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NOVEMBER 2016 Vol. 38, No. 11; p. 121-132

Opioid Epidemic Brings Patient Safety Risks

The opioid addiction epidemic is introducing a new patient safety risk to healthcare facilities: the possibility of desperate and clever opioid addicts diverting medications from patients, which could leave the provider liable for any consequences.

Healthcare providers should respond by stepping up security for controlled substances and providing increased oversight for patients receiving the opioid medications most commonly sought by addicts, experts advise.

Opioid addiction has increased rapidly in recent years, according to data provided by HHS. More people died from drug overdoses in 2014 than in any year on record, and more than six out of 10 involved an opioid. The rate of overdose deaths involving opioids, including prescription opioid pain relievers and heroin, has nearly quadrupled since 1999, and more than 165,000 people have died from prescription opioid overdoses since then. Healthcare providers dispense more than 650,000 opioid prescriptions every day and an average of 3,900 people start nonmedical use of opioids each day.

> MORE PEOPLE DIED FROM DRUG OVERDOSES IN 2014 THAN IN ANY YEAR ON RECORD, AND MORE THAN SIX OUT OF 10 INVOLVED AN OPIOID.

Those numbers mean that all healthcare facilities are likely to see opioid addicts in some way, says **Rebecca J. Flood**, MHS, LCADC, NCACII, BRI II, the CEO of New Directions for Women, an exclusively female drug and alcohol rehabilitation center in Costa Mesa, CA. Those coming in for addiction treatment are obvious, but they also will visit hospitals and other facilities

Financial Disclosure: Author **Greg Freeman**, Senior Accreditations Officer **Lee Landenberger**, Managing Editor **Jill Drachenberg**, 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. **Arnold Mackles**, MD, MBA, LHRM, physician reviewer, 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.

AHC Media

HEALTHCARE RISK MANAGEMENT™

Healthcare Risk Management™, ISSN 1081-6534, including HRM Legal Review & Commentary™ is published monthly by AHC Media, LLC, One Atlanta Plaza, 950 East Paces Ferry Road NE, Suite 2850, Atlanta, GA 30326

Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices
GST Registration Number: R128870672

POSTMASTER: Send address changes to: Healthcare Risk Management, P.O. Box 550669, Atlanta, GA 30355

SUBSCRIBER INFORMATION: Customer Service: (800) 688-2421. Customer.Service@AHCMedia.com
AHCMedia.com

SUBSCRIPTION PRICES: USA, Print: 1 year (12 issues) with free CE nursing contact hours and free *AMA PRA Category 1 Credits*™, $519. Add $19.99 for shipping & handling. Online only, single user: 1 year with free CE nursing contact hours and free AMA PRA Category 1 Credits™, $469. Outside USA, add $30 per year, total prepaid in USA funds.

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for conditions not related to their addictions, and they will accompany or visit other patients.

In all of those cases, there is the risk of the addict trying to obtain pain medications, Flood says.

"Emergency rooms are flooded with addicts who have not taken care of their health and therefore develop urgent matters, or as a result of an accident, overdose, or attempted suicide," Flood says. "They're diagnosed with various health conditions they've neglected and end up on your med-surg floors. The truth is that nurses, doctors, and other healthcare professionals are not taught much about what addiction is or how to assess for it, so that puts hospitals and healthcare providers at greater risk because they don't know and don't understand the potential impact of dealing with addicts."

Obligation to Protect?

The prevalence of opioid addicts could be seen as creating an obligation for healthcare providers to protect them from themselves while in the facility, and also to protect other patients who could be harmed by the addict's drug-seeking behavior. *(For more information on the legal aspects, see related story on page 124.)*

Flood points out that addicts' behavior can be a danger not only to themselves but also to other patients, such as when a patient receiving pain medications is targeted for theft by an addict. Even when the pain medication is provided intravenously, addicts have been known to manipulate someone's IV line to obtain the drug for themselves, says **Jim Reynolds**, EdD, an addiction and substance abuse counselor and professor in the College of Counseling at Argosy University in Sarasota, FL.

"I've met addicts who preyed on cancer patients because they are likely to be on strong painkillers. They will find an excuse to go into the home and head straight for the medicine cabinet in the bathroom or even to the bedside and steal drugs there," Reynolds says. "I certainly can see an addict doing the same thing in a hospital, where there is so much more opportunity. Even those who are only visiting the hospital, it's the proverbial candy shop for them."

Flood agrees, and says this brings the possibility of harm and suffering to the patient, and a potential overdose for the addict.

"Without question, addicts will see that as an opportunity," Flood says. "A hospital is a great place for an addict to try to get medications."

Hospitals typically have tight regulations for controlled

EXECUTIVE SUMMARY

The epidemic of opioid addiction in the United States can threaten patient safety. Addicts may steal drugs from patients in various ways.

- Narcotics security should be assessed and improved as necessary.
- Visitation policies may be restricted for addicted patients.
- The prevalence of addiction may create an obligation to protect both addicts and other patients.

substances, but Flood notes those safeguards usually are focused more on medication security up to the point that the patient receives the medication. That may be inadequate in some circumstances to prevent theft by an addict.

Staff Can Also Be Addicted

Hospital staff and physicians also may be addicted and have the ability to circumvent controlled substance restrictions, Reynolds adds.

"We have seen instances of nurses and physicians, other staff, going to great lengths to obtain narcotics," he says. "With the opioid epidemic growing as rapidly as it is, there's no reason to think it won't affect healthcare employees as well, and they sometimes have special access that makes it more likely they can obtain the drugs."

Changes Might Be Needed

Flood suggests reaching out to local addiction treatment centers for help in educating physicians and staff about the prevalence of opioid addictions and the common behaviors to expect. Healthcare facilities may need to change some policies and procedures, such as ensuring that illegal narcotics are not in checked patient belongings, she says. Visitation policies are another potential area of improvement.

"If you have a patient who is identified as an addict, you might consider some form of restricted visitation because that is where drugs can get brought in that you are unaware of," Flood says. "If the patient is on an IV, they are going to be very familiar with how to introduce that illegal narcotic without there being any evidence that would be obvious to the nurse or doctor."

Hospitals also may need to increase the availability of naloxone, a medication used to treat opioid overdose, Flood suggests. In addition to making the drug available in the ED, hospitals should consider providing it on inpatient units and possibly even in the room of known addicts, she says.

