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INSIDE

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Strict Rules Addressing Opioid Crisis Create Risks for Physicians

The opioid crisis has led regulators and law enforcement at both state and federal levels to implement strict limitations on prescribing that can create substantial risks for individual physicians and the organizations that employ them or credential them. Staying out of trouble requires a clear understanding of the rules.

In August 2017, the Department of Justice formed the Opioid Fraud and Abuse Detection Unit, which uses prescribing data to prosecute healthcare professionals engaged in opioid-related healthcare fraud. In the unit's search for pill mills, any physician or organization prescribing a high volume of opioids can come under scrutiny.

DATA FROM PRESCRIPTION DRUG MONITORING PROGRAMS SERVE AS A PRIMARY SOURCE FOR FEDERAL PROSECUTORS ENFORCING OPIOID STANDARDS.

The Drug Enforcement Administration (DEA) also is fighting opioid abuse by revoking controlled substance registrations for those who prescribe excessively. The DEA demonstrated its power to do so in February and March of 2018 by arresting 29 people and revoking 147 controlled substance registrations. *(More information on the DEA fraud unit is available online at: https://bit.ly/2VTw75S.)*

Losing a controlled substance registration means the physician or organization can no longer prescribe or dispense controlled substances. For most, that means they cannot continue operating in healthcare. Healthcare organizations are responding to the increased oversight.

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A survey by healthcare performance improvement company Vizient in Irving, TX, found that 64% of hospitals have increased their investment in opioid medication management over the previous year, with 78% implementing more prescriber education. Fifty-six percent introduced new technology to monitor prescribing, 54% added new options for acute pain management, and 44% limited dosage and quantities for prescribers.

In assessing the interventions they have introduced, survey respondents were most happy with dosage guidelines for acute care patients upon discharge, with 74% saying they were extremely or very effective. The next two most effective strategies were adding new staff to monitor opioid use and introducing new technologies to monitor opioid prescribing.

Opioids Come With Danger

Federal prosecutors have started issuing letters directly to medical prescribers, warning them that their opioid prescribing is a "source of concern," says **Sarah Hall**, JD, a former federal white-collar crime prosecutor and now senior counsel with the Thompson Hine law firm in Washington, DC. She has extensive experience in prosecuting criminal healthcare fraud.

She calls the letters especially concerning for healthcare providers. There is little precedence for warning letters, so it is unclear what the reaction should be, Hall says.

The closest precedent is the "target letter" that federal prosecutors sometimes send to a target of an investigation. Hall explains that the federal *Justice Manual* describes a target as "a person as to whom the prosecutor or the grand jury has substantial evidence linking him or her to the commission of a crime and who, in the judgment of the prosecutor, is a putative defendant."

That signals that prosecutors are taking the issue quite seriously, Hall says.

"The world of opioids is a very dangerous place these days for doctors, patients, and society in general," Hall says.

Data from prescription drug monitoring programs serve as a primary source for federal prosecutors enforcing opioid standards, she says.

"Healthcare organizations should have a good understanding of their

EXECUTIVE SUMMARY

Opioid prescribing is under intense scrutiny from federal and state prosecutors, creating significant risk for both individual clinicians and healthcare organizations. Any high volume of prescribing or other anomaly can trigger an investigation.

- Failure to comply with prescribing guidelines may result in revocation of a controlled substance registration.
- Hospitals in certain geographic areas of high opioid use are already under scrutiny.
- Hospitals must closely monitor their physicians' prescribing practices.

physicians' prescribing practices. The feds look for outliers in billing, so with opioids that can be high volumes of opioids overall, or high volumes in relation to the size of the practice or hospital," she says. "They are looking at geographic areas where opioid prescribing is high, so if a hospital is operating in that area, it may automatically get attention from federal prosecutors. If you are in south Florida, Houston, Dallas, Baton Rouge, Detroit, and other areas mostly clustered on the East Coast, you're already under greater scrutiny than most healthcare organizations across the country."

Risk Greatly Increased

The risk level related to opioids has increased significantly in recent years, says **Harry Nelson**, JD, chairman of Nelson Hardiman law firm in Los Angeles and founding board chair of the Behavioral Health Association of Providers, which consults with addiction treatment facilities.

"Not only are state and federal prosecutors becoming more aggressive, but state medical boards are taking a much more in-depth approach of comparing hospital records, physician records, and coroner reports in cases in which patients have died," Nelson says. "They are asking questions about whether the immediate cause of death had any connection to opioid prescribing."

Also, any opioid prescription over 150 morphine milligram equivalents (MME) is now scrutinized closely, Nelson says.

"Any prescribing at that level is being viewed with intense suspicion. State medical boards are generally identifying anything over 80 to 90 MME as questionable, and after that, it is definitely going to be suspicious," he says "They will look for a reason to excuse it, and they are more lenient with palliative care like for cancer patients and with patients with a history of trouble tapering off. But they are going to look at it very closely, and that was not always the case."

Nelson says there also is an uptick in medical malpractice cases related to opioid prescribing.

"We are in a very high-risk environment where we've seen the pendulum shift from a focus on the risk of undertreatment of pain a decade ago to now this intense focus on overprescribing," Nelson says. "We're missing some pieces of the puzzle that doctors and hospitals need to have in place to have confidence in prescribing. We're missing a whole set of protocols that are condition- and setting-specific for appropriate use of opioids because now we have a one-size-fits-all guidance document from the CDC."

Nelson expects those more specific guidelines to come out within a few years, and in the meantime, he suggests risk managers develop internal guidance for physicians.

