HEALTHCARE RISK MANAGEMENT™

THE TRUSTED SOURCE FOR LEGAL AND PATIENT SAFETY ADVICE FOR MORE THAN THREE DECADES

INSIDE

Enclosed in this issue:

DECEMBER 2015 Vol. 37, No. 12; p. 133-144

Printing 3D medical devices comes with substantial liability risk

Just a few years ago, 3D printing was a futuristic breakthrough that seemed to have endless potential for manufacturing and other industries. The future is here, and healthcare is one of the fields in which professionals are using 3D printing to create models and even surgical devices that are otherwise unavailable.

The medical community is excited about all the ways 3D printing can be incorporated into patient care, but risk managers might need to be the ones who pull back on the reins and consider the potential liability. Creating a device in-house opens up the hospital to an area of potential liability that previously affected only commercial medical device manufacturers. Normally, when a device is blamed for an adverse outcome, the hospital can direct the plaintiff to the manufacturer and escape liability, but not when you made the device yourself.

IF YOU END UP IN COURT, YOU WANT TO SHOW THAT THE PATIENT WAS WELL-INFORMED ..." — PAVEN MALHOTRA, OF KEKER & VAN NEST

Healthcare providers use 3D printing in two principle ways: either creating a 3D model that helps physicians plan and practice surgery and other procedures, or making temporary tools. Some of the tools are templates affixed to bone to guide the surgeon in shaping the patient's bone structure to accommodate an implant of standard size, or drill guides that help the surgeon place screws in the right place based on the patient's unique dimensions.

Other tools are being made in the hospital, including splints, stents, spinal cages, hip prosthetics, and artificial bone structure for repairing facial injuries or birth defects.

Hospitals that are making their

Financial Disclosure: Author Greg Freeman, Executive Editor Joy Daughtery Dickinson, 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.

MULTIPLE COPIES: Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at (866) 213-0844.

Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. Back issues, when available, are $87 each. (GST registration number R128870672.)

ACCREDITATION: AHC Media, LLC is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. This activity has been approved for 1.5 nursing contact hours using a 60-minute contact hour. Provider approved by the California Board of Registered Nursing, Provider #CEP14749, for 1.5 Contact Hours.

AHC Media designates this enduring material for a maximum of 1.5 *AMA PRA Category 1 Credits*™. Physicians should claim only credit commensurate with the extent of their participation in an activity.

Healthcare Risk Management™ is intended for risk managers, healthcare administrators, healthcare legal counsel, and physicians. This activity is valid 24 months from the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

EXECUTIVE EDITOR:
Joy Daughtery Dickinson
(404) 262-5410
joy.dickinson@AHCMedia.com
DIRECTOR OF CONTINUING EDUCATION AND EDITORIAL: Lee Landenberger.

EDITORIAL QUESTIONS
Questions or comments?
Call Editor **Greg Freeman**, (770) 998-8455.

own surgical devices are assuming the risk of their failure, says **Max Gaujean**, JD, a malpractice attorney and founding member in the White Plains, NY, office of the Brown, Gruttadaro, Gaujean & Prato law firm. In addition to the possibility of immediate failure, hospitals don't test their homemade devices for long-term wear and tear, he notes.

"Hospitals are also removing a deep pocket, namely the manufacturers, exposing themselves to enormous economic risk," Gaujean says. "Hospitals may also be assuming any risk that the doctor may expose them to since the physician may not have been trained to install the custom device."

Physicians also are exposed to the usual malpractice complaints: that they did the procedure incorrectly, that they were not properly trained to handle the surgery or the device, or that they failed to provide informed consent with regard to risks associated with the device.

Gaujean recommends that risk managers require informed consent for use of any hospital-made device. It also would be a good idea to obtain the opinion of the hospital's medical ethics board, he says.

The biggest risk from 3D printing, also known as additive manufacturing, is lack of education and unrealistic expectations by healthcare professionals, says **Adam Clark**, the founder of Tangible Solutions in Matthews, NC, a consultancy and provider of 3D printing/additive manufacturing and engineering design services.

"Sticking a printer in a hospital, and letting a doctor or nurse print stuff, is currently very risky because there is a serious knowledge gap in additive manufacturing methods, materials, and finishing processes," Clark says. "Currently levels of expectations of the technology from the general population are relatively unrealistic. Healthcare professionals are really good at what they do, taking care of people when they are sick or injured. This does not mean they are qualified to print a new device off a [3D printer] the hospital decided to buy because they got pulled into the hype."

Nevertheless, Clark says 3D printers are in hospitals and will play a bigger role in the future. Hospitals should, at least, consult with a company specializing in 3D printing and possibly partner with one in the same way hospitals outsource diagnostic or scanning services. "Education will enable an understanding of what additive manufacturing is and how it can be implemented, not just from

EXECUTIVE SUMMARY

Hospitals are adopting 3D printing for a variety of uses without fully exploring the potential risk. Creating a medical device brings substantial liability exposure.

- 3D modeling does not pose the same risks as creating a device to be used on a patient.
- Risk managers should weigh the potential risks of any 3D printing project before allowing it to proceed.
- A surgical device created in the hospital will bring product liability potential.

the user perspective, but how additive manufacturing fits into the organization from an enterprise level," Clark says. "This will help manage risk, and the technology can be exploited for the good of their patients."

Tort liability in 3D

Tort liability is a primary concern with 3D printing in healthcare, notes **Colleen T. Davies**, JD, partner with Reed Smith in San Francisco. The firm recently launched the white paper titled *3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles. (The paper is available online at http://tinyurl.com/pr8dlgr.)* If a 3D printed medical device is at issue in a lawsuit, Davies says, a key question will be who the manufacturer of the device is.

"Is it the 3D printer company? Is it the creator of the software used to make the design? Or it the surgeon? Or the hospital?" she says. "That is as of now an unresolved issue. It's not clear in the law yet, so it definitely has to be considered when assessing risk."

That question has not yet been tested in the courts, Davies says. There are many unanswered questions regarding the technology and healthcare, but it is clear that risk managers should be involved in overseeing its use in the hospital, she says. As with other technologies, there must be a process for quality control with the machine, maintenance, and supply chain, she notes.

There is a possibility that hospitals will have some protection from liability related to 3D items. State laws vary, but in general, they do not impose strict liability on hospitals for medical devices, says **Paven Malhotra**, JD, partner with the law firm of Keker & Van Nest in San Francisco. States are more concerned with commercial sellers of a product and are not likely to see the hospital in that way for 3D printed devices, he says.