> "WITH THE OPIOID EPIDEMIC GROWING AS RAPIDLY AS IT IS, THERE'S NO REASON TO THINK IT WON'T AFFECT HEALTHCARE EMPLOYEES AS WELL."

The effectiveness of naloxone is impressive, Reynolds says.

"Administering this drug can turn around a drug addict who is experiencing a serious overdose," he says. "In some communities it is carried by first responder, and it makes sense to have it readily available in a hospital."

Detox Beds May Be Best

Many hospitals have drug and alcohol detox units, and when a patient is known to be an addict, Flood suggests that might be the best place for a known opioid addict even if he or she is being treated for a completely unrelated condition. The hospital could reserve a few beds for med-surg patients in the detox unit, where physicians and staff are more experienced and capable of dealing with any addiction-related issues, both clinical and behavioral.

When healthcare professionals are unfamiliar with opioid addiction, they can make poor clinical decisions, Flood notes. Even if the physician or staff member realized the patient is addicted, a prescription may be provided that is counterproductive and potentially harmful, she says. The prescription may not be for an opioid, but it might be a drug like lorazepam to treat withdrawal symptoms, which can be inappropriate and enabling for some addicts.

"The healthcare provider may dispense something to make the patient more comfortable, because that's what healthcare professionals do. They try to stop the patient's discomfort and suffering," Flood says. "That might be the wrong thing to do, but you can't blame most doctors and nurses who get maybe one hour or five hours of training in addiction treatment." ■

SOURCES

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Addicts Pose Legal Risks to Hospitals

The growing presence of opioid addicts in healthcare facilities can create a legal obligation to anticipate the patient safety risks they can introduce, says **Erin L. Muellenberg**, JD, partner with the law firm of Arent Fox in Los Angeles.

"The risk is pretty significant, especially if this patient injury was something that could have been foreseen," Muellenberg says. "Then there is a duty to guard against it. If the hospital is not doing what is necessary to guard against that injury, then there is going to be a liability."

Impaired clinicians also pose a significant risk, and the opioid epidemic only heightens the need to prevent theft and misappropriation from patients, she says. A patient injured by an addict's behavior — whether that person was a clinician, patient, or visitor — could sue for professional malpractice, she explains.

"There is the potential for direct liability exposure, and if the harm is caused by an impaired clinician you have the potential for negligent credentialing exposure," Muellenberg says. "If you have a nurse diluting pain medications or just not giving them to the patient, the hospital can be negligent for not having looked into that individual's background."

Another significant exposure is for subjecting the patient to unnecessary pain and suffering because the hospital did not take proper steps to prevent drug theft, she says.

"There is a lot of talk about overprescribing and keeping drugs out of the hands of addicts, but there also are a lot of requirements for providers to adequately treat pain," Muellenberg says. "That creates a lot of tension for providers who have to walk that line, and they're subject to consequences if they err on either side. Then you have to throw in the possibility that the doctor prescribes the pain medication properly, but it never gets to the patient."

Some hospitals are establishing prescribing-review committees, a medical staff peer review committee that reviews a sampling of pain prescriptions to ensure that the patients' needs were met. Muellenberg says this is an excellent strategy to address the potential legal risks as well as clinical quality. She also suggests monitoring patient readmissions through the ED, looking for patients on opioids who return within 30 days. If the patient returns because of pain, then opioid theft, addiction, or underprescribing should be considered.

Muellenberg points out that hospitals could be subject to a version of "the barkeeper's law," the legal theory that holds an establishment responsible for the damage caused by a drunk driver if it can be shown that the alcohol was not provided responsibly.

"It's not that different to think that if an addict goes out and does something terrible while high on drugs that you never should have prescribed, you could be held liable," she says. ■

SOURCE

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Eliminating Alarms Can Help Reduce Falls

So much of the effort to reduce patient falls has focused on the use of alarms and physical aids that the suggestion of eliminating those tools can sound heretical. But some healthcare facilities are forgoing alarms and other methods on the theory that they can give both patients and staff a false sense of security.

Between 700,000 and 1 million people fall in U.S. hospitals every year, according to a recent report from The Joint Commission, with about a third resulting in injury. Even worse, 11,000 hospital falls a year are fatal. Risk managers know that these falls also have a significant effect on the healthcare organization, as injuries related to falls result in an average additional 6.3 hospital days. The cost of a serious fall with injury averages $14,056 per patient. *(For more information on The Joint Commission report, see related story on page 126.)*

Oakwood Lutheran Senior Ministries in Madison, WI, was no different. Oakwood experienced falls at its six continuing care retirement centers even though it had employed the typical alarms, fall pads, and low beds. But two facilities are trying a new approach by eliminating those tools. Director of Quality Assurance and Risk Management **Lauren Hartlaub,** RN, WCC, CLTC, says the results have been encouraging.

One nursing home already

was alarm-free, and another considered the change as part of an organizationwide fall quality improvement project in 2015, Hartlaub says. Each facility implemented a different fall prevention strategy, and Oakwood created a new falls reporting and review system that is available to all of them, tracking trends such as type of fall, time of day, and primary causes.

"There is a lot of research suggesting that they don't decrease falls and actually can increase falls. Patients and family turn the alarms off, or staff forget to turn them on," Hartlaub says. "Staff members also have alarm fatigue, so they don't always run to the alarm. They tune it out — not intentionally, but because they have so many alarms and other noise."

False Sense of Security

For those reasons, the fall alarms can give everyone a false sense of security, including patients and family members, Hartlaub explains. Without alarms, staff are forced to round more frequently and focus on efforts to prevent falls rather than being notified after they happen, she says.

Eliminating alarms also improves the patient experience, particularly by providing more restful sleep.

"Often the batteries are running low, or if they're not positioned perfectly on the mat, the alarm will sound or chirp at them," she says. "Patient and customer satisfaction is better without alarms."

The second facility launched Operation Quail in April 2016, with the goal of becoming an alarm-free facility by July 1. Fall mats and low beds also were phased out as part of the change. That facility already was not a heavy user of alarms because most patients were rehab and not the elderly or dementia patients more common in other Oakwood centers.

A flier and poster promoting the project included this reassurance: "This is going to a be a scary but exciting change in the direction toward more person-centered fall interventions and an overall culture change." Operation Quail kicked off with an ice cream social with all staff and corporate leaders invited.

That initial presentation of the idea was key to the program's success, Hartlaub says. Staff might resist such a change if they do not understand the reasoning behind it and how it will work for their day-to-day activities, she says, so the kickoff event allowed everyone to learn and get on board.