"The biggest problem I see is that the level of fear is keeping doctors from prescribing and leading to an enormous amount of suffering. I hear about cases in which doctors and nurses are emotionally wrought at their inability to treat serious pain, apologizing to patients who are genuinely suffering," Nelson says. "Organizations shouldn't wait for better national guidance. Work internally to articulate more specific guidance so that doctors will know they are safe in using particular dosages and duration in specific settings."

Many Regulations to Cover

Hospitals and individual physicians can find it difficult to keep up with all the new regulations regarding opioids, says **Joanna Starrels**, MD, attending physician at Montefiore Health System and associate professor at Albert Einstein College of Medicine in New York City. She focuses on the safety and effectiveness of opioids.

"Clinicians are increasingly aware of the opioid crisis, and they know that they should be taking more precautions and implementing these processes, but they may not have the time or resources to do that in a thoughtful and nuanced way," Starrels says. "There are multiple new regulations, CDC guidelines, and Joint Commission requirements for a pain management committee, that patients be screened for addiction, monitoring pain in a standardized way, monitoring opioid prescribing, and training employees in opioid management. There can be a lot for healthcare professionals to keep up with and implement."

Opioid tapering can be particularly difficult for some healthcare providers, Starrels says. The CDC recommendations include guidance on how to reduce the prescriptions of some patients receiving high dosages of opioids, but Starrels says that often is misinterpreted.

"Many providers and health systems feel they need to use blunt measures to reduce everyone who is on these higher-dose opioids to these thresholds stated by the CDC or below. That seems to be causing the most problems," she says. "For risk managers, there are two sides to the coin. On one side, careless

opioid prescribing can lead to serious consequences like addiction or overdose, but underprescribing opioids also can bring negative consequences. So patients and families are coming forward with complaints from both sides."

Some strategies that can help clinicians manage the increased regulation of opioids include increased staff support, team-based care, adding clinical decision support tools to the electronic health record, data monitoring of opioids to identify outlier providers, and better patient education, Starrels says. Good patient education is required now, she notes, and most physicians do not have the time to do it adequately. Hospitals and health systems can step in to provide more extensive education to patients.

"It sounds like a lot, and it is," Starrels says. "That's why the best model for this is a team-based approach."

Starrels believes the regulation of opioids, while well intentioned, is moving faster than the research used to support it. There already is evidence that patients are being harmed by underprescribing, and she suspects there could be more backlash coming.

"Some of the recommendations are not yet ready for prime time, in that we don't fully understand the consequences of implementing them across the board," she says. "In the past year or so, I've seen some hints of correction or slowing of this train that I think is appropriate."

Starrels does expect more health systems to continue implementing a comprehensive approach to data monitoring and opioid stewardship programs. She acknowledges that healthcare organizations can be left in a difficult position when the risks of noncompliance are so severe but says it is important to keep in mind the effect on patients.

"I do have some hesitation that being too aggressive in overcorrecting the problem of overprescribing opioids can have negative consequences for patients that are poorly understood. I caution health systems about implementing these changes — which are mostly recommendations and often based on data that is not proven — too aggressively."

Hospitals Can Be Liable

Criminal charges will fall on the individual prescribing the opioids unless prosecutors can prove the involvement of the employer, such as a hospital, Hall says. But broader civil liabilities and sanctions can be brought against the healthcare organization, she says, and those can bring extensive damage to its reputation along with substantial fines and other expenses.

"Hospitals definitely need to be involved with the prescribing practices of their physicians because the liability can come back on them in various ways," Hall says. "The more the hospital has a handle on medical professionals' prescribing practices, the better it will be able to avoid any potential investigations."

Hospitals and health systems are increasingly worried about consequences from opioid investigations, says **Dianne K. Pledgie**, JD, partner and compliance counsel with the law firm of Feldesman Tucker Leifer Fidell in Washington, DC.

"From the provider side, we are fielding concerns about ensuring appropriate opioid prescription practices are in place and followed, especially because of increased enforcement from the Office of Inspector General [OIG] and other authorities," she explains. "From a compliance and risk management perspective, we are working with providers to develop clear processes for treating chronic pain, including requiring providers to query the Prescription Drug Monitoring Program, having patients sign pain contracts, and conducting regular chart audits and peer review to ensure prescribing is appropriate."

At the same time, Pledgie says, many healthcare organizations are expanding their substance use disorder offerings. The compliance concerns for these new offerings include meeting licensing requirements for facilities and staffing. The federal government, as well as state governments, have supported the development of these services through grant funding, which requires compliance with a host of grant management rules, she says.

"In this area, too, the OIG has announced audits of the Substance Abuse and Mental Health Services Administration ranging from how grants are awarded to state-level controls over opioid treatment programs," she says. "Our clients are also partnering with other organizations to provide additional support to those with substance use disorders. These partnerships often create compliance challenges related to sharing patient information as a variety of state and federal laws come into play, including 42 CFR Part 2, the federal regulations which heighten the privacy protections for certain substance use disorder records."

Patients must consent in writing to the sharing of their records protected by Part 2 for purposes

of treatment or care coordination, unless one of a very few exceptions applies, Pledgie explains. Under HIPAA, such written consent is not required to disclose protected health information for treatment or care coordination. The Part 2 regulations affect the disclosure of patient records through health information exchanges, to law enforcement, to auditors, and more, she says.

Risks Extend Across Industry

The risk management challenges related to opioids extend throughout the entire healthcare industry, says **Alicia Marsiglia**, vice president and head of Allied Healthcare at the New York City office of Hiscox, an insurance underwriter.

"It's clear that states, cities, and counties are adopting the perspective that the whole health system should be held accountable for creating the opioid crisis. We see insureds or potential insureds in the treatment and distribution space — pharmacies, clinics, counseling, wholesale distributors — at a high risk of claims and regulatory scrutiny related to opioids," Marsiglia says. "I don't think we can say that it's only a physician's problem. Litigation can really be targeted at any provider in the continuum of care."