"That could change if a hospital were printing these devices in bulk, using them in the hospital, and selling them as well," Malhotra explains. "That could push them over the line so that the courts see the hospital as a commercial seller. If you stay with printing the item as needed or in small batches to use in the hospital, you're unlikely to be held strictly liable."

However, courts would be likely to accept a claim of negligence, he notes. But what is negligence in 3D printing of medical devices? The practice is so new that it would be difficult to prove a standard of care or bring in expert witnesses to testify, he says. *(For more on standard of care and reimbursement issues, see the story in this issue.)*

"Hospitals should think of best practices in general and how you can apply that to 3D printing," Malhotra says. "Explain it all to the patient, everything: the risks, how new this item is, the fact that there is no liability record to draw on, and you explain the benefits as well. If you end up in court, you want to show that the patient was well-informed and you didn't hide anything about this new device."

Follow usual safeguards

Risk managers should be very cautious with 3D printing and insist on at least the same safeguards that would be required for any other item used in the hospital, says **Amy Alderfer**, JD, a products liability attorney with the law firm of Cozen O'Connor in Los Angeles. The FDA has approved about 85 3D printing products for use in healthcare, and confirming that approval for any particular device is a good starting point, she suggests.

The risk manager might have to be the one who says no to a surgeon who has printed a device and is planning to use it on a patient, Alderfer says. Just because it is created through 3D printing doesn't make it different from any other medical device in regard to ensuring safety and quality. After all, Alderfer says, you wouldn't let a surgeon use a device that he made in his garage and brought to the hospital, at least not before getting the proper clearances and quality assurances.

"If I have surgeon who announces he has this hot new item that he printed at home or on the hospital's 3D printer, I'm going to say 'Whoa!' and slow this down. There are a lot of things we need to step back and evaluate," she says. "This is always a challenge in risk management, having to temper the excitement of clinicians who are eager to do something new and innovative."

When 3D printing is used for modeling rather than with a patient, the risk manager need not apply such strict review, she says. However, the hospital should remind surgeons and others that the same approval process for medical devices still applies to 3D printing. FDA approval is available on an emergency basis for any medical device, she notes.

"Just because you have a new technology doesn't mean that you don't have any regulations or we're going to develop new regulations," Alderfer says. "The existing framework you have for ensuring that you use approved medical devices still applies here. The danger is that a surgeon will think it doesn't because this technology is so different and exciting, and not take his or her device through the approval process."

If that happens, the potential liability is huge, Alderfer says.

A plaintiff's attorney would see many avenues to pursue and many defendants.

"The hospital doesn't want to be in a position of being sued and asked how you allowed this to happen, how you let somebody make their own medical device and use it on a patient without all the appropriate safeguards," Alderfer says.

SOURCES

- **Amy Alderfer**, JD, Attorney, Cozen O'Connor, Los Angeles. Email: aalderfer@cozen.com.
- **Adam Clark**, Founder, Tangible Solutions in Matthews, NC. Telephone: (800) 393-9886.
- **Colleen T. Davies**, JD, Partner, Reed Smith, San Francisco. Email: cdavies@reedsmith.com.
- **Max Gaujean**, JD, Brown, Gruttadaro, Gaujean & Prato, White Plains, NY. Email: mgaujean@bggplaw.com.
- **Paven Malhotra**, JD, Partner, Keker & Van Nest, San Francisco. Email: pmalhotra@kvn.com. ■

Standard of care and reimbursement questioned with 3D printing

Soon there also can be a risk for hospitals that *don't* use 3D printing, says **Lisa Baird**, JD, an attorney with the law firm of Reed Smith in Los Angeles. As the technology becomes more widespread, it could become the standard of care in some circumstances to create your own model or tool, she notes.

"If you are not able to make your own, you can be said to have fallen behind the times and failing to meet the standard of care," Baird says. "This won't happen overnight, but as the best heart surgeons in the country use this 3D modeling more and more, I think we will see it become an expected part of treatment."

Reimbursement also becomes an issue with 3D printing, notes **Farah Tabibkhoei**, JD, an attorney with the law firm of Reed Smith in Los Angeles. "Reimbursement continues to be an obstacle because 3D printing is such a new technology. In order for it to be reimbursed, you have to show that it is medically necessary and provides a substantial clinical benefit," Tabibkhoei says. "While it's been said that 3D printing will shorten procedure times and offer benefits to the patient, there isn't enough long-term data to show that. So at the moment, we're seeing a lot of 3D printing used in academic medicine, where they have grant funding, but we haven't seen it be eligible for reimbursement."

SOURCES:

- **Lisa Baird**, JD, Reed Smith, Los Angeles. Telephone: (213) 457-8036. Email: lbaird@reedsmith.com.
- **Farah Tabibkhoei**, JD, Reed Smith, Los Angeles. Telephone: (213) 457-8219. Email: ftabibkhoei@reedsmith.com. ■

Disclosing medical errors to children is usually the right move

The medical community has embraced the concept of disclosing medical errors to patients promptly and honestly, but there is still some question about how to handle pediatric patients. Should you tell a child that you made a mistake? If so, how?

In a recent study involving Chicago pediatricians, nearly all of them supported disclosing errors to parents, but only about half supported disclosure to children. Among those who supported disclosure to children, most agreed that 12 years old was the age at which the patient is developmentally ready to be told about medical errors. *(An abstract of the report,published in* Academic Pediatrics, *is available online at http://1.usa.gov/1SwgYjr.)*

The study was an attempt to fill a gap in research regarding medical disclosure, says **Irini Kolaitis**, MD, an instructor in pediatric hospital-based medicine at the Ann & Robert H. Lurie Children's Hospital of Chicago. Previous research has confirmed that pediatricians support disclosure as much other medical professionals, but it has not been clear if they fully supported disclosure to children or just to parents.

"We support disclosure fully, and we have risk management and hospital administration involved," Kolaitis says. "But there is no policy at our hospital in terms of policies or general statements on when and if to talk to a pediatric patient about an error. I think that's typical of hospitals nationwide."

Kolaitis surveyed 1,200 members of the American Academy of Pediatrics and asked the doctors about one of four possible cases that only varied by patient age (16 or 9 years old) and by whether the medical error resulted in reversible or irreversible harm. The hypothetical medical error was a medication error that led to kidney damage in a chemotherapy patient, with one permanently injured and on dialysis and the other recovering.