"Sometimes as risk managers we get excited about an idea and want to go full force with implementing it, but the staff are the ones who will actually be doing it, so we have to get their buy-in from the beginning," she says.

Staff More Aware of Falls

The Oakwood facility met its goal of going alarm-free by July, and Hartlaub says the effort has been a success. The reduction in falls is not dramatic so far, going from four falls at the facility in January 2016 to three in June as the facility neared total elimination of alarms, but Hartlaub says the experience confirmed that the change was the right move.

"Their fall rate is extremely low so we didn't expect to see any huge decrease in the numbers, but staff are more aware of falls and that was one of the primary goals," she says. "We're focusing on really being proactive and anticipate the residents' needs."

Low beds and fall pads were eliminated because they actually can cause falls, Hartlaub explains. At Oakwood facilities, self-transfer was the most common root cause of falls and those tools can increase the danger for residents who have difficulty rising on their own.

When a resident has been advised not to get up without assistance but does so anyway, trying to rise from a low bed can be more difficult and create more instability, she explains. Fall mats can be helpful when a resident rolls out of bed, but for someone trying to get up without help the fall mat can become a trip hazard and a slippery, unsteady surface for standing.

Eliminating alarms requires more patient and family education about falls, Hartlaub notes. Many Oakwood residents are transitioning from hospitals where fall alarms were common and expect the same at the

EXECUTIVE SUMMARY

Some healthcare facilities are eliminating fall alarms and other preventive measures. Advocates say the alarms give a false sense of security, and patient safety is improved without them.

- Alarm fatigue can lessen the usefulness of fall alarms.
- Educate staff well before changing alarm use.
- Maintaining mobility is important for elderly patients.

new facility.

"We have to take the time to explain how alarms don't reduce falls and actually can have a lot of adverse effects," Hartlaub says. "They understand once you explain, but you do have to take the time to inform them."

Fall alarms also can impede mobility and increase falls that way, says **Marcus Escobedo**, program officer with the John A. Hartford Foundation, a nonprofit in New York City dedicated to improving the care of older adults. Alarms can send the message that patients should not be mobile because it is too dangerous, but increasing mobility is one of the best ways to reduce falls, he says.

"There are similarities with the use of restraints," he says. "The fall alarm may not physically restrain the patient, but it tells them that they should stay where they are or an alarm will sound. If they comply with that, or if you're using restraints or chemical restraints like sedatives, they get less mobile with time and the risk of falling increases."

Better strategies include those that do not reduce mobility but help the patient or resident get stronger and walk without falling, Escobedo says, such as handrails and proper footwear. Escobedo recommends reviewing the fall prevention strategies used by the Pioneer Network, which supports better living for the elderly. *(See Pioneer's advice online at: http://bit.ly/2dG64uD.)*

Elderly people experience a 5% muscle mass loss for every day they stay in bed, says **Elizabeth Landsverk**, MD, geriatric medicine and dementia specialist, and adjunct clinical professor at the Stanford (CA) University School of Medicine. For younger adults, immobility results in a 1% loss of muscle mass per day.

"There should be a focus on keeping people active," she says. "The admission process should include a physical therapist consult, and then there should be a plan for keeping this person mobile. I'm a huge fan of physical therapists."

There is little substitute for supervision by staff, with frequent rounds and proactive steps to prevent falls, she says. Landsverk still supports the judicious use of alarms but agrees that they can give a false sense of security in some situations.

"I've seen patients who were more cognitive figure out that they can unclip the alarm and just walk around with it in their shirt pocket. It doesn't sound because they didn't pull apart the magnetic breakaway connector," she says. "It's that kind of thing that you have to keep in mind so you don't put too much faith in technology." ■

SOURCES

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The Joint Commission Offers Tips on Fall Prevention

A project involving seven hospitals has yielded fresh information on the causes of patient falls and possible solutions, The Joint Commission said in a new report.

The project was part of the Joint Commission Center for Transforming Healthcare preventing falls with injury project and involved seven U.S. hospitals using Robust Process Improvement, a TJC methodology that incorporates tools from Lean Six Sigma and change management. The hospitals studied fall injuries on their inpatient units, including four medical-surgical units, one medical oncology unit, a cardiology unit, and a medical-surgical/stroke/telemetry unit.

Each hospital identified the factors that most commonly led to falls with injury and developed solutions targeted to those contributing factors, which varied with each facility. They identified 30 root causes and developed 21 targeted solutions to address them.

The top 10 contributing factors for falls and falls with injury were grouped into six categories: 1) fall risk assessment issues, 2) handoff communication issues, 3) toileting issues, 4) call light issues, 5) education and organizational culture issues, and 6) medication issues.

The solutions developed for those problems were then pilot-tested with five additional hospitals for validation and solutions. TJC provides the results in the report "Preventing Patient Falls: A Systematic Approach from the Joint Commission Center for Transforming Healthcare Project," available online at: http://bit.ly/2dVesJW. ■

Kaiser Accused of Shorting Meds to Save Money

An anesthesiologist is suing Kaiser Permanente for $9 million, claiming that he was fired for complaining when told to reduce patient medications so they could be discharged sooner.

Erik Franck, MD, is suing Kaiser in Multnomah County Circuit Court, alleging whistleblower retaliation after he resisted what he says were systematic attempts to save money at the expense of patient safety and comfort. He provided anesthesia services at several Kaiser clinics and surgery centers in the Portland, OR, area.

Claims of Threats to Patient Safety

Franck says the trouble began in 2013 when Kaiser began decreasing staff levels at one surgery center and he complained about the threat to patient safety. He advised his superiors at Kaiser that it was not safe to supervise pediatric cases at a ratio of less than 1:2, especially with only one anesthesiologist on site, the lawsuit claims. Kaiser also adopted a policy, he alleges, that required anesthesiologists and staff to complete pre-op preparations and evaluations of surgical patients and have patients in the operating rooms so that surgery began promptly at 7:30 a.m. "If patients had complicated medical issues which required time-consuming pre-surgical evaluations or if the patients had questions or concerns and requested further consultation, the anesthesiologists were encouraged to prioritize getting the patients to the operating rooms by 7:30 a.m. over patient safety and patient concerns," the lawsuit says.

The Kaiser chief of anesthesia advised anesthesiologists and staff to "take the patient in with their street clothes on if you have to," in order to make the 7:30 a.m. deadline, Franck claims. Kaiser continued to push for faster patient turnover by making other cuts and policy changes that concerned Franck, the lawsuit says. At one point, he says, anesthesiologists received an email saying, "Anesthesiologists are asked not to go into operating rooms during [cesarian sections] unless absolutely necessary," an order that Franck said was dangerous.