Managing compliance upfront is much easier than managing claims and license actions after the fact, Marsiglia says.

"The best way to defend against claims and regulatory scrutiny in most scenarios is to manage expectations with patients and be clear and upfront with patients about the available options," she says. "Prescribe and fill prescriptions like someone else is watching because at this point, it's likely the case. The level of oversight has necessarily increased to meet the challenges facing this industry."

Opioid compliance is one more burden for clinicians and risk managers already dealing with a variety of challenges, notes **Carla M. DewBerry**, JD, partner with the K&L Gates law firm in Seattle.

RISK MANAGERS SHOULD HELP THEIR ORGANIZATIONS DEVELOP A WORK PLAN TO STAY ABREAST OF DEVELOPMENTS IN OPIOID COMPLIANCE AND TO AVOID PITFALLS.

"Both practitioners and hospitals will be held accountable. Hospitals may have an easier time defining expected patterns and practices because this is standard work in a hospital," DewBerry says. "Some of the intensity of the new requirements may be a more challenging issue for clinicians. But doctors should anticipate that their home states may have adopted a stance similar to that in Washington, where the regulations now state that appropriate pain management is the treating physician's responsibility."

Risk management is similar for both individuals and institutions, DewBerry says. Both hospitals and clinicians have licenses to protect and they are possible defendants in cases that can come from many corners, DewBerry notes.

They both are required to produce and keep records of their actions, and therefore, their own files can be evidentiary; they rely on information from others such as patients, referral sources, and staff; and they have reputations to protect.

"You are seeing some of these risks being played out already in lawsuits which examine prescriptive practices, in new best practice guidelines and in the adoption of new regulations which clinicians must follow," DewBerry says.

"For example, many states have adopted rules for prescribing and monitoring opioids. These rules initially impact clinicians, and they can vary depending on factors such as the age of the patient, nature of the pain, the site of service, and impact of recent treatment received by the patient."

Outline for Risk Management

Risk managers should help their organizations develop a work plan to stay abreast of developments in opioid compliance and to avoid pitfalls, DewBerry says. The work plan would vary based on the size of the organization and its role in the delivery of care, but she offers this general outline:

- provider education on drug abuse and addiction;
- internal treatment protocols;
- grading patient pain levels;
- required assessments of the benefits and harm of opioid therapy for specific patients;
- required reassessments at a

specific time or based on identified factors;

• prioritizing nonopioid treatment, as appropriate;

• tapering the use of opioids;

• protocols for an assessment of the potential for misuse of medications by a patient;

• defining appropriate laboratory testing for drugs of abuse to identify the misuse (or nonuse) of prescribed medications.

Pursue Compliance in Usual Ways

Opioid compliance should follow the same general steps as any other compliance effort, says **Samuel J. Louis**, JD, an attorney with the Clark Hill law firm in Houston. Know what the regulations are, who the regulators are, and any guidance issued. Use that information to develop a compliance plan and train your employees, he says.

Louis recently worked with a hospital client to address opioid compliance, bringing in a DEA official to meet with hospital leaders. He notes that hospitals should be motivated to educate prescribing clinicians because of the potential risk of liability to the institution.

"Make sure that whatever your treatment regimen is, you can justify it through documentation of your patient over time. Documentation is key if you're trying to show that the amount of drugs you've prescribed is within the range of what is acceptable in the specialty and for that patient," Louis says. "Understand the sea change with respect to these prescriptions and ensure that you are in step with what regulators are expecting now with respect to determining need, dosage, and length of the prescription. On the administrative side, risk managers need to ensure those policies are not just in place but are actually being followed."

Hospitals and physicians are making a strong effort to curb the prescription of opioids, says **Scott Olson**, CEO of the addiction treatment center Pathway Healthcare in Birmingham, AL, which works closely with several hospitals.

"Most people are trying to determine, from a clinical diagnosis standpoint, when you should and shouldn't have an opioid prescription, and that is a change from how it was done in the past," Olson says.

"The thinking used to be that any pain is bad and you shouldn't have it, opioids work on the pain and insurance covered it, and doctors were incentivized to reduce your pain to zero. Now, there is more of a closer look at whether an opioid is what you really need, and if so, how long you need it." ■

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Obstetrical Claims Are Expensive, Require Focus on Unique Aspects of Care

Obstetrical claims are among the most common malpractice cases and can result in unusually large payouts because of their heartbreaking nature. The unique features of obstetrical care mean risk managers must guide clinicians to be highly attuned to the risks of individual patients while adhering to evidence-based practices — even when patients may have other wishes.

The unusual and potentially risky features of obstetrics were highlighted in an analysis of closed claims by Coverys, a malpractice insurer based in Boston. Obstetric-related events are the fifth-largest category of medical professional liability claims for this insurer, and they also represent the fourth-highest category of indemnity payments. Eighty percent involve injuries such as neonatal brachial plexus injury or neonatal neurological/brain damage fertility that are classified as "significant permanent," the highest clinical severity, or "major permanent," or death.

Coverys analysts say in the report that the financial costs can be "astronomical." The high costs stem from the fact that infants born with permanent injuries may require constant care. The difficulty of caring for an injured child may prompt some families to sue even when they don't perceive that any particular individual or facility is to blame for the injury, the report says.

THE DATA ANALYSIS ALSO REVEALED THAT MANY OF THE PATIENT SAFETY AND RISK MITIGATION ISSUES OCCUR EARLY IN THE PREGNANCY, NOT JUST IN LABOR AND DELIVERY.

(The report is available online at: https://bit.ly/2ClNcND.)

The severity of OB claims set them apart from other risk management issues and justify extra attention, says **Marlene Icenhower**, JD, CPHRM, senior risk consultant with Coverys. There also are unique complicating factors, she says, such as the emotional component that is more exaggerated with cases relating to children.