Kolaitis and her colleagues found that 98% of respondents believed it was "very important" to disclose medical errors to parents, while only 57% had the same approach to pediatric patients. Assuming the pediatric patients were developmentally normal, the respondents indicated that medical errors could be disclosed to them at a mean age of 12.15 years old and older. They were largely in agreement that medical errors should not be discussed with patients below a mean age of 10.25 years old.

Most of those surveyed, 72%, said physicians and parents should jointly decide whether to disclose an error to pediatric patients. When disclosing an error to a young patient, 88% of respondents said the parents should be present.

"They thought it was particularly important to disclose to an older patient when it was an irreversible error, like a kid ending up on dialysis," Kolaitis explains. "If the parents asked them not to disclose, most of them would acquiesce to the parents' request, but they wouldn't lie if the patient asked them directly."

Kolaitis notes that pediatric patients know more about their illnesses than parents and health professionals think they do.

"This should be a partnership with the parents and the hospital administration as well," Kolaitis says. "The physicians clearly felt there was an age where most pediatric patients would be able to receive that information well, but it seemed there might not be a concrete rule in pediatrics. With adult patients, the consensus is clear that you disclose errors, but with pediatrics, you might have to assess each case on its merits and determine what's right."

SOURCE

- **Irini Kolaitis**, MD, Ann & Robert H. Lurie Children's Hospital of Chicago. Email: ikolaitis@luriechildrens.org.

EXECUTIVE SUMMARY

Some healthcare professionals debate whether medical errors should be disclosed to pediatric patients in the same way as they are to adults. A recent report suggests there is general acceptance of the practice for some patients.

- Most physicians surveyed thought a 12-year-old patient should be informed.
- The age of the patient will dictate how the message is delivered.
- There was nearly unanimous agreement that parents should be informed.

Do EMRs take so much time that they threaten patient safety?

Electronic medical records (EMRs) can be polarizing: Some people love them, some people hate them. However, there is concern among some healthcare professionals that there is more to the issue than personal preference. EMRs can be so time-consuming that nurses spend less time with the patient, critics say, and that change could threaten patient safety.

The burden of entering so much data in the EMR rather than caring for the patient is one reason **Teri Dreher**, RN, CCRN, iRNPA, left hospital nursing after 40 years as an intensive care nurse. She is now owner and CEO of North Shore Patient Advocates, a Chicago company that provides assistance to patients with navigating the healthcare system. The time required for documentation has long been a complaint of nurses, and Dreher notes that even 15 years ago, a nurse working a 12-hour shift would spend about two hours on documentation.

The introduction of EMRs only made the problem worse because much of the data entry is duplicative, Dreher says.

"When I left bedside nursing last year, we were tracking it and found that nurses were spending six to eight hours of a 12-hour shift doing computer work," she explains. "It's common sense to me, as a seasoned ICU nurse, that when you take doctors and nurses away from the bedside, you're not going to get safer patient care. I think that's one reason medical error rates are not getting

EXECUTIVE SUMMARY

Some healthcare professionals are concerned that electronic medical records (EMRs) require so much of a nurse's or physician's time and attention that patient safety might suffer. Others feel that the EMR can free up more time if used properly.

- The design of the EMR will affect how much time is required to use it.
- Some clinicians might not appreciate the efficiency of EMRs compared to paper records.
- Staffing ratios might be at fault when nurses complain of EMRs monopolizing their time.

significantly better."

Dreher says many of the EMRs in use at hospitals are cumbersome for nurses to use. She says, for example, that when she left her hospital last year, getting medication to a patient required 14 steps of data entry in the EMR or the drug inventory system.

"What's really happening is that nurses are just learning to override the system. It's just override, override, override, because when the patient is in pain, the nurse is caught between relieving the patient's suffering versus taking care of the computer," Dreher says. "The systems that are used now are just ridiculous. Every nurse that I know who is still working in healthcare is greatly frustrated with EMRs."

Computers distract nurses

Dreher has seen nurses neglect patient needs because they were so focused on the EMR. She recalls one incident in which she helped another experienced ICU nurse admit a lung cancer patient to the unit. The woman was to be the other nurse's patient, but Dreher helped get the patient settled while the other nurse took care of the EMR. After getting the patient set, Dreher notified the other nurse that the patient needed to be intubated. The other nurse was looking at the computer screen but said she would intubate the patient.

"I came back 15 minutes later, and she was still at the computer making sure she had all the bells and whistles covered. I walked in the patient's room, and she was turning blue. I had to call a code and have the patient resuscitated," Dreher recalls. "This was an experienced ICU nurse, but she was so consumed with making sure everything was right in the computer that she was neglecting her patient."

Not everyone agrees that EMRs monopolize nurses' time or threaten patient safety. On the contrary, EMRs can allow nurses to spend more time with the patient and patients' family members, says **Akram Alashari**, MD, a surgeon working in general surgery, surgical critical care, and trauma at Grand Strand Regional Medical Center in Myrtle Beach, SC.

Contrary to Dreher's experience, Alashari says clinicians spend less time typing in the electronic record than previously with handwritten notes. Time also is saved because the EMR means no time is spent searching for the written chart and no time spent waiting for other physicians and consultants to document in the chart. EMRs also improve care because physicians and nurses can review labs and images in the patient's room, which allows them to interact with the patient in real-time.

Most complaints about EMRs monopolizing clinicians' time make a false comparison between using an EMR and doing little or no documentation. From that perspective, EMRs do consume a lot of time. However, the real comparison must be to the non-EMR alternative, which was the voluminous paperwork of yesteryear, Alashari says. People actually are complaining about the documentation burden, not the use of EMRs, he says.

"I hear a lot of complaints about EMRs, typically that they're not spending enough face-to-face time with the patient and most of their time is face to computer," Alashari says. "But when you look at how it worked with written charts, nurses and doctors spent a great deal of time looking for the chart, waiting for someone else to finish working with the chart, and figuring out where someone put it down last."

In addition to how an EMR makes far more information available then a paper chart, Alashari notes that most people type much faster than it would take to write the same information.

"I don't see why they're saying that it's so difficult," he says. "Do we really want to go back to when you had to leave the patient's room to find the chart, stand outside while you read it because infection control doesn't want it near the patient, and spend time trying to understand the doctor's handwriting? It's really much better than it was before."

Design of system

The design of the system and how it is used in the hospital can have a significant influence on whether clinicians feel it is monopolizing their time, says **JoHannah Monk**, RN, senior delivery manager with the Buffalo, NY, office of CTG, a company that provides IT services to healthcare systems and other

industries. If the EMR simply automates what was already a bad work flow, the electronic system can increase time demands rather than making the process more efficient, Monk says.