> THE INSTRUCTION STATED THAT "ALL PROVIDERS WILL EMPHASIZE SAME MESSAGE FOR THE PATIENTS: YOU ARE GOING TO HAVE PAIN AND NAUSEA RELATED TO SURGERY AND ANESTHESIA."

Withholding Pain Medications

Franck cites a 2014 instruction from Kaiser that the anesthesia department was to return patients to the recovery room awake or easily awakened, made possible by decreasing pain medications. The instruction stated that "all providers will emphasize same message for the patients: You are going to have pain and nausea related to surgery and anesthesia." Anti-anxiety medications were not to be prescribed unless absolutely necessary, Franck claims the order stated.

"As a result of these policies, Dr. Franck became increasingly concerned that his pediatric patients were having their IVs pulled too soon after arrival in the recovery room while they were still crying with pain," the lawsuit says.

After repeated complaints about patient safety, Franck was told that his contract would not be renewed and his employment with Kaiser ended in August 2015.

Kaiser issued a statement saying it is committed to the highest standards of quality. "The claim is meritless and we are confident the facts will readily reflect that," the statement says. Franck's attorney did not respond to requests for comment.

Franck is not the first to accuse Kaiser of sacrificing patient safety for higher turnover. Oncologist **Jennifer Lycette**, MD, filed a $7 million lawsuit in 2014, alleging she was forced to quit after complaining about orders to rush patients through bone marrow biopsies before pain medications had taken effect. Four months later, **Radhika Breaden**, MD, sued for $9 million, alleging that she was pressured to quit because she complained that sleep-deprived patients were forced to drive long distances to access a sleep laboratory.

Both of those suits are still pending. The Franck complaint is available online at: http://bit.ly/2dNSq7X. ■

Physician Theft Charges Dropped in Videotape Case

The anesthesiologist at the center of a scandal involving a hospital that videotaped thousands of women in compromised positions is no longer facing theft charges.

The Medical Board of California recently dropped the theft charges against anesthesiologist **Adam Dorin**, MD, who had been accused of stealing drugs at Sharp Grossmont Hospital's Women's Health Center in La Mesa, CA. Suspicions of drug theft led to a 2012 sting operation in which the hospital used video cameras to try to catch a thief in the act. The hospital mounted video cameras inside computer monitors attached to mobile anesthesia machines in its ORs to detect anyone stealing sedatives from the carts, according to a statement released by the hospital. The hospital claims the recordings show Dorin putting vials of propofol and other drugs in his scrub top pocket. Hospital leaders suspended Dorin after viewing the footage, but relented when other physicians confirmed his explanation that propofol was in such short supply that they often hoarded the drug for emergency use.

The hospital continued the surveillance for a year until administrators realized the footage violated patient privacy in some instances, including women undergoing cesarean sections. The patients did not know they were being recorded, the hospital stated. The hospital reports that there are approximately 14,000 video clips in all.

After the Medical Board of California investigated and filed a formal accusation against Dorin, his defense attorney requested access to the hospital recordings. He found instances in which female patients could be identified in the recordings. When patients became aware that the videotapes had been made without their consent, many of them filed a class-action civil suit against the hospital. The suit is still pending. *(The class action lawsuit is available online at: http://bit.ly/2e3tcBM.)*

The board let stand two unrelated charges and is still seeking the suspension or revocation of Dorin's medical license for allegedly having sent fraudulent e-mails in 2012. The board claims he sent the emails to the employer of his girlfriend's husband, in an attempt to give her leverage in divorce proceedings. *(For more on the case, see "Drug Diversion Sting Goes Wrong and Privacy Is Questioned,"* Healthcare Risk Management*, July 2016, at: http://bit.ly/2cU5KFW.)* ■

Tenet to Pay $513 Million for Fraud, Kickbacks

Tenet Healthcare Corporation and two of its Atlanta-area subsidiaries have agreed to pay more than $513 million to resolve criminal charges and civil claims relating to what the government says was a scheme to defraud the United States and to pay kickbacks in exchange for patient referrals.

The Tenet subsidiaries, Atlanta Medical Center and North Fulton Medical Center, have agreed to plead guilty to conspiracy to defraud the United States and to pay healthcare kickbacks and bribes in violation of the Anti-Kickback Statute (AKS), the Department of Justice (DOJ) announced recently. The kickbacks involved payments for referring pregnant women to their medical centers.

"Atlanta Medical Center Inc. and North Fulton Medical Center Inc. were charged in a criminal information filed today in federal court in Atlanta with conspiracy to defraud the United States by obstructing the lawful government functions of HHS and to violate the AKS, which, among other things, prohibits payments to induce the referral of patients for services paid for by federal healthcare programs," the DOJ announced. "The two Tenet subsidiaries have agreed to plead guilty to the charges alleged in the criminal information and will forfeit over $145 million to the United States — which represents the amount paid to Atlanta Medical Center Inc. and North Fulton Medical Center Inc. by the Medicare and Georgia Medicaid programs for services provided to patients referred as part of the scheme."

In addition to the payments, Tenet and the subsidiaries entered into a non-prosecution agreement (NPA) with the Criminal Division's Fraud Section and the U.S. Attorney's Office of the Northern District of Georgia related to the charges in the criminal information. Under the terms of the NPA, they will avoid prosecution if

they cooperate with the government's ongoing investigation and enhance their compliance and ethics program and internal controls. Tenet also agreed to retain an independent compliance monitor to prevent the recurrence of violations of the AKS by any entity owned in whole, or in part, by Tenet. The NPA is in effect for three years, but the DOJ could extend it another year.

The civil settlement calls for Tenet to pay $368 million to the federal government, the state of Georgia, and the state of South Carolina to resolve claims asserted in a lawsuit filed by a Georgia resident in the Middle District of Georgia under the federal and Georgia False Claims acts.

The federal share of the civil settlement is $244,227,535.30, the state of Georgia will recover $122,880,339.70 and the state of South Carolina will recover $892,125.

The resident bringing the lawsuit will receive $84.43 million. ■

The Joint Commission Updates Notification Policy

The Joint Commission recently updated its policy regarding notification of changes within accredited organizations, requiring advance notice before the move is made.

The "Notifying The Joint Commission About Organization Changes" policy appears in the Accreditation Process (ACC) chapter of the Comprehensive Accreditation Manuals.