With families understandably sensitive about the outcome of a vulnerable child, some may sue even when they don't think any particular physician or other clinician did anything wrong, she notes.

Clinicians also are challenged by the fact that obstetrics always involves two patients, the mother and child. When their health interests conflict, clinicians can face dilemmas that can complicate their judgment and may lead to dissatisfaction no matter what choice is made, she says.

"Another thing that makes OB different from other specialties is that patients come in with expectations about how their experience should happen in the hospital. You don't have that when you come in for heart surgery, a set of expectations that you got from the internet or from other people," Icenhower says.

"Risk mitigation is all about open communication and setting expectations early on with the pregnancy, continuous training, and good documentation."

The data analysis also revealed that many of the patient safety and risk mitigation issues occur early in the pregnancy, not just in labor and delivery, notes **Maryann Small**, MBA, director of data governance and business analytics with Coverys.

"In the past, we've spent a lot of time talking about managing labor and delivery, thinking that's where all the risk is. But with more and more patients having comorbidities like obesity and hypertension, physicians can be reluctant to even

EXECUTIVE SUMMARY

Obstetrical malpractice claims are among the most serious and result in high payouts. There are unique aspects to obstetrics that create risk management challenges.

- Managing expectations is key to reducing liability risk in obstetrics.
- Identifying high-risk obstetric patients early in the process is important.
- Vaginal deliveries, not cesarean sections, account for more than half of claims.

label their patients high-risk and address those challenges early on," Small says.

Tips for Improving OB Care

Coverys recommends these strategies for improving obstetrics care and reducing liability risks:

- Simulate regularly. Run simulations when patient volume is low.
- Examine the dynamics of team relationships, communication impasses, turf wars, and politics. "Don't wait until giving a deposition or court testimony to get honest about difficult relationships, unwritten chain-of-command struggles, internal politics, or unnecessary pecking orders among OBs, family medicine, CNMs [certified nurse midwives], and nursing," the report says.
- Adapt your patient assessment process to address patients' cultural expectations as well as their biases and hopes for how the delivery process will unfold.
- Recognize and document high-risk pregnancies. "It's important to document why the patient is considered to be high-risk and how you are monitoring and treating the risk factor(s) throughout the pregnancy," the report recommends.
- Emphasize training. This should be the second-highest priority, only behind actually caring for patients, the report says. The department budget should reflect this.
- Develop a "bias toward decisiveness." Act when appropriate rather than delaying. But at the same time, clinicians must be open to reconsideration as situations evolve, the report says.

Vaginal Deliveries Make Majority of Claims

Small notes that the data show 52% of obstetrics claims involve vaginal deliveries — more than many people might expect.

"I think people expect that most of these are c-sections gone bad, but really, many of them are related to the challenges of staying watchful during a long, difficult laboring process that ends with a vaginal delivery," Small says.

Much of the risk management effort must be directed to the early stages of pregnancy, Icenhower notes. That includes identifying high-risk patients and developing a plan for referring them at the appropriate time to high-risk maternal fetal medicine specialists, she says.

"Setting expectations early on is very important because patients go into the delivery room with expectations that they're going to have a natural childbirth with no medical intervention, and when things go bad, nobody has prepared them for it," Icenhower says. "Everyone wants childbirth to be a positive experience, and people don't want to talk about what can go wrong. Setting expectations early on is huge in mitigating some of the risks."

Clinicians also can get out of practice with responding to serious but uncommon situations like shoulder dystocia, Icenhower notes. This is a particular risk in rural communities or other settings with a low volume of deliveries, she says.

"For smaller hospitals especially, it is important to have a system of drilling and simulations to maintain competency," she explains. "Sometimes, you have to look outside your own facility to find ways to stay current and give people the experience that makes them confident enough to handle that challenge when it arises." ■

SOURCES

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Run Drills to Improve Operating Room Emergency Responses

Hospitals typically run drills for a wide range of emergency scenarios, everything from shoulder dystocia in childbirth to an active shooter. But not as many run drills for an emergency response to the operating room.

This shortcoming became apparent in a hospital where **Charles Dinerstein**, MD, MBA, FACS, FSVS, previously was surgical chair. He is now senior medical fellow at the American Council on Science and Health in New York City.

With more than 25 years of experience as a vascular surgeon, Dinerstein saw multiple instances in which a patient suffered cardiac arrest in the OR and a code team was summoned.

"The code team arrived, violating every possible sterile field in street clothes, without masks to assist in care already being delivered by anesthesia and OR staff. Everybody came running into that room, including the family practice residents who were doing the cardiac codes," Dinerstein recalls. "All sorts of people were wandering into that room. It became abundantly clear that we had not had any practice, the staff was not familiar with standard routines, and that the surgeons had no plan for protecting the field."

Dinerstein realized the clinical teams needed a better plan for maintaining sterility, accessing needed supplies, and identifying key team members.

"We arranged for a simulation in an OR environment so that we could review what communications broke down, where equipment was located, and how to respond. It was a very significant learning experience for everyone, and it might be worthwhile for hospitals to have a series of simulations throughout the year," Dinerstein says. "Often times, continuing education closes the OR for an hour at the beginning of the day once a month or every other week, providing opportunities for drills without impacting routine care."

Dinerstein's hospital conducted drills in an available OR with a typical contingent of physicians and staff for surgery in the room. The drill started by declaring that the patient was in cardiac arrest and calling for a code team. After the simulation, the OR team debriefed and looked for ways to improve.

The drills made the OR team more confident about their roles in the emergency, highlighting the need for them to maintain control of the overall situation while allowing the code team members to do their jobs. The hospital also trained the code team in proper protocol for entering the OR and maintaining the sterile field.