"The EMR offers many benefits, but there are still issues that will dictate how much time your nurses spend with it. Where is the computer? Where are the meds? What are your staffing levels?" she says. "Do you have a work flow process that optimizes the nurse's time, or are you blaming the EMR for a process that also would be problematic without the EMR?"

Monk agrees with Alashari that, whatever the documentation requirements, entering data in an electronic record will always be faster than writing by hand. Some nurses also might not realize how EMRs save time, she says. For example, nurses new to the field might not appreciate how much time used to be consumed by tasks such as trying to reach a doctor because a drug order was illegible.

However, Monk also cautions that the promises of increased efficiency can tempt administrators to lower the nurse-to-patient ratio. That change can create difficulties that are blamed on the EMR when the real problem is staffing.

If nurses are complaining about the time required by an EMR, Dreher suggests that risk managers develop a task force to address the EMR's threat to patient safety and work with IT, nursing, and physicians to find solutions

"The patient is not at the center of the care model anymore. That's the computer's position now," Dreher says. "A lot of the physicians and nurses I know are just at the end of their rope."

SOURCES

- **Akram Alashari**, MD, General Surgery, Surgical Critical Care, and Trauma, Grand Strand Regional Medical Center, Myrtle Beach, SC. Telephone: (407) 617-4795. Email: akramalashari@gmail.com. Web: www.thepowerofpeakstate.com.
- **Teri Dreher**, RN, CCRN, iRNPA, Owner and CEO, North Shore Patient Advocates, Chicago. Telephone: (312) 788-2640. Email: teri@northshoren.com.
- **JoHannah Monk**, RN, Senior Delivery Manager, CTG, Buffalo, NY. Telephone: (800) 992-5350. ■

Final Stark rule still leaves uncertainty

The Centers for Medicare and Medicaid Services (CMS) has issued the final rule on the Stark law regarding kickbacks. CMS clarified some points, but left questions unanswered.

The final rule establishes two new waivers intended to accommodate accountable care organizations (ACOs), as well defining some regulatory terminology and requirements. *(The rule is available online at http://tinyurl.com/o8f8f3x.)*

The Stark law has long been a source of frustration and confusion within the healthcare industry, with its provisions widely regarded as overly complex, unwieldy, and open to differing interpretations that make compliance difficult, time-consuming, and expensive, notes **Karl Thallner**, JD, partner with the law firm of Reed Smith in Philadelphia.

CMS touted the pending changes as finally providing long-sought clarity to the regulations governing physician referrals, relaxing various technical requirements, and creating exceptions to help ease the regulatory burden for providers seeking to comply, Thallner says. "Yet with CMS now on the verge of issuing its final rules as part of its update to the Medicare Physician Fee Schedule for 2016, it appears the new rules will fail to simplify key areas of the law and it will remain, in the words of a recent federal appeals court opinion, a 'booby trap,'" Thallner says.

Thallner offers this summary of the uncertainty in key areas:

• Uncertainty over how to apply the law's requirements.

Many Stark Law exceptions require that compensation cannot "take into account" the volume or value of referrals. The recent Fourth Circuit decision in *Drakeford v. Tuomey Healthcare System* highlights the uncertainty as to how this requirement should be applied to commonly used productivity-based physician compensation methodologies.

• Risks to hospitals that employ physicians.

Many Stark Law exceptions require that an arrangement with a physician must be "commercially reasonable." Recent settlements of False Claims Act/Stark Law cases suggest that the government believes that it is commercially unreasonable for hospitals to employ physicians in situations in which the collections of professional service fees are insufficient to cover the costs. This view creates a significant risk for many hospitals because hospital-owned physician practices typically do lose money.

• Expensive settlements for

unproven allegations under the False Claims Act.

In recent years, violations of the Stark Law have been increasingly used as the basis for False Claims Act actions. The potential penalties for violating the Stark Law already are inordinately high, but when combined with the penalties available under the False Claims Act, they become catastrophic. For this reason, hospitals agree to settle these cases for millions of dollars, rather than challenge the government's interpretation of the law.

• Inhibiting efforts to improve quality and reduce healthcare costs. Fear of violation of the Stark Law impairs other priority objectives of the government.

Health reform initiatives have aimed for higher quality care delivered more efficiently by encouraging integration of providers across the continuum of care. If hospitals and physicians are reluctant to develop financial relationships that will foster collaboration for fear of violating the Stark Law, the objective of health reform will be thwarted ■

Hospital to pay $72.4 million to settle Medicare False Claims case

Tuomey Healthcare System in Sumter, SC, will pay $72.4 million to settle a $237 million judgment following the Department of Justice allegations that it illegally billed the Medicare program for services referred by physicians with whom the hospital had improper financial relationships.

In addition to the $72.4 million payment, the settlement agreement requires that Tuomey Healthcare System be sold to Palmetto Health, a multi-hospital healthcare system based in Columbia, SC, according to an announcement by Principal Deputy Assistant Attorney General **Benjamin C. Mizer**, JD, head of the Justice Department's Civil Division.

"Secret sweetheart deals between hospitals and physicians, like the ones in this case, undermine patient confidence and drive up healthcare costs for everybody, including the Medicare program and its beneficiaries," Mizer said. "This case demonstrates the United States' commitment to ensuring that doctors who refer Medicare beneficiaries to hospitals for procedures, tests, and other health services do so only because they believe the service is in the patient's best interest, and not because the physician stands to gain financially from the referral. The Department of Justice is determined to prevent the kind of abuses uncovered in this case, and we are willing to take such cases to trial to protect the integrity of the Medicare program."

Tuomey Healthcare System also will be required to retain an independent review organization to monitor any arrangements it makes with physicians or other sources of referrals for the duration of the five-year Corporate Integrity Agreement.

The judgment against Tuomey Healthcare System relates to violations of the Stark Law, which prohibits hospitals from billing Medicare for certain services (including inpatient and outpatient hospital care) that have been referred by physicians with whom the hospital has an improper financial relationship. The Stark Law includes exceptions for many common hospital-physician arrangements, but it generally requires that any payments that a hospital makes to a referring physician be at fair market value for the physician's actual services and not take into account the volume or value of the physician's referrals to the hospital.