Accredited organizations previously needed to notify TJC within 30 days after a significant change. Now TJC says it wants time to consider the potential accreditation effect of changes before they are made, so the policy was updated to require organizations to provide written notification "when the change is initially contemplated." TJC defines that as "when leadership within the organization has approved moving forward with the proposed change and identified a timeframe for implementing that change."

Among other considerations, The Joint Commission will determine if the change will necessitate an on-site survey afterward. TJC also plans to update a similar policy, "Notifying The Joint Commission About Staffing Firm Changes," in the Health Care Staffing Services Certification Manual to reflect the revisions.

After the change has been made, The Joint Commission expects the organization to update its electronic application for accreditation (E-App) within 30 days.

More information on the policy change is available online at: http://bit.ly/2cRw5I2. ■

GAO Calls for More HIPAA Oversight

A recent federal Government Accountability Office (GAO) report calls for the Department of Health and Human Services (HHS) to make significant improvements in its guidance and oversight of HIPAA regulations.

'Struggle to Adequately Assess Risk'

In particular, the GAO report cites the failure of HIPAA regulations to address all elements of the Commerce Department's National Institute of Standards and Technology (NIST) Framework for Improving Critical Infrastructure Cybersecurity. That leaves electronic health records (EHRs) vulnerable to hacking, the GAO said.

"HHS officials said they intended their guidance to be minimally prescriptive to allow flexible implementation by a wide variety of covered entities," the report said. "However, until these entities address all the elements of the NIST Cybersecurity Framework, their EHR systems and data are likely to remain unnecessarily exposed to security threats."

Covered entities have struggled to adequately assess risk to protected health information and develop an effective risk management approach, the GAO report said. The GAO noted that there has been an increase in healthcare cybersecurity attacks, citing HHS data on healthcare data breaches affecting 500 or more individuals from 2009 to 2015. Hacking and IT breaches also have steadily increased each year, the report said.

The GAO report is available online at: http://bit.ly/2dFoNYZ.

VA OIG Reports on HIPAA Violation

An investigation by the Veterans Affairs Office of Inspector General (OIG) into HIPAA violations by business associates is a reminder to covered entities about the risk from these partners.

The investigation was prompted by a December 2014 call to the OIG's hotline with an allegation that ProCare Home Medical (ProCare) was improperly storing and sharing VA sensitive data on contractor personal devices in violation of federal information security standards. The caller claimed that ProCare was allowing its employees to use personal computers and phones to access the company computer system and download VA sensitive data, including veterans' personal health information.

"We substantiated the allegation that ProCare employees, according to its staff, accessed electronic sensitive veteran data with their personal computers from home through an unauthorized cloud-based system without encryption controls," the VA OIG reported recently. "We also noted that ProCare employees or malicious users could potentially use personal devices on an unauthorized wireless network to access sensitive veteran information. In addition, we determined that ProCare was storing sensitive hard copy and electronic veteran information in an unsecured manner at their facility."

ProCare could not provide evidence that applicable ProCare personnel had completed VA-required security awareness training or signed the Contractor Rules of Behavior prior to receiving access to VA sensitive data, the report said.

"These security deficiencies occurred because VA did not provide effective oversight of ProCare personnel to ensure the appropriate protection of veteran information at the contractor facility," the OIG reported. "As a result, veteran sensitive information was vulnerable to loss, theft, and misuse, including identity theft or fraud."

The OIG recommended the VA provide more oversight and conduct a site assessment of ProCare information security controls to ensure compliance with VA information security requirements. The report is available online at: http://bit.ly/2dtndsE. ■

Internists Sued More Often for Injuries

Internists more likely to be sued for high-severity injuries than doctors in other specialties, according a study of 1,180 claims against internal medicine physicians insured by The Doctors Company, the nation's largest physician-owned medical malpractice insurer, based in Napa, CA.

The most common malpractice claims in internal medicine are diagnosis related, with both hospitals and physician practices at risk. Based on claims that closed from 2007 to 2014, the analysis found that 39% of all claims alleged failed, delayed, or wrong diagnosis, with 56% alleging inadequate patient assessments such as failure or delay in ordering diagnostic tests.

High-severity injuries accounted for 58% of claims against internal medicine specialists, much higher than the 34% of claims against all physicians. More than a third of all injuries prompting malpractice claims in internal medicine took place in hospitals.

The study involved practicing physicians who reviewed the cases to determine the top factors that contributed to patient injury. The top three factors were patient assessment issues (33%), patient factors such as noncompliance with the treatment plan (25%), and communication breakdown between patient or family and the provider (21%). In many cases, more than one factor often contributed to the injury. *(The study results are available online at: http://bit.ly/2cXLHIH.)*

"This study reinforces that physicians fail to diagnose and treat accurately for a variety of reasons," said **Howard R. Marcus**, MD, internal medicine physician with Austin (TX) Regional Clinic in a statement released with the study results. "The average primary care physician will diagnose about 400 different diseases a year and occasionally encounters a rare medical condition that he or she may have never seen before. It is in this context that failure to diagnose may be caused by an error or lapse in reasoning

COMING IN FUTURE MONTHS

- Growing Importance of Patient ID
- Reducing Perinatal Harm Liability
- Speech Recognition Errors in EHR
- Making the Most of Handoffs

rather than a failure of knowledge or clinical skill. The case studies in this study will be used in our medical group's continuing medical education to demonstrate to our more than 250 primary care physicians how to avoid pitfalls in medical decision-making."

The Doctors Company offered advice on how to avoid the most common malpractice complaints in internal medicine. "Physicians and office staff should take the time to explore patient complaints, especially when the patient makes similar complaints on return visits," according to the report. "Diagnosis and treatment depend on skilled patient assessments. Patient complaints are the first opportunity to gather information. The ability to engage the patient in order to obtain an accurate history is especially important when developing a differential diagnosis."

The report also recommends thoroughly evaluating all age groups of patients with atypical chest pain, noting that 22% of the patients in this study who had myocardial infarction or cardiac were in their 40s and presented with atypical chest pain.

Healthcare providers also should pay close attention to calls and concerns from postoperative patients, the report says, especially since community-acquired and nosocomial infections can be difficult to diagnose.

"Diagnosing postoperative infections and other complications might be even more challenging. Internists are often called upon to provide postoperative care at a time when patients are unable to determine whether symptoms are a normal part of recovery or are complications that need medical assistance," the report says. "Clearly document the clinical history and physical examination. Document the details of telephone advice, and include any follow-up and appointment information."

