hard enough. Further, the patient claimed that while she was pushing, the physician left the room multiple times to assist other patients, delivered another baby, made an eight-minute call to his stockbroker, and was out of the room when the child eventually was delivered.

The child's parents, individually and on behalf of the minor child, filed a complaint for damages. The plaintiffs claimed that due to the physician's negligence, the child

will require 24-hour nursing for the rest of his life with projected economic damages in excess of $25 million. At the age of 18 months, the child required feeding through a peg-tube, could not stand, crawl, or support himself, and underwent a tracheotomy that required suctioning every three to five minutes.

The medical expert for the plaintiffs testified that restarting the Pitocin and multiple attempts with the vacuum was dangerous and a gross deviation from acceptable standards. The trial judge granted summary judgment on the limited factual issues that the vaginal birth of the child led to his injuries, and that the patient was a Medicaid recipient at the time of the birth. The court left the causation issue for trial.

The action proceeded to a bench trial. On April 17, 2017, the judge issued a ruling that the physician breached the standard of care by not offering a cesarean section to the plaintiff mother and that this breach caused the child's injuries. The court awarded damages in the amount of $33.8 million, comprising $29.4 million in damages for the child, $3.3 million for the mother, and $1.1 million for the father.

Following the delivery, the patient discovered that the physician was sued for two additional negligent deliveries in 2013 — the same year of this tragic birth. One case involving the rushed use of a vacuum device causing disfigurement settled for $92,000. The second case, which is still pending, involves an alleged delay in an emergency cesarean section that resulted in brain injuries to the child.

What this means to you: The most salient issue presented by this case was the lack of internal oversight. To prevent cases like this, hospitals should invest in an internal audit team designed to assess and reduce internal risks. This team would be responsible for creating and executing a plan for exposing risks within the hospital, suggesting prioritization of those issues, and developing possible solutions. To prevent potential biases, this team should be comprised of neutral individuals who are not in regular contact with hospital employees. At a minimum, the following areas should be evaluated in the audit: general patient safety and quality of care, pharmacy procedures and adherence to those procedures, legal and regulatory compliance, human resources, patient admissions and registrations, cash management procedures, and patient management.

This case also illustrates the need to screen physicians and establish an interview process capable of vetting candidates on criteria such as criminal history, history of litigation involvement, and evidence of professional education and experience. Hospital recruiters should be charged with evaluating the risk associated with each new physician and medical professional, and should evaluate the risk relative to the benefit of their job performance. Criteria should be established to assess risk in an objective manner, and that risk must be considered throughout the hiring process.

When a physician applies for a position, the hospital should require the physician to list all previous medical experiences, including education, places of employment, areas of special expertise, and all litigation issues both pending and completed. Employers generally, and hospitals specifically, are charged with validating all information presented on the application. Information available publicly and online typically is simple to search for and review, and may reveal past litigation and the outcome of adjudicated litigation, against physicians or staff. In any event, relying solely on an individual's application materials lends itself to unwanted surprises. Also, if an applicant is accepted and credentialing is completed, the new staff physician should undergo proctoring by a senior physician for a period to assure competence.

Physicians and medical professionals must engage in continuing medical education. Medical professionals must refresh their education on best practices, as practices and standards are an evolving measurement rather than static determination.

Training both obstetricians and nursing staff in a standardized interpretation of fetal monitoring strips will eliminate much disagreement and controversy between both parties when rapid decisions are needed. Nurses, well-trained and confident, feel empowered to approach a physician who may miss an important symptom or sign due to multiple patient responsibilities. If the physician continues to provide care inconsistent with what seems appropriate to nursing, the availability of additional expertise can be accessed through activation of the formally established chain of command.

Finally, this case demonstrates the necessity of discipline. Swift and appropriate consequences should be enacted to anyone who knowingly records a false entry in the medical record. To eliminate any appearance of impropriety, all hospital personnel must be subject to disciplinary action for failure to comply with ethical standards, legal requirements, and

hospital policies or procedures. The physician here ultimately was fired, but his negligent and lazy approach should have been discovered much earlier and he should have been reprimanded or terminated to avoid such unfortunate injuries to a patient. Disciplinary actions inherently vary based on the severity of the offense, but such actions that may be appropriate include oral warnings, written warnings, temporary suspension, mandatory education, increased supervision, financial penalties, demotion, and termination. ■

REFERENCE

Decided on April 17, 2017, in the United States District Court, S.D. Florida; case No. 1:15-cv-23502.

Defense Verdict in Spinal Fusion Case Despite Difficult Surgery, Complicated Post-op Needs

News: In 2013, a middle-aged man underwent a spinal fusion surgery that was expectedly difficult. After the surgery, the patient remained at the hospital for postoperative care and management of his severe pain. During that time, the patient's oxygenation level drastically and suddenly dropped. He was administered medication, which ultimately stabilized him. The patient alleged that he was resuscitated, but evidence contradicted that allegation.

The patient filed suit, alleging that negligence by the hospital's rapid response team, including an aggressive head tilt, dislodged the hardware recently implanted in his spine. The case proceeded to trial, where a "battle of the experts" ensued and the hospital presented arguments that its own medical staff contributed to the failure of the hardware in the patient's spine. The jury rendered a special verdict in favor of the defendants.

Background: On Aug. 20, 2013, a 53-year-old man underwent a posterolateral spinal fusion surgery. This was a co-surgeon operation performed by two spinal surgeons. The surgery was noted to be particularly challenging, as it required twice the usual operating room time and significant operative devices, including a microscope, stereotactic navigation, and operative neurologic monitoring.