The government argued in this case that Tuomey Healthcare leaders, fearing that the health system could lose lucrative outpatient procedure referrals to a new freestanding surgery center, entered into contracts with 19 specialist physicians that required the physicians to refer their outpatient procedures to Tuomey Healthcare and, in exchange, paid them compensation that far exceeded fair market value and included part of the money Tuomey Healthcare received from Medicare for the referred procedures. The government argued that Tuomey Healthcare ignored and suppressed warnings from one of its attorneys that the physician contracts were "risky" and raised "red flags."

On May 8, 2013, after a month-long trial, a South Carolina jury determined that the contracts violated the Stark Law. The jury also concluded that Tuomey had filed more than 21,000 false claims with Medicare. On Oct. 2, 2013, the trial court entered a judgment under the False Claims Act in favor of the United States for more than $237 million. The U.S. Court of Appeals for the Fourth Circuit affirmed the judgment on July 2, 2015.

The case arose from a lawsuit filed on Oct. 4, 2005, by Michael K. Drakeford, MD, an orthopedic

surgeon who was offered, but refused to sign, one of the illegal contracts. The lawsuit was filed under the *qui tam*, or whistleblower, provisions of the False Claims Act, which permit private individuals to sue on behalf of the government for false claims and to share in any recovery. The act allows the government to intervene and take over the action, as it did in this case. Drakeford will receive approximately $18.1 million under the settlement. *(For more on the Tuomey case, see* Healthcare Risk Management, *December 2013.)* ■

The Joint Commission cautions about temporary newborn names

If the parents have not yet decided on a baby's name, it is common at many hospitals to give the newborn a temporary name like Babyboy Smith for use in the hospital. The Joint Commission (TJC) is warning that the practice can lead to patient identification errors and should be reconsidered.

Though well-intended, the use of temporary names creates a situation in which multiple babies will have similar identifiers, and they also might have the same or similar dates of birth and gender.

"Newborns also are a unique patient population as they are unable to participate in the identification process. This unique need requires a reliable system that is hardwired among all providers to prevent error," TJC writes in a recent warning to hospitals. "An example of a typical temporary name is Babyboy Smith, using the baby's gender and the parent's last name. This naming convention is not distinct enough to prevent patient identification errors that could result in harm."

Ten sentinel events related to temporary names have been reported to the TJC since 2010. All were wrong-person surgery and resulted in circumcision being performed on the wrong patient. TJC also cites these additional errors that could occur when temporary baby names are mixed up:

- feeding a mother's expressed breast milk to the wrong infant;
- reading imaging tests or pathology specimens for the wrong patient;
- incorrect documenting of medications, vascular lines, and patient weight;
- administering blood products to the wrong patient;
- collecting lab specimens from the wrong patient.

The post in TJC's *Quick Safety* describes how one hospital experienced a 36.3% reduction in wrong-patient electronic orders by instituting a new way to temporarily name babies. The hospital uses the mother's first name, followed by the letter "s" and the baby's gender, then the parent's last name. An example would be "Judysgirl Smith" or "Amandasboy Adams."

For multiple births, the hospital adds a number in front of the name so that the babies are named "1Judysgirl Smith" and "2Judysgirl Smith," for example.

TJC also cites research from one hospital that determined the causes of wrong-patient errors in its neonatal intensive care unit. The hospital traced the errors to similar-appearing medical record numbers, identical surnames, and similar-sounding names.

To lower the risk of misidentification, TJC recommends that hospitals stop using Babyboy or Babygirl as any part of the temporary name. Hospitals should adopt a method of assigning temporary names that results in more distinct names and change the baby's medical record as soon as the parents provide the actual name.

The *Quick Safety* article is available online at http://tinyurl.com/o72xwx8. ■

Medication errors happen in about half of surgeries

A recent study indicates that medication errors occur in about half of all surgeries, possibly because patient safety policies and procedures are relaxed in the operating room.

The results came from an analysis of Massachusetts General Hospital's initiative to measure and prevent drug errors during surgery. The study in *Anesthesiology* indicates that a medication error or adverse drug event was documented in 124 of 277 surgeries, which is about half. Of the 3,675 medication administrations during the procedures, 193 medication errors and adverse drug events were recorded, the researchers from Harvard University in Boston

found. That number works out to be about 5% of all medication administrations in surgery.

The mistakes included drug labeling errors, incorrect dosing, drug documentation mistakes, and/or failing to properly treat changes in a patient's vital signs during surgery.

Many of the errors occurred because common patient safety policies and procedures were loosened or bypassed in the surgical environment, the researchers suggest. Surgical teams often feel justified in not following all safety procedures when fast-moving events and changing circumstances require quick decisions and immediate action, they concluded.

Two-thirds of the drug errors were categorized as serious, 2% were considered life-threatening, and the rest were considered significant. Eighty percent of the errors were considered preventable. *(An abstract of the study is available online at http://tinyurl.com/odsz6q6.)* ■

Whistleblower revealed in $70 million fraud case

Federal officials have revealed the identity of a Fort Lauderdale, FL, orthopedic surgeon who blew the whistle on a hospital system that ended up paying nearly $70 million to settle charges of healthcare fraud.

Michael Reilly, MD, an orthopedic surgeon in private practice, filed suit in April 2010 claiming Broward Health was guilty of illegal physician kickbacks, complicit hospital administrators, and negligent financial oversight. Reilly issued a statement saying he felt vindicated and that "[s]omeone had to stop this machine." He will receive $12 million from the financial recovery.

Reilly first raised concerns about improper physician payments to the hospital's board of directors and administrators in 2003. His lawsuit claimed that Broward Health administrators awarded employment contracts to a group of top physicians, including cardiologists and other specialists, that paid the doctors more than fair market value based on their ability to increase patient referrals to the hospital system, in violation of federal law.

Physicians also were penalized for referring uninsured patients, Reilly claimed. Broward Health, which admitted no wrongdoing in the agreement, issued a written statement noting that new leadership had put the federal investigation behind the $1 billion-a-year healthcare system, which includes four acute care hospitals, numerous outpatient clinics, and other medical facilities throughout the county. *(More information is available online at http://tinyurl.com/opv827g.)* ■

Boston hospital pays record amount for drug diversion allegations

In the largest settlement of its kind involving allegations of drug diversion at a hospital, Massachusetts General Hospital (MGH) in Boston has agreed to pay the United States $2.3 million to resolve allegations that lax controls enabled MGH employees to divert controlled substances for personal use. MGH voluntarily disclosed the diversion.

MGH also has agreed to implement a comprehensive corrective action plan to address future diversions, U.S. Attorney **Carmen M. Ortiz**, JD, announced. "Under the law, hospitals like MGH have a special responsibility to ensure that controlled substances are used for patient care and are not diverted for non-medical uses," Ortiz said.