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CME/CE QUESTIONS

1. **Which of the following is true of opioid-addicted patients, according to Rebecca J. Flood, MHS, LCADC, NCACII, BRI II?**

   A. Opioid addicts are unlikely to visit a hospital's ED.
   B. EDs are seeing an increase in opioid addicts.
   C. Opioid addicts rarely attempt to steal medications in a hospital.
   D. The detox unit is never appropriate for an opioid addict being treated for an unrelated condition.

2. **Which of the following is true, according to Jim Reynolds, EdD, an addiction and substance abuse counselor and professor in the College of Counseling at Argosy University in Sarasota, FL?**

   A. A hospital's controlled substance precautions will suffice to prevent theft by addicts.
   B. Hospitals may want to review their controlled substance precautions and consider the possibility of theft by addicts.
   C. Hospitals are not responsible for preventing drug theft by addicts.
   D. Opioid addicts should be handled the same way as prisoner patients.

3. **Of the 700,000 to 1,000,000 hospitals falls every year, about how many are fatal?**

   A. 3,000
   B. 11,000
   C. 80,000
   D. 100,000

4. **In the lawsuit against Kaiser Permanente filed by Erik Franck, MD, what does he allege regarding the use of anesthesia and anti-anxiety drugs?**

   A. Kaiser wanted the drugs used sparingly to speed discharge after surgery.
   B. Kaiser would not provide accurate accounting for the drug inventory.
   C. Kaiser wanted the drugs used more to improve reimbursement.
   D. Kaiser insisted that unqualified staff administer the drugs.

HEALTHCARE RISK MANAGEMENT™

United States Postal Service

Statement of Ownership, Management, and Circulation

1. Publication Title	2. Publication Number	3. Filing Date
Healthcare Risk Management	1 0 8 1 _ 6 5 3 4	10/1/16
4. Issue Frequency	5. Number of Issues Published Annually	6. Annual Subscription Price
Monthly	12	$519.00

7. Complete Mailing Address of Known Office of Publication *(Not printer) (Street, city, county, state, and ZIP+4)*
950 East Paces Ferry Road NE, Ste 2850, Atlanta
Fulton County, GA 30326-1180

Contact Person: Regenia Sims
Telephone: 404-262-5473

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not printer)*
950 East Paces Ferry Road NE, Ste 2850, Atlanta, GA 30326-1180

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do not leave blank)*

Publisher *(Name and complete mailing address)*
AHC Media LLC, David Fournier, President and CEO
950 East Paces Ferry Road NE, Ste 2850, Atlanta, GA 30326-1180

Editor *(Name and complete mailing address)*
Joy Dickinson, same as above

Managing Editor *(Name and complete mailing address)*
same as above

10. Owner *(Do not leave blank. If the publication is owned by a corporation, give the name and address of the corporation immediately followed by the names and addresses of all stockholders owning or holding 1 percent or more of the total amount of stock. If not owned by a corporation, give the names and addresses of the individual owners. If owned by a partnership or other unincorporated firm, give its name and address as well as those of each individual owner. If the publication is published by a nonprofit organization, give its name and address.)*

Full Name	Complete Mailing Address
AHC Media LLC	950 East Paces Ferry Road NE, Ste 2850, Atlanta, GA 30326-1180
David Fournier	950 East Paces Ferry Road NE, Ste 2850, Atlanta, GA 30326-1180
~~Bethany Schilling~~	~~950 East Paces Ferry Road NE, Ste 2850, Atlanta, GA 30326-1180~~
~~Lone Peak Capital Group, LLC~~	~~79 West Paces Ferry Road, Suite 200-A, Atlanta, GA 30305~~

11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages, or Other Securities. If none, check box → ☒ None

Full Name	Complete Mailing Address

12. Tax Status *(For completion by nonprofit organizations authorized to mail at nonprofit rates) (Check one)*
The purpose, function, and nonprofit status of this organization and the exempt status for federal income tax purposes:
☑ Has Not Changed During Preceding 12 Months
☐ Has Changed During Preceding 12 Months *(Publisher must submit explanation of change with this statement)*

PS Form **3526,** October 1999 *(See Instructions on Reverse)*

13. Publication Title: Healthcare Risk Management			14. Issue Date for Circulation Data Below: September 2016	
15.		Extent and Nature of Circulation	Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
a.		Total Number of Copies *(Net press run)*	287	266
b. Paid and/or Requested Circulation	(1)	Paid/Requested Outside-County Mail Subscriptions Stated on Form 3541. *(Include advertiser's proof and exchange copies)*	231	216
	(2)	Paid In-County Subscriptions Stated on Form 3541 *(Include advertiser's proof and exchange copies)*	0	0
	(3)	Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Non-USPS Paid Distribution	3	3
	(4)	Other Classes Mailed Through the USPS	21	16
c.		Total Paid and/or Requested Circulation *(Sum of 15b. (1), (2),(3),and (4))* ▶	255	235
d. Free Distribution by Mail *(Samples, complimentary, and other free)*	(1)	Outside-County as Stated on Form 3541	12	11
	(2)	In-County as Stated on Form 3541	0	0
	(3)	Other Classes Mailed Through the USPS	0	0
e.		Free Distribution Outside the Mail *(Carriers or other means)*	5	5
f.		Total Free Distribution *(Sum of 15d. and 15e.)* ▶	17	16
g.		Total Distribution *(Sum of 15c. and 15f)* ▶	272	251
h.		Copies not Distributed	15	15
i.		Total *(Sum of 15g. and h.)* ▶	287	266
j.		Percent Paid and/or Requested Circulation *(15c. divided by 15g. times 100)*	94%	94%

16. Publication of Statement of Ownership
☑ Publication required. Will be printed in the November 2016 issue of this publication. ☐ Publication not required.

17. Signature and Title of Editor, Publisher, Business Manager, or Owner: *David R. Fournier* — Publisher & CEO — Date: 09/12/2016

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PS Form **3526,** October 1999 *(Reverse)*

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

Doctor's Jury Verdict Affirmed in Planted Gun Case

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News: A hospital's chief of staff opposed its acquisition by a holding company, which he believed lacked the financial backing to operate the facility properly. He feared that client safety would be put in jeopardy should the holding company take over. The chief of staff organized protests against the proposed purchase and formed a competing doctor-investor group to purchase the facility. In 2005, the holding company acquired the hospital despite the chief of staff's efforts. The company defaulted on one of its loans and the chief of staff notified officers of the hospital and other medical staff. The company then filed a suit against the chief of staff, which it lost, and was forced to pay the physician's attorney fees. Following the appellate hearing, the CEO stated he would "humble" the chief of staff. Shortly thereafter, an anonymous 911 call led police to search the physician's car, where they found a gun and gloves. The police arrested him, but he was released quickly as there was insufficient evidence to indict him. The chief of staff filed a suit against the holding company and won a $5.7 million verdict for framing him. The verdict was upheld by a four-judge panel in late April 2015.