"The roles of the CRNA [certified registered nurse anesthetist] and anesthesiologist were pretty straightforward, but we reassigned the roles of the scrub nurse and the surgeon to focus on caring for the patient, specifically to protect the sterile field, and we reassigned the circulating nurse to control the crowd coming and going," he says. "Those needs had not been immediately apparent to us before."

Drills should focus on issues such as who will be in charge, how to manage the room, and what decisions are being made by the team as the situation evolves. The drills should vary the situations, even in the same general topic such as cardiac arrest, so that participants can practice how to respond and change their assumptions.

"We have a habit of giving people an advanced life support card and telling them they're good to go," he says. "But what they encounter in actual situations may be different than what they're expecting or what they've done before because every patient is different."

The success of the drills led Dinerstein and colleagues at the hospital to develop similar simulations for other emergency scenarios like massive blood loss during surgery.

"The key insight is that this is another thing we can learn from the airline industry. The airlines require their teams to train regularly in simulators, with a focus on team management and communication," Dinerstein says. "This is something that hospitals have been a little bit slow to think about. There is not enough of that required in our hospitals, and we could be getting a lot more benefit from that kind of training." ■

EXECUTIVE SUMMARY

Emergency responses to the operating room should be drilled to improve performance and patient safety. Infection prevention is a priority.

- Code teams may be unprepared for maintaining sterility.
- OR team members should manage those coming to the room.
- Practice variations on similar scenarios to better prepare clinicians.

Avoid Simple Mistakes That Lead to HIPAA Violations, Data Breaches

A HIPAA compliance program must address the high-tech risks and threats that can lead to a data breach, but many violations are the result of simple, easily avoidable errors by employees. Focus on those as much as the more complex technological solutions, one expert suggests.

Recent research from Johns Hopkins Carey Business School in Washington, DC, and Michigan State University in East Lansing found that mailing mistakes by employees were the second most common cause of data breaches in a review of 1,138 incidents, accounting for 10.5%. Only theft by outsiders or unknown people accounted for more data breaches, with 32.5%. The third most common cause was theft by current employees, at 9%. *(An abstract of the report is available online at: https://bit.ly/2VUPCeh.)*

Pay Attention to Emails

The data support the need for technological safeguards like encryption, but they also highlight the need to help employees avoid basic mistakes like sending an email to the wrong person or sharing an Excel file with hidden tabs of patient data, says **Mark Bower**, chief revenue officer of Egress Software in Boston.

"Misdirected email is quite a significant risk for organizations. It comes about because with tools like Outlook or Gmail, you have the autofill feature that fills in an email address you're typing, but quite often, it is the wrong one," Bower says. "That can result in content that is inadvertently sent to the wrong recipient because the person was trying to do the right thing but the automation failed them."

Another common risk is accidentally sending additional data along with the intended content, Bower says. This is an easy mistake with a spreadsheet program like Excel, he says.

"You may be intending to send only something fairly mundane, like how many new customers you acquired this month. But the report you send may have another tab on the spreadsheet, not obvious to you, that contains medical information on those patients or Social Security numbers," Bower explains. "This is a simple error that even experienced users can make."

Focus on Training to Avoid Errors

Better training and reminders about the risk can help with problems like misdirected email, Bower says. Some organizations also are beginning to use technology with artificial intelligence that can detect abnormal behavior — such as sending a type of data file to an email recipient who has never been sent that file before — and provide an alert, with options for correcting the possible error, Bower says.

"There is a shift toward taking on these guiderails from machine learning and artificial intelligence, providing a technological solution that addresses these very basic human errors, especially the kind that are facilitated by imperfect automation," Bower says. "They aim to detect errors in even the most common situations. Then you can use the accumulated data to look at the employee population and see where you might have hot spots of employees who might need a little more guidance and training."

In addition to simple errors, some employees resort to practices that they might know are improper because the employer has not provided a more secure way of communicating.

"Quite often, there are gaps created by the need to share information outside the realm of the electronic health record, which has built-in compliance controls," Bower says. "You may need to share information with outside organizations for analysis or expert opinion. If the system makes that difficult, you can find people using workarounds like sending old-style CDs, jump drives, or even mailing out data in order to collaborate and get on with the job of providing healthcare." ■

SOURCE

- **Mark Bower**, CEO, Egress Software, Boston. Phone: (800) 732-0746.

EXECUTIVE SUMMARY

Some of the most common HIPAA violations stem from employees making simple mistakes. A compliance program should emphasize this risk.

- A common mistake is sending an email to the wrong person.
- An Excel file may contain hidden tabs of protected health information.
- Look for groups of employees who may need more training.

'Credible' Fraud Allegations in Billing, Data Privacy Challenge Compliance

Healthcare compliance challenges are constantly evolving, but two issues are always of concern: healthcare fraud and data privacy. Both need constant attention and a substantial amount of compliance resources.

Fraud allegations in billing are more common than ever before, says **C. Timothy Gary**, JD, an attorney with the Dickinson Wright law firm in Nashville, TN.

With the advent of the Affordable Care Act and the enhanced remedies for fraud, it seems like every billing dispute raised by both governmental auditors or commercial payers begins with the words "credible allegations of fraud" to enhance the leverage on the payer side, Gary says.

HIPAA's Move to the Information Age

"Healthcare providers need to be more proactive than ever in putting compliance protections in place. They should regularly conduct penetration testing on their electronic data and operations systems," Gary says.

"Also, they need to pay special attention to billing issues. They can have outside firms conduct billing audits utilizing the same protocols employed by CMS/OIG and their auditors. Best practices would dictate having these tests conducted at the direction of legal counsel by outside consulting companies so that the results remain privileged if problems are discovered."