In 2013, an investigation was launched after MGH disclosed to the Drug Enforcement Administration (DEA) that two of its nurses had stolen large volumes of controlled substances. The two nurses stole nearly 16,000 pills, mostly oxycodone. Both nurses stole from automated dispensing machines.

DEA's ensuing audit of MGH's controlled substances revealed count discrepancies totaling more than

COMING IN FUTURE MONTHS

- Addressing LGBT concerns
- Immigrants and false identification
- Liability risks from concurrent surgeries
- Lawsuits from delayed triage

20,000 pills, missing or incomplete medication inventories, and hundreds of missing drug records.

MGH cooperated with the DEA's investigation and subsequently disclosed additional violations of the Controlled Substances Act (CSA). Specifically, MGH disclosed the following:

- a pediatric nurse with a 12-year substance abuse problem had injected himself with Dilaudid at work;
- a physician had prescribed controlled substances for patients without seeing them and without maintaining medical records;
- several nurses were able to divert prescription drugs for many years without being detected;
- medical staff had failed to properly secure controlled substances and even had brought them to lunch on occasion.

The corrective action plan that MGH accepted includes the establishment of an internal drug diversion prevention team; the creation of a full-time drug diversion compliance officer position; mandatory training of all staff with access to controlled substances, including on how to identify the signs and symptoms of substance abuse; enhanced diversion monitoring by supervisors and management; annual external audits to ensure compliance with the CSA; and increased physical controls of controlled substances, including limiting and monitoring access to automated dispensing machines through fingerprint identification. ■

Hospitals sued for excessive fees to obtain medical records

Two plaintiffs are suing two Washington, DC, hospitals for what they say are excessive and illegal charges for providing copies of their electronic medical records (EMRs).

The lawsuit accuses MedStar Georgetown University Hospital and George Washington University Hospital of violating local consumer protection laws, according to the *Washington Business Journal*. The patients say the hospitals tried to charge them hundreds, and in at least one case, thousands of dollars for copies of the EMRs. *(The full story is available at http://tinyurl.com/p3ge39j.)*

The potential liability could increase if the court grants class-action status, which the plaintiffs are seeking on behalf of all patients who obtained medical records from the hospitals.

The plaintiffs sought medical records from MedStar Georgetown, and a third-party contractor responded with bills for $1,168 and $1,559, according to the lawsuit. The contractor explained that the charges were based on a base fee of $22.88, plus 76 cents per-page copying fees, and a shipping fee of $16.38. The invoices explained that the contractor provides only paper copies of the EMR, rather than transferring it electronically or making a CD.

When the plaintiffs complained, MedStar Georgetown directed them to an online portal for electronic copies of records. However, that portal requires the patient to pay per-page fees and a membership fee to store the records electronically, the lawsuit claims.

The plaintiffs received their records electronically, but one was charged the 76 cents per page for a paper copy, plus other fees, for a total of $2,481. The other plaintiff was charged 49 cents per page, for a total of $655. The lawsuit notes that, in the HITECH Act, the Department of Health and Human Services (HHS) says a "covered entity may impose a reasonable, cost-based fee," providing that the fee is based on labor, supplies, and postage. HHS stated that the rule applies to paper and electronic copies. Providers are specifically prohibited from charging a fee for paper records when the patient has requested an electronic record. Both plaintiffs requested electronic records.

Furthermore, the HITECH Act says that, "With respect to electronic copies, we asserted that a reasonable cost-based fee includes costs attributable to the labor involved to review the access request and to produce the electronic copy, which we expected would be negligible." ■

CNE OBJECTIVES

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

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

HEALTHCARE RISK MANAGEMENT™

CNE INSTRUCTIONS

To earn credit for this activity, please follow these instructions:
1. Read and study the activity, using the provided references for further research.

2. Scan the QR code to the right or log on to the AHCMedia.com site to take a post-test. Go to "My Account" to view your available CE activities. First-time users will have to register on the site using the subscriber number printed on their mailing label, invoice, or renewal notice.

3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed.

4. After completing the test, your browser will be automatically directed to the activity evaluation form, which you submit online.

5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

CNE/CME QUESTIONS

1. **According to Colleen T. Davies, JD, partner with Reed Smith in San Francisco, in regard to tort liability, who would be considered the manufacturer of a device 3D printed in a hospital?**

   A. The 3D printer company
   B. The creator of the software used to make the design
   C. The hospital
   D. It is, as of now, an unresolved issue.

2. **In a recent study published in *Academic Pediatrics* regarding disclosing errors in pediatrics, what was the consensus of the pediatricians surveyed?**

   A. Most physicians surveyed thought a 12-year-old or older patient should be informed.
   B. Most physicians thought a patient should not be informed until the age of 16.
   C. Most physicians thought pediatric patients should never be informed of errors.
   D. Most physicians thought all pediatric patients should be informed of errors.

3. **According to Teri Dreher, RN, CCRN, iRNPA, how can electronic medical records threaten patient safety?**

   A. Drug dosages can be changed unintentionally.
   B. Patient identification can be comingled.
   C. Nurses are distracted by the time required to use the electronic medical record.
   D. Incorrect standing orders are repeated.

4. **In the study published in *Anesthesiology* finding that half of all surgeries include medication errors, what did the authors conclude was one likely cause?**

   A. Surgical teams often feel justified in not following all safety procedures when fast-moving events and changing circumstances require quick decisions and immediate action.
   B. Some patient safety policies are outdated.
   C. Medication dispensing systems can make mistakes.
   D. Surgical teams are distracted by too many alarms.

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

State malpractice cap shelters healthcare facility from paying $3.5 million of $7.5 million jury award

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

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

David Vassalli*, 2016 JD Candidate*
Pepperdine University School of Law
Malibu, CA

News: In 2010, a woman had a section of her colon removed and believed there was a cancerous mass on the removed section. The remainder of her colon was stitched together by a surgeon at a medical center. The woman became increasingly ill over the next couple of months and received follow-up care from a physician at the same healthcare facility where the surgeon performed the original procedure. The woman underwent multiple surgeries and tests in an effort to find the source of the infection, with no success. Four months after the initial surgery, a colonoscopy revealed her colon was leaking where it had been stitched together. This leaking was causing damage to the liver, internal bleeding, and pain for the woman. She sued the healthcare facility for the conduct of its staff, particularly the botched surgery by the surgeon and the poor follow-up care by the other physician. The jury found both physicians acted negligently and awarded the woman $7.5 million in damages against the healthcare facility, which was responsible for the actions of the physicians. The damages consisted of $4 million in non-economic damages for pain and suffering, disfigurement, and permanent injury; $3.24 million for medical expenses and loss of income; and $300,000 for her husband's loss of consortium claim. However, state law caps non-economic damages at $500,000 unless the physician was grossly negligent or reckless. The jury considered the steps taken by the physicians, including the warning of the risks involved with the procedure, and decided the physicians were not *grossly* negligent or reckless. As such, the healthcare facility's liability was reduced from $7.5 million to $4 million.