FOLLOWING THE BUSINESS TORT SUIT, THE CEO OF THE HOLDING COMPANY TOLD THE PRESIDENT OF THE COMPANY THAT HE WOULD "HUMBLE" THE CHIEF OF STAFF.

Background: In 2004, a hospital was put on the market for sale along with three other hospitals. The chief of staff, an infectious disease specialist, opposed its acquisition by a holding company, which he believed lacked the financial backing to operate the facility properly. He feared that client safety would be put in jeopardy should the holding company take over the hospital. He then organized protests against the proposed purchase and formed a competing doctor-investor group to purchase the facility. Despite his efforts, the holding company purchased all four hospitals in 2005. The physician continued speaking out publicly against the holding group and convinced a state senator to conduct public hearings on the acquisition and the quality of healthcare at the hospital. These hearings resulted in an agreement between the holding company and the chief of staff to maintain the quality of healthcare at the hospital.

In May 2005, the holding company received a default notice on one of its loans used to purchase the hospital. The physician sent an email to some of the hospital officers and medical staff alerting them to the notice, and noted a decrease in hospital admissions. The holding company then sued the chief of staff for defamation, breach of contract, and other business torts. That suit ended in favor of the physician with the holding company paying his $150,000 attorney fees.

Following the business tort suit, the CEO of the

holding company told the president of the company that he would "humble" the chief of staff. He also said he "could have [things] done to people he was displeased with." He went on to say he had two police officers on his payroll or in his pocket. The CEO told the company's president about an individual he knew who does some business that is not so legitimate. He then directed the president to draft a $10,000 contract with that individual's company to help with their website, which the president questioned, but prepared for his boss anyway.

Several days after this conversation, the chief of staff was approached by two policemen who stated he was seen brandishing a firearm in a heated road rage incident by an anonymous 911 informant. The physician consented to a search of his car, where the police found a gun and gloves. They arrested him despite his protests that he was being framed because he had just defeated the company in court. He was taken to jail, strip searched, and put in a cell that reeked of vomit. The chief of staff was released a few hours later because DNA tests did not link him to the gun or gloves. After the CEO returned from vacation, he told the president, "people don't know how powerful I am."

Almost two years later, after the president left the company, he disclosed the information about his interactions with the CEO, which prompted a suit by the chief of staff. At trial, the jury found the CEO acted within the scope of his employment, thus the holding company itself was liable for his actions. The jury awarded the chief of staff $5.7 million for infliction of emotional distress. The trial court reversed this verdict on a motion by the defense, but the appellate court reversed again in April 2015, and the physician was entitled to the full $5.7 million and his costs of the appeal.

What this means to you: This case shows that while illegitimate business practices may pay off in the short term, good business practices tend to be more sustainable than unlawful business, a principle that applies to the business of medicine as much as anywhere else. The chief of staff was concerned over the safety of his patients and acted fairly, and he was successful in multiple court proceedings. The use of unlawful intimidation is prohibited by legislation and the court systems. The CEO left a trail of bread crumbs that easily led to his involvement in the setup. Additionally, because of his intimidation of the president, as well as his failure to compensate him, the CEO found himself at the mercy of his former subordinate's testimony.

This case also illustrates the virtues of persistence and fighting for good causes. It is imperative the medical community keep in focus the priorities and purposes of the medical profession. It shows how little the holding company cared about its patients by inflicting emotional distress on the chief of staff. Patient health is always more important than earning more money or getting revenge. Along that same vein, it is important to keep the future in mind when making large business decisions like acquiring four hospitals at once. If a company spreads itself too thinly and fails to diversify, it will surely suffer, as well as those that it services.

Another important lesson to be gleaned from this case is to report before it is too late. The president of the holding company knew for two years that the CEO was involved in the framing but failed to disclose that information until he left the company. There are protections in place for employees who report wrongdoings in the workplace. It is prudent to ensure the information disclosed is actually protected, but if the president had reported earlier, he would have saved a lot of grief for the chief of staff. The president indicated he feared for his own safety, especially after incidents involving the vehicles of the chief of staff's wife and daughter. The failure to report simply served to encourage the CEO's behavior and put the president at an increased risk of harm. This also continued to put the chief of staff and his family in harm's way. There is an incentive for companies to encourage employees to report misconduct. This case shows the effect of allowing wrongdoings to fester. The cost of the chief of staff's emotional distress for the holding company would have been less had it not been overlooked for such an extended period of time.

This case shows the negative effects of conducting business in an immoral way and discourages slothful reporting of professional misconduct. Healthcare companies must maintain proper priorities. Otherwise, criminal activity motivated by greed will continue to thrive, ultimately raising costs, reducing quality, and increasing risks for both providers and patients. ■

REFERENCE

Court of Appeal of California, Fourth Appellate District, Division Three, Case Number G048413, April 30, 2015.

Botched Gallbladder Surgery Yields $900,000 Verdict

News: The Illinois Appellate Court upheld a $900,000 jury verdict in a medical malpractice suit for a man's death caused by a negligently performed gallbladder surgery. The patient's primary care physician determined the patient had gallbladder disease and referred him to a doctor for a surgical consultation. The doctor accidentally severed the patient's common bile duct rather than the cystic duct. As a result, the man suffered months of medical complications related to the incident and eventually died. The jury found for the plaintiffs, awarding them $910,742.79 in damages. The hospital appealed the verdict in September 2013, and the appeal was heard by an appellate panel on Dec. 21, 2015. The panel unanimously affirmed the lower court's decision.

Background: In 2008, a man told his primary care physician on several occasions that he had experienced heartburn, stomach and back pain, nausea, and diarrhea. The doctor determined his symptoms were caused by gallbladder disease and referred him to another doctor for a surgical consultation, at which point it was decided to remove the gallbladder. On Jan. 12, 2009, the man received preoperative clearance and underwent gallbladder surgery at a hospital.