For HIPAA, the healthcare world has moved into the information age, with vast amounts of protected health information (PHI) being stored electronically and the constant battle between information security systems and hackers who either want to steal data or hold it for ransom, he notes. As more PHI is stored electronically, risk managers must devote more resources to protecting it, he says.

Balancing Compliance With Existing Laws

That task becomes even more important as data privacy is becoming increasingly regulated, explains **Kirk J. Nahra**, JD, partner with the law firm of Wiley Rein in Washington, DC.

"In the United States, we are seeing new challenges from a California state law, which is creating both substantial compliance challenges and is motivating entities at other levels, including other states and the federal government, to evaluate whether additional privacy laws are appropriate," Nahra says. "Healthcare companies also have to balance compliance with a wide range of existing laws, which often create overlapping and sometimes inconsistent obligations."

These challenges are particularly difficult for some kinds of new technologies where the application of today's regulations are entirely unclear, Nahra says. There also are new compliance challenges when concepts of health broaden to include social determinants of health.

The healthcare industry also is seeing ongoing compliance challenges for companies in connection with data security and cybersecurity. There is a widespread view among regulators, consumers, and others that the healthcare industry is not strong enough on security protections, he says.

"Whether you agree or not, it is clear that there are tremendous challenges to stay at or ahead of the curve, as technology changes and hackers and others become more sophisticated. We also are seeing related challenges because of increasing technological and operational entanglements in the healthcare industry between different entities," Nahra says.

"All of these entanglements create security risks, and the industry is trying to change how healthcare is provided while keeping these security risks to a manageable level." ■

SOURCES

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- Kirk J. Nahra, JD, Partner, Wiley Rein, Washington, DC. Phone: (202) 719-7335. Email: knahra@wileyrein.com.

COMING IN FUTURE MONTHS

- Managing risk for CRNAs
- Responding to subpoenas
- Informed consent dilemmas
- Career choices for risk managers

HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **What is the effect of the DEA revoking a healthcare provider's controlled substance registration?**
   a. The provider may no longer dispense or prescribe federally controlled substances.
   b. The provider must submit to an elevated level of scrutiny regarding prescribing histories.
   c. The provider can prescribe federally controlled substances only to a limited number of patients.
   d. The provider will be able to prescribe federally controlled substances but may not be reimbursed or receive payment of any kind for the prescription.

2. **What does Alicia Marsiglia suggest as a strategy for remaining compliant with opioid prescribing requirements?**
   a. Manage expectations with patients and be clear and upfront with them about available options.
   b. Keep a separate database of patients receiving opioids and have it audited periodically.
   c. Prescribe opioids only for patients with whom the clinician has a long relationship.
   d. Establish a process for contacting opioid patients frequently to inquire about usage.

3. **In an analysis of closed claims by Coverys, a malpractice insurer, vaginal deliveries accounted for what percentage of the claims?**
   a. 12%
   b. 32%
   c. 52%
   d. 72%

4. **What was one change made when Charles Dinerstein, MD, MBA, FACS, FSVS, helped organize a code drill for a hospital's operating room?**
   a. The circulating nurse was assigned to control the flow of people in and out of the room.
   b. The anesthesiologist was placed in charge of maintaining sterility.
   c. The scrub nurse was found to be unneeded during the code.
   d. Code team members were barred from entering the OR.

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

Failure to Diagnose and Treat Oxygen Deprivation During Birth Results in $50 Million Verdict

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News: When a pregnant patient arrived at a hospital to give birth, she presented normally and without any exceptional or exigent circumstances. Fetal monitor readings initially indicated that the fetus was healthy. However, over the next several hours, the readings dramatically changed and fell to nearly undetectable levels. The physician failed to quickly identify and treat the fetus's oxygen deprivation, and the fetus suffered severe brain injury.

The child and his parents brought suit years later against the hospital, a physician, and a nurse, alleging that the failure to treat the oxygen deprivation caused the brain injury. A jury found all three liable and awarded the plaintiffs $50 million in damages.

Background: In March 2009, a 35-year-old pregnant patient checked into a local hospital when she was scheduled to have labor induced, accompanied by her husband. Vital signs on admission appeared normal and unexceptional. While the delivery was approximately five days later than expected, the patient otherwise experienced a healthy pregnancy. The patient went into labor naturally earlier in the day and did not require induced labor. Fetal monitor readings were initially reassuring and indicated that the fetus was healthy with a good heart rate.

Three hours into labor, the fetus's heart rate dropped dramatically; however, it eventually returned to normal levels. This heart rate deceleration and subsequent acceleration occurred multiple times while the patient was in labor. After one such drop and rise, the physician ordered that the patient's labor be augmented with Pitocin, which strengthens contractions but increases the stress on the fetus. The patient was in labor for 12 hours when the fetal heart rate eventually fell to essentially undetectable levels. The physician finally ordered a routine, rather than emergency, cesarean section.

THE PHYSICIAN FAILED TO QUICKLY IDENTIFY AND TREAT THE FETUS'S OXYGEN DEPRIVATION, AND THE FETUS SUFFERED SEVERE BRAIN INJURY.

The infant was delivered with blue skin and an extremely low heart rate, unable to breathe on his own. Physicians performed chest compressions in an attempt to get oxygen into the baby's body, but by this time, the injury had already occurred. The baby suffered a severe and permanent brain injury known as hypoxic ischemic encephalopathy (HIE) from the oxygen deprivation. The child developed cerebral palsy as a result of the brain injury and suffers from severe physical and mental debilitations, including struggling with basic tasks, an extremely limited vocabulary (knowing only approximately 30 words at nine years old), decreased motor skills, and difficulty walking. He will require extensive medical care and support for the entirety of his life.