THE JURY CONSIDERED THE STEPS TAKEN BY THE PHYSICIANS ... AND DECIDED THE PHYSICIANS WERE NOT *GROSSLY* NEGLIGENT OR RECKLESS.

Background: In June 2010, a woman with concerns of colon cancer had a portion of her colon removed and the remainder stitched together by a surgeon. The woman then received follow-up care with a different physician in the same facility where she underwent the initial procedure. In the following four months, the woman became increasingly ill, suffered kidney failure, and had three surgeries to find the source of the problem. In October 2010, four months after the initial surgery, a colonoscopy revealed a tear and leakage where the colon had been reattached. A corrective surgery was successfully performed by a different hospital, but the woman claims she still suffers pain and will require more treatment. The woman sued the original healthcare facility for the negligence of the surgeon who performed the surgery and the physician who provided her postoperative care. The

Financial Disclosure: Author Greg Freeman, Executive Editor Joy Daughtery Dickinson, 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. Damian Capozzola, Jamie Terrence, and David Vassalli, co-authors, have no relevant relationships to disclose.

healthcare facility maintained that the surgery was performed correctly, the postoperative care was appropriate, and the woman was informed of the risks and benefits of the procedure.

The jury found the surgeon and other physician negligent and found the healthcare facility liable for the $7.5 million in damages to the woman. The jury awarded the woman $4 million in non-economic damages, particularly for pain and suffering, disfigurement, and permanent injury; $3.24 million for medical expenses and loss of income; and $300,000 for her husband's loss of consortium claim.

However, North Carolina, the state where this case was heard, has a medical malpractice cap on non-economic damages, such as pain and suffering, disfigurement, and permanent injury. The cap restricts the amount a patient can receive to $500,000, unless the physician was *grossly* negligent or reckless.

The jury was not made aware that the amount of compensation the woman ultimately receives is dependent on the manner in which they concluded the physicians acted. The jury considered the evidence and decided the physicians were negligent but not grossly negligent or reckless. As such, the non-economic damages portion of the jury award was reduced from $4 million to $500,000, which lowered the healthcare facility's total liability from $7.5 million to $4 million.

What this means to you: This case illustrates the ability of medical malpractice liability caps to shelter physicians and facilities from certain types of liability. Just more than half of the states in the United States have some form of medical malpractice cap that limits the amount of non-economic damages a plaintiff can receive. A handful of states have "umbrella" caps, which limit the total amount of any type of damages the plaintiff can receive. The caps placed on damages vary from a $250,000 cap on non-economic damages in California, to a $750,000 cap on non-economic damages in Wisconsin, and an overall cap of $2 million on all damages in Virginia.

Work closely with qualified counsel in your state concerning these issues, because the issue of medical malpractice caps is evolving constantly. For example, in 2014, California voters voted down Proposition 46, which would have raised the cap on non-economic damages from $250,000 to $1.1 million. While the Proposition was voted down by a more than two-thirds vote, the $250,000 limit on non-economic damages still is being fought in the court system. The Supreme Court of California has twice refused to hear appeals on the cap this year, which signifies that the $250,000 cap will remain in place. Whether a physician or healthcare facility is sheltered by a medical malpractice cap on certain types of damages, and to what extent, varies greatly from state to state, and those in the medical practice should be aware of the current medical malpractice caps and how they work in their respective states.

> ... THE ISSUE OF MEDICAL MALPRACTICE CAPS IS EVOLVING CONSTANTLY.

With respect to how the state's medical malpractice cap on damages operates, this case illustrates how the conduct of the physician can greatly affect the overall outcome as to the amount of the damages that were awarded against the healthcare facility and must be paid.

In North Carolina, the patient is limited to $500,000 in non-economic damages, but this cap is removed if the jury finds the conduct leading to liability was grossly negligent or reckless. It is explained to the jury that negligence is a departure from what a reasonable physician who was similarly situated would have done, and that recklessness and gross negligence occurs when a physician has acted with an utter lack of concern for the patient's safety or acted in disregard of a known risk to the patient. However, the jury was not informed about the cap on damages or that its application is reliant on their determination of the manner in which the physician acted, which is typical.

In this case, the jury analyzed the conduct of the healthcare facility's staff and determined they were only negligent, which reduced the facility's liability by $3.5 million. Bearing this difference in mind, prudent physicians will take steps that ensure they can show they were aware of risks, took steps to mitigate known risks, and made an effort to act with the patient's safety in mind. These steps are particularly relevant when treating patients who are having difficulties and also applies to conduct after the treatment is administered. A jury hearing that the physician was cordial, worked hard to assist the patient, and continues to treat the patient, which is what occurred in this case, is more likely to find that a physician was only negligent

and not reckless or grossly negligent. As such, a physician treating a patient, and even a physician being concurrently sued by a patient, should remain acting in the patient's best interest and document acts which demonstrate that conduct.

It also is prudent to carefully document the physician's effort to obtain informed consent from the patient. This includes keeping a record of not only what was discussed with the patient, including risks, benefits, alternative treatments, recovery time, etc., but also acknowledgement that the patient understands and accepts the risks and benefits. This goal can be achieved by asking the patient to repeat back information discussed and by having a family member present during the discussion to reinforce details with the patient later. This step not only assures the physician that the patient is making an informed choice, but it also displays to the jury that the physician is truly concerned about the welfare of the patient.

REFERENCE

Cumberland County Superior Court, North Carolina, Case Number 13-CVS-3475 (Sept. 30, 2015). ■

Failure to diagnose cervical cancer leads to $9.6 million liability for medical center

News: In 2011, a 61-year-old woman was informed she had stage 3 cervical cancer. She was told this news at the same medical center from which she had received her last three yearly vaginal examinations. In each of her prior three examinations, the woman complained of pain, but she was informed her Pap smears were negative for cancer. The slides that were produced from her last three Pap smears were examined by the same technician each time at the medical center. The pain that the woman had been experiencing in her vaginal area for years worsened, and she returned to the hospital a few months after the third time she was told she had no signs of cervical cancer. She saw a different gynecologist at the medical center this time who found the woman had stage 3 cervical cancer, which the woman's prior Pap smears indicated she had been suffering from for the past three years.