Initially, the doctor began with a laparoscopic procedure, but found a significant amount of inflammation around the gallbladder and converted to an open procedure. After working to dissect the patient's gallbladder from the surrounding structures, the doctor cut through what he thought was the cystic duct. Unfortunately, the severed structure was the common bile duct. Immediately the doctor called in his colleague, who continued with the dissection until he was able to confirm that the common bile duct had been cut. The doctor then called a hepatobiliary specialist to attempt to repair the severed duct. The gallbladder dissection was completed, and then the hepatobiliary specialist performed a Roux-en-Y reconstruction, a procedure by which the flow of bile is rerouted through a loop of intestine. The entire surgery, including the reconstruction, lasted approximately eight hours.

Following his surgery, the patient suffered from an intermittent bile leak, which required the insertion of two drains. He was initially discharged a week after the surgery, but was readmitted the next day. He spent another month in the hospital before he was briefly admitted to a nursing and rehabilitation facility on Feb. 20. Four days later, he had to be admitted to another hospital. Toward the end of this hospitalization, he became severely septic and passed away on March 19. The doctor completed and signed the death certificate a day or two thereafter, listing "bile duct injury" as "the underlying cause, disease or injury that initiated the events resulting in death last."

On Dec. 22, 2010, the patient's wife brought a wrongful death and survival action against the doctor and the hospital. The wife then passed away, and the patient's daughter resumed the suit as a special administrator of the patient's estate. The amended complaint alleged that the doctor "[n]egligently and carelessly surgically transected" the common bile duct, "[f]ailed to perform the necessary precautionary methods to ensure a safe gallbladder removal," and "[f]ailed to call for assistance from a specialist with expertise in biliary surgery" before cutting the common bile duct. The daughter further alleged that her father died "[a]s a direct and proximate result of one or more of the foregoing negligent acts and/or omissions."

The six-day trial began on Jan. 25, 2013, with testimony from various expert and fact witnesses. One doctor described a four-step process that ensures the common bile duct is not cut in gallbladder surgeries. The jury returned a verdict on Feb. 1, 2013, in favor of the patient's estate against both the doctor and hospital jointly and severally, awarding $910,742.49 in damages. The defense moved for a judgment notwithstanding the verdict to nullify the jury verdict, but the court denied the motion.

The doctor and hospital appealed, alleging the lower court erred in allowing evidence of the doctor's actions without expert testimony proving the injury would have been avoided had the doctor completed all the steps. The Appellate Court of Illinois, in a unanimous opinion, stated, "[w]e believe the circuit court correctly viewed defendants' efforts to hold [the doctor] to a standard of absolute certainty as being akin to requiring plaintiff to prove that, but for the claimed negligence, a better result would have been obtained. This is contrary to established precedent." The appellate court upheld the jury's verdict, affirming the family's monetary award.

What this means to you: This case shows the need for taking reasonable care when transecting critical body structures. The medical malpractice cause of action is rooted in negligence. The district court in this case stated that to be successful in a medical malpractice claim, the plaintiff must prove: (1) the applicable standard of care; (2) a provider's negligent failure to comply with the applicable standard of care; and (3) a resulting injury proximately caused by the alleged negligence. Negligence can be defined analytically as when the burden is less than the product of the chances of injury multiplied by the gravity of harm. In this case, the equation was skewed because the gravity of harm was huge. One of the experts that testified for the plaintiff's side stated "everything is better than cutting the common bile duct." Because the gravity of harm is so large, it is paramount for surgeons to take care consistent with the standard of care established within the medical community.

A lesson to be learned from this case is to constantly stay up-to-date on the best practices for ensuring patients are treated safely. In this case, an expert for the plaintiff testified that a reasonably careful surgeon performing a gallbladder surgery should employ four precautionary steps to minimize the chance of misidentifying and cutting the common bile duct.

The first step is to utilize a technique called the critical view of safety (CVOS), which involves a three-part process: (1) dissection of an area called Calot's Triangle; (2) removal of the infundibulum, i.e., the bottom part of the gallbladder, from the liver; and (3) confirmation that the two structures going into the gallbladder are not heading back to the liver. The expert stated the standard of care requires a reasonably careful surgeon to try to achieve the CVOS before cutting a structure.

Second, the expert stated if the CVOS cannot be achieved, the surgeon should take alternative steps to correctly identify the common bile duct so as to avoid injuring it. One option is to perform an intraoperative cholangiogram, or IOC, a procedure in which a small hole is made in the duct and a dye agent is injected through a catheter. X-rays are then taken to assess and identify the relevant structures through real-time images. An IOC is not a risk-free procedure, but the expert confirmed that studies show the procedure is generally safe and reliable.

> NEGLIGENCE CAN BE DEFINED ANALYTICALLY AS WHEN THE BURDEN IS LESS THAN THE PRODUCT OF THE CHANCES OF INJURY MULTIPLIED BY THE GRAVITY OF HARM.

Third, if the surgeon is unable to identify the various ductile structures through the CVOS technique or an IOC, the next precautionary step he or she should take is to consult with another surgeon — ideally a hepatobiliary surgeon — for a second opinion before cutting the suspect structure.

Fourth, if the surgeon still is unable to clearly identify the anatomical structures, then he or she should perform only a partial removal of the gallbladder instead of a complete removal. The surgeon should get as much of the gallbladder off the liver as possible, divide it there, leave a drain, and (in the words of the plaintiffs' expert) "call it good." The expert acknowledged a partial removal is not ideal because a portion of the diseased gallbladder would be left behind and there would be a risk of a bile leak. However, he explained, a procedure called an endoscopic retrograde cholangiopancreatography could be performed later to resolve the possible bile leak.

These steps, if utilized, could have prevented the harm here and could prevent future injuries to patients having gallbladder surgeries.

Finally, note that this surgeon also had an opportunity to request the assistance of the hepatobiliary specialist before the common bile duct was severed. Once the surgeon realized the patient's condition prevented the procedure from being performed laparoscopically due to excessive inflammation around the gallbladder, an expert could have been brought in before proceeding further. Inflamed tissues surrounding delicate anatomical structures make visualization and dissection extremely difficult unless the surgeon has had extensive specialized training in dealing with similar cases. Additionally, though initial diagnostic testing may not have revealed the surrounding inflammation, it should have been anticipated by the surgeon as a possible complication. Expert hands, available immediately, should have been brought in before the less experienced surgeon began the dissection. ■

REFERENCE

Appellate Court of Illinois For The First District, Case Number 1-13-2927, December 23, 2015.