The patient remained at the hospital for postoperative care and pain management. He received pain medication and he reported that the pain levels vacillated between an eight and nine out of 10. The pain management team consisted of physicians and a physician assistant. Approximately five days after the surgery, the patient's oxygen saturation levels were notably low and on Aug. 26, 2013, his oxygenation level dropped into the 70s.

A rapid response team was called in and three doses of Narcan were administered over a five-hour period. Shortly thereafter, the patient's oxygen saturation levels normalized, and he remained more alert and arousable until his discharge on Aug. 28, 2013.

The patient filed a medical malpractice action against the hospital and the physician assistant, alleging inappropriate management of his postoperative pain. Specifically, the patient alleged he was over-sedated on narcotics, which purportedly necessitated manual chest compressions to resuscitate him. He also claimed that, because of the rapid response team's use of an Ambu bag for oxygen administration, which included an alleged "violent" chin and head tilt, the surgically implanted spinal hardware loosened, thus requiring a subsequent repair surgery. The patient further alleged that the Narcan caused violent shakes and seizures, further causing or contributing to the loosening of the spinal hardware and loss of fixation.

The plaintiff requested $250,000 in non-economic damages and between $564,000 and $798,043 in special damages for the cost of repair surgery and future medical care.

The hospital contended that its nursing and ancillary personnel complied with the standard of care for this patient throughout his hospitalization. The hospital claimed that the administration of the prescribed doses of medication to the patient and the continued monitoring of his reactions to the medications were in accordance with the applicable standard of care.

The hospital further alleged that no action or inaction by its staff caused or contributed to the displacement of the instrumentation screws implanted in the plaintiff's spine. Interestingly, the hospital argued that the displacement of the instrumentation screws was caused by a less-than-optimal screw fixation at the C5, C6, and C7 levels during the initial spinal fusion surgery. Moreover, the rods used during the surgery were shown to be too stiff relative to the anchoring ability of the bone, exerting additional pressure on the screws.

The physician assistant similarly defended himself on the basis that he

complied with the standard of care for pain management and medication administration and adjustments. The assistant contended his work was reviewed by supervising physicians as part of a team overseeing the patient's pain management. He further claimed that the administration of the medication did not result in a code blue situation requiring CPR. The assistant also claimed a chin tilt could not cause the loss of fixation of the patient's spinal hardware, and the Narcan did not cause side effects that could generate the requisite force to dislodge the screws.

On Aug. 17, 2017, the trial court entered a judgment in favor of the defendants, reflecting the jury's special verdict finding no negligence by the hospital or the physician assistant.

What this means to you: This case offers insight into proper postoperative care in difficult situations. The hospital conformed to the appropriate standard of care throughout these events, including teams on standby and available to respond quickly, by properly monitoring medication, by establishing a treatment approval process, by maintaining a good medical record, and by maintaining a knowledge of medications and their side effects. While it is difficult to quantify which of these measures are necessary and which are best practices, the cumulative effect of the hospital's extensive care satisfied the applicable standard.

Rapid response teams are imperative in any hospital. Stabilization of patients in rapidly deteriorating conditions can be a deciding factor in whether a patient recovers. These rapid response teams are becoming more commonplace in hospitals, and they can offer nurses and physician assistants a chance to address problems in a patient's condition that otherwise is not immediately reported to physicians. If hospitals fail to institute procedures that enable medical professionals to report symptoms amounting to an undefined condition or fail to adhere to their own standards, rapid response teams can act as a safeguard. The creation of rapid response teams can reduce the number of code blues, intensive care bed days, patient deaths, lawsuits, and the duration of patient stays.

The procedure of the hospital in this case to require supervision of physician assistant treatment by a physician — with appropriate documentation of that oversight — helps reduce treatment errors that negatively affect the patient's health. Close collaboration between medical professionals encourages communication and transparency, and hospitals should strive to foster mutual respect between physicians and supporting medical staff. Physicians should be encouraged to set forth clear procedures for medical staff, and the staff should be empowered to respectfully negotiate those procedures, where appropriate, to produce efficient and actionable courses for any given circumstance.

Hospitals should establish specific and detailed procedures for rapid response teams and those who work with the teams. Thorough and appropriate training and documentation is critical not only to the success of the teams and to a patient's safety, but also aids in defense if a patient alleges medical malpractice.

This case also provides some guidance concerning prospective procedures for rapid response teams. Objective criteria should be listed to define situations where staff should call for a rapid response team. Such circumstances may include low respiration rate, wet lungs, shortness of breath, elevated heart rate, chest pain, mental status change, and reduced blood pressure. Calls for rapid response should be made through the hospital's designated emergency phone line. The teams must arrive equipped and prepared to stabilize patients quickly, as the emergent nature of their services is expected. On-duty nurses and physician assistants must be trained on how to integrate into, and work closely alongside, the rapid response to team to provide comprehensive treatment. Thorough and accurate documentation is critical; staff must be trained and instructed on how to properly document events.

Whether a medical record is helpful or harmful, clear information and knowledge enable hospitals and physicians to later evaluate the circumstances when a patient alleges malpractice. Unfortunately, it may be the case that the standard of care was not met. If the medical record unequivocally demonstrates such a case, a defendant hospital or physician, working with an attorney, may wish to take the necessary steps to settle the matter rather than engage in arduous, expensive, and lengthy court proceedings.

Finally, this case presents an interesting catch-22 in the form of arguing its non-defendant physicians performed the surgery in a less-than-ideal fashion. Arguing that its physicians operated, to some degree, negligently opens the hospital to a determination that it failed to conform to the standard of care. In any event, the hospital's argument does well to show that a hospital is only as strong as its weakest link, and as such, constant internal oversight is essential. ■

REFERENCE

Decided on Aug. 17, 2017, in the Superior Court, Orange County, California; Docket No. 30-2014-00754443-CU-MM-CJC.