The child and his parents brought suit when the child was nine years old, naming the hospital, a physician, and a nurse as defendants. The plaintiffs argued that

the physician and nurses failed to recognize the signs of fetal distress, and that the administration of Pitocin constituted medical malpractice. The defendants denied liability, although they did make a settlement offer of $10 million during trial. The family rejected that settlement offer, as they determined it was insufficient to cover the child's extensive medical care and needs.

After a nearly two-week trial, the jury reached a verdict and awarded the plaintiffs $50 million against all three defendants. The jury broke down this award as $12 million for future medical costs, $3 million for future lost earnings, $1.3 million for future pain and suffering, $1.5 million for increased risk of harm, $2 million for past emotional distress, $6.5 million for future emotional distress, $4 million for past loss of a normal life, and $20 million for future loss of a normal life. The defendants unsuccessfully attempted to challenge the verdict on the basis that they were prevented from offering evidence about the child's autism, which defendants argued contributed to the child's limited communication and mobility.

What this means to you: This case reveals the need for prompt diagnoses and treatment, particularly given emergent circumstances such as a patient's oxygen deprivation. While the physician in this case eventually realized that the fetus's heart rate indicated distress, that realization ultimately came too late, and the physician's subsequent actions failed to conform with the applicable standard of care. Oxygen deprivation of any patient poses significant risks, and those risks may result in dramatically increased damages when the patient is a fetus or infant. In this case, the physician correctly ordered a cesarean section once the fetus was in distress, but the physician did not order it to be performed on an emergency basis. The family argued, and the jury agreed, that this constituted care below the applicable standard, as a reasonable physician given the same or similar circumstances would have required that the cesarean section be performed as soon as possible based on the fetus's declining monitor readings.

Physicians and care providers often are tasked with juggling many different patients, but it is critical to assess and prioritize the care and treatment of patients who require immediate attention in order to prevent catastrophic injury. While this frequently occurs in emergency room settings, physicians and care providers in all practices and settings must be cognizant of the applicable conditions and injuries that may present. When time is of the essence in treating a patient, failure in this regard may constitute medical malpractice.

In this case, the family's expert opined that the child's injury was fully preventable if the cesarean section had been performed in a timely manner, and if the mother was never given Pitocin. Thus, the physician took the proper course of action by ordering the cesarean section, but it was the delay that resulted in the significant injuries, and a reasonable physician in the same or similar circumstances would have identified that the fetal distress warranted immediate action, rather than a nonrush procedure.

The labor and delivery department of a hospital functions under the same standards as an emergency department. Patients arrive in all stages of labor, and each patient — both mother and fetus — require immediate attention. Fetal monitoring, which primarily keeps track of the fetal heart rate in response to the mother' uterine contractions, is a science within itself. All healthcare providers, including nurses, midwives, obstetricians, and family practice physicians who are credentialed for deliveries, require very specific training in the interpretation of fetal monitor tracings.

The fetal heart rate is usually given a category level during the course of delivery, which provides a method to triage the labor progression so that care providers can be where the most urgent needs are, especially in a busy department. Heart rate decelerations are not always abnormal, especially during a contraction, and recover to baseline quickly. A slow recovery or an acceleration to a rate higher than baseline can indicate fetal distress from many sources such as pressure on the umbilical cord causing a decrease or interruption of blood flow from the placenta to the fetus.

During later stages of labor, the fetal heart rate can change from a reassuring category 1 to a devastating category 3 very quickly. Physicians and nurses should both be keeping a close eye on the tracings and confer frequently to ensure that there is agreement between them that the tracings are within an acceptable range. If the fetal heart rate is not reassuring to the team, interventions to bring the heart rate back within range must occur immediately.

If the woman's labor is being augmented with Pitocin, it is usually turned off for a period of time to see if the heart rate improves. It is not started in the presence of fetal distress. Cesarean sections are not ordered in the late stages of labor in the presence of fetal distress except on an emergent basis. There is a common standard of care for "crash" cesarean sections of 30 minutes from decision to incision. Both nurses and

physicians have a shared responsibility to make this happen. There is no hierarchy in labor and delivery rooms; nurses must intervene if a physician does not act promptly. Minutes matter, and with each second that care is delayed, the damage potential rises exponentially. The key to a successful outcome is training and teamwork.

After an unfavorable jury verdict, physicians and healthcare providers always have options to appeal the decision or to challenge unsupported verdicts. However, as seen in this case, such challenges often are uphill battles, with the presumption that the decision at the trial court was correct or supported by the weight of the evidence. Here, the defendants raised such a post-verdict challenge, arguing that the child's autism was a possible reason for his limited communication and mobility challenges and that the autism was unrelated to the birth injury. If successful, the challenges could have undermined the jury verdict or, at a minimum, reduced the amount of the damages awarded. The court summarily rejected the defendants' arguments and upheld the $50 million verdict.

Physicians and healthcare providers should consult with legal counsel to determine the best course of action following a favorable or unfavorable verdict, as either situation presents new opportunities and challenges, including new items to negotiate with the opposing party such as a waiver of appellate rights in exchange for a waiver of the losing party paying the winning party's court costs. ■

REFERENCE

Decided on Feb. 7, 2019, in the Circuit Court of Cook County, Illinois; Case Number 2014-L-013348.

$3 Million Verdict Affirmed for Negligent Delivery Claim

News: A pregnant patient was delivering her child when the baby's shoulder became obstructed by the mother's pelvis. In an attempt to dislodge the baby's shoulder, the physician used excessive force, causing shoulder nerve damage known as a brachial plexus injury. The baby suffered permanent Erb's palsy as a result.

The patient and her child brought suit years later, alleging that the physician breached the standard of care through use of excessive force. The jury agreed and awarded the plaintiffs $3 million in damages, plus $1.5 million in prejudgment interest.