Experts testified that her likelihood of a complete recovery went from 95% to 50% because of the three-year delayed diagnosis. However, the woman subsequently went through chemotherapy and numerous surgeries to treat her cervical cancer, which was in remission when she sued the medical center. She sued the medical center for the negligence of her gynecologist and the technician who incorrectly read her test results. The gynecologist later was dropped from the suit, but the jury found the hospital liable for $9.6 million for the technician misreading the test results and failing to diagnose the woman's cervical cancer. The award included $818,000 for past medical costs, $818,000 for future medical costs, $5 million for pain and suffering, $1 million for permanent impairment, and $2 million for her husband's loss of consortium.

Background: In 2009, 2010, and 2011, a woman received her regularly scheduled vaginal examinations with her gynecologist. Each time the woman was examined, she complained of pain in her vaginal area. A technician at the same medical center was tasked with examining the Pap smear each year she had been examined. The technician indicated that, despite the woman's pain and the gynecologist's report that reflected the pain, she was cancer-free. A few months after her third examination in 2011, the woman returned to the medical center and complained that her pain was worsening. Due to her gynecologist being unavailable, another physician examined the woman and, after further examination and testing, informed her that she had stage 3 cervical cancer. It also was determined that she had cervical cancer for the past three years, and the slides and scans from her Pap smears indicated this cancer was present in all of her past examinations.

The woman had to undergo chemotherapy and numerous surgeries, and she spent many weeks in the hospital. The treatment was successful, and the woman's cancer has been in remission since 2012. However, she still suffers from loss of brain function due to the chemotherapy, loss of blood flow to the small bowel, and chronic pain and fatigue. Also, she must use a colostomy bag. The woman filed a lawsuit against the medical center for the negligent conduct of its gynecologist and technician. The gynecologist later was dropped from the lawsuit, and the lawsuit focused on the negligent conduct of the technician who failed to diagnose the cervical cancer. The woman's attorney had another physician

look at the slides, and the physician determined they all showed signs of cancer, starting with stage 1 cervical cancer in 2009. As such, the woman particularly alleged the failure to diagnose the cervical cancer for three years caused her chance of a complete recovery to drop from 95% to 50%, as well as causing the need for the medical treatment she received, the medical treatment she will have to receive, and her current poor health.

Despite the woman being cancer-free from 2012 to the time of her trial in 2015, the jury deliberated for just more than one hour before holding the medical center liable for $9.6 million. The jury awarded $818,000 for past medical costs, $818,000 for future medical costs, $5 million for the woman's pain and suffering, $1 million for permanent impairment, and $2 million for her husband's loss of consortium.

What this means to you: This case shows the need of all staff members to remain diligent when dealing with routine procedures. The failure to remain diligent can be seen in this case from the technician as well as the gynecologist. The technician simply failed to detect signs of cervical cancer on three occasions. With a diagnosis as consequential as cancer, physicians and supporting staff must put in their due diligence when reviewing test results for it. Not only can the patient suffer greatly from such serious test results not being thoroughly examined, but the physician or staff will be harshly judged by jury members who likely fear something similar could happen to them. This concern of the jury was illustrated by the jury taking just 75 minutes to decide the medical center should pay nearly $10 million to the woman and her husband for not detecting the cancer earlier when a proper reviewing of the test results would have done so. Given the high cost to the patient, hospital, and the staff at times, the results of routine tests for serious ailments should be carefully examined.

Another lesson that can be learned from this case is the need to listen and give consideration to the patient's expressed symptoms. In this case, the gynecologist eventually was dropped before the case went to trial. However, the gynecologist's patient was diagnosed with stage 3 cancer, and the medical center where he works lost a large lawsuit. Had the woman's three years of complaining about pain in her vaginal area, which the woman claims was so bad she could not sit down at times, elicited further inquiry into her test results by her gynecologist, the cervical cancer could have been discovered at an earlier stage, and the hospital could have avoided significant liability. Furthermore, learning that the test results were negligently misread, even though the woman was repeatedly complaining of pain in the region that was being tested, likely will lead members of the jury to believe the patient's concerns were being ignored. It likely will lead them to a sympathetic view for the patient, who is arguably doing everything the patient can to have something that is concerning them treated.

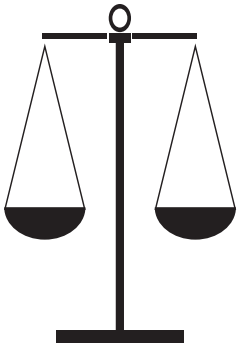
> ... THE RESULTS OF ROUTINE TESTS FOR SERIOUS AILMENTS SHOULD BE CAREFULLY EXAMINED.

Moreover, in this case a pathologist, which is a physician expert in recognizing cancerous cells in human tissue, should have been consulted to review the slides. In fact, a technician, no matter how well trained, is usually not licensed to make a diagnosis. Technicians collect and report data to a licensed independent practitioner, who proceeds to make a diagnosis based on the data. By law, human tissue removed during a surgical procedure is sent to a pathology laboratory where technicians prepare the tissue to be sliced thin enough to enable visualization of individual cells when viewed under a microscope. The final review should be made by a pathologist.

Too often, technicians document the presence or absence of disease when assisting physicians such as pathologists, as well as radiologists who also review countless results. This practice is dangerous, especially if the physician comes to rely too strongly on the technician's opinion. In this case, the treating physician should have confirmed the negative test result with the pathologist when the woman returned with complaints of continued pain. In sum, an additional step or two by a physician who is dealing with a patient consistently complaining of a symptom could result in better care for the patient and shelter the medical center and possibly the physician from liability.

REFERENCE

Androscoggin County Superior Court, Maine, Case Number CV-12114 (May 19, 2015). ■



HEALTHCARE RISK MANAGEMENT™

2015 Index

When looking for information on a specific topic, back issues of Healthcare Risk Management *newsletter, published by AHC Media, might be useful. If you haven't activated your online subscription so that you can access the newsletter archives through the company web site, go to www.AHCMedia.com and click on "Register" at the top of the page. Or contact our customer service department at (800) 688-2421. E-mail: customerservice@AHCMedia.com.*