Background: In 2008, a healthy, pregnant patient was delivering her child when the child's shoulder became obstructed by the mother's pelvis. The obstetrician/gynecologist physician attempted to dislodge the baby's shoulder but was initially unsuccessful. The physician subsequently applied additional force, which successfully dislodged the baby's shoulder but also caused nerve damage known as a brachial plexus injury. As a result, the child suffered from permanent Erb's palsy, or paralysis of the arm.

The child's mother, individually and on behalf of the child, brought suit in 2014 against the physician and medical practice, alleging that the physician used excessive force in attempting to dislodge the baby's shoulder and that this constituted a breach of the standard of care. The mother additionally alleged that the physician failed to properly inform her of the risks of the procedure, and that she would not have agreed to it if she had been fully informed of the risks connected to the delivery. During the seven-day trial, the plaintiffs offered testimony from two medical experts: one testified on the applicable standard of care for obstetricians, and the other testified about causation and the child's injuries.

The jury deliberated for about three hours before returning a verdict for the plaintiffs. The jury concluded that the physician breached the standard of care when he performed the delivery, and the jury awarded the plaintiffs $3 million in damages. Due to procedural delays, the trial was not held until 2017, nine years after the negligent delivery; in addition to the $3 million, the court awarded $1.5 million based on the prejudgment interest accrued since the injury occurred.

The defendants appealed the verdict to the state supreme court. However, the court affirmed the jury verdict and award. The defendants attempted to challenge the admission of the plaintiff's standard of care expert testimony and the plaintiff's causation expert testimony, alleging that the testimony was inadmissible because it was based solely on the fact that the child suffered an injury. The state supreme court found that the standard of care expert properly relied on the medical records, eyewitness accounts, and his nearly 30 years of experience as an obstetrician/gynecologist in forming his opinion. The state supreme court also determined that statistical testimony about the rarity of brachial plexus

injuries was permissible and directly rebutted the defendants' trial theory that the mother's endogenous forces caused the injury.

What this means to you: While this case is yet another example of a negligent delivery, the factual circumstances and legal issues presented are different. In this case, the obstetrician/gynecologist did not fail to diagnose or timely act but instead used a technique and excessive force that caused the child's permanent injury.

The plaintiff alleged that the physician failed to inform her of the risks of the procedure — which reveals an important lesson about providing patients with sufficient information to provide informed consent to a procedure. Physicians and care providers have an obligation to adequately inform the patient about the likelihood of success and the risks associated with a proposed treatment or procedure, and the failure to do so may constitute medical malpractice. This is not set in stone, and a physician or care provider is not required to explain minor risks that are unlikely to occur. Risks of death, serious injury, or significant potential complications should be explained to the patient prior to the procedure or treatment. If a physician or care provider has doubts as to whether a fact or risk rises to the level of materiality, it is better to err on the side of caution and to inform the patient of the risk. Documenting that a patient has been fully informed, including the specific risks and dangers, may later prove invaluable in overcoming a patient who was injured but actually informed of the risks and dangers.

Shoulder dystocia, a not uncommon complication during vaginal deliveries, can often be predicted based on a series of pre-existing conditions or risks such as maternal diabetes, macrosomia, or a higher-than-normal estimated fetal weight. There are multiple maneuvers that physicians and nurses can use to release the entrapped shoulder without damage to the brachial nerve, or other injuries such as fracture or dislocation of the humerus or clavicle.

As in the first case, teamwork and training of both physicians and nurses is essential. Many departments require that all staff participate in drills using life-size dummy models. This prepares everyone to manage a shoulder dystocia quickly and successfully using acceptable maneuvers to release the entrapped arm. It is preferable to start with the least traumatic maneuver — which just requires that the mother be repositioned — and then advance to more aggressive procedures such as applying mild pressure to one side of the uterus, internal maneuvering of the fetus, or reaching in and manually releasing the entrapped arm. Once the head is on the perineum and a dystocia is recognized, team members assemble and assist the supervising physician or midwife to complete the delivery. Because the mother cannot refuse the maneuvers despite the risks inherent in all of them, informing her before the dystocia occurs is crucial, especially if there are one or more risk factors.

Even under the most ideal circumstances, with all precautions taken, injures can still occur and — not uncommonly — are recognized after the infant has been discharged. It is prudent for the hospital pediatrician who discharges the infant to recommend to the parents that the infant be seen by an orthopedic physician if a shoulder dystocia occurred during delivery.

Another lesson to be learned from this case is that while an injury may occur, litigation does not necessarily immediately follow. If the injured party is a minor, such as in this case, the party is permitted but not required to bring the litigation right away. A state's statute of limitations permits a certain amount of time whereby an injured party is required to initiate the litigation, but this time period is "tolled," or paused, while the party is a minor. Thus, if an infant is injured during birth, the child may wait until he or she is 18 years old and then bring a lawsuit against the physician or care provider. While the child in this case did not wait 18 years, the family did wait approximately six years until after the injury to start the litigation, which was finally resolved approximately nine years after the injury.

For physicians and care providers, there are important aspects to consider when presented with such circumstances. One of the most important items to facilitate anticipated future litigation is maintaining thorough records, as memory necessarily fades over time. Contemporaneous documents are vital to defend against medical malpractice claims, and it is likely that many of the parties involved will have hazy memory — or even no memory whatsoever — of actions and decisions taken 10 years prior.

Medical records and notes taken during that time are crucial, and physicians and care providers should create and implement policies ensuring that such written documentation is thorough and preserved for years, particularly for records in which a patient has suffered an unexpected or undesired outcome. ■

REFERENCE

Decided on Feb. 4, 2019, in the Supreme Court of the State of Delaware; Case Number 133.