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INSIDE

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Patients Leaving Against Medical Advice Create Liability Risk

Patients who leave against medical advice (AMA) create dilemmas for physicians and staff who want to provide the best care possible, and they pose major liability risks and require extra attention.

Healthcare organizations must have policies and procedures in place that formalize how clinicians respond to a patient refusal, including careful documentation processes and follow-up.

AMA actually can involve several different scenarios, and each requires a different sort of planning and response, notes **Kevin Klauer**, DO, EJD, FACEP, chief medical officer for hospital-based services and the chief risk officer for Knoxville, TN-based TeamHealth.

> HEALTHCARE ORGANIZATIONS MUST HAVE POLICIES AND PROCEDURES IN PLACE THAT FORMALIZE HOW CLINICIANS RESPOND TO A PATIENT REFUSAL.

The scenario that comes to mind first for most people is one in which the patient has been seen by a clinician and then refuses further care or certain types of care, he says. In this case, there has been an interaction with the physician or other clinician and there is the opportunity to counsel the patient about the possible consequences of refusing care.

The focus in that situation would be on educating the patient about why care is necessary, trying to learn why the patient is refusing, and trying to address those concerns, he says.

"But often, particularly in emergency medicine, you also have people who have gone through triage, and maybe tests have been ordered, but then the person leaves without saying a word to anyone,"

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Klauer says. "There is no informed refusal. They just leave."

Once a patient is examined beyond triage and tests are ordered, a departure at that point might be classified as left without completing treatment (LWCT), Klauer notes.

There also are patients who have been through triage, but no tests have been ordered and no formal examination has occurred. These patients are usually categorized as left without being seen (LWBS), but Klauer points out that they interacted with the hospital.

"They haven't been seen yet, but the facility has touched them. They signed in and then they decided to leave," Klauer says. "All of these can be considered AMA, but they are very different scenarios that involve a range of responsibilities, obligations, and potential for liability or other unfortunate results."

Within each of those types of AMA, there may be further breakdowns in terms of why the person is leaving, he notes. The patient may not want any care of any kind, or the refusal may be more limited — refusing the particular type of care being offered, for instance, but still willing to be treated. The reasons for refusing also may be wide-ranging, everything from worries about the cost to fear about pain or dying, or dislike of being touched, shots, surgery, or drugs.

"It really is more complex than some people give this discussion credit for," Klauer says. "Those complexities need to be considered because they all need to be addressed differently."

Cannot Write Patient Off

When patients leave without telling anyone, the hospital and clinicians do not have an opportunity to intervene in real time and obtain any signed acknowledgment that they refused care. But that doesn't mean there is no further obligation or risk of liability, Klauer says.

"The tendency in a busy facility is to say that person left, so OK, let's move on to the next person who does want our care. It shouldn't stop there," Klauer says.

There should be a formal process for two things, Klauer says. First, the hospital must reconcile any outstanding diagnostics, because if any tests were ordered, the hospital is still responsible for checking the results to be sure nothing serious was identified, he says. If so, the patient must be contacted and informed.

Klauer recalls a patient from several years ago who presented with chest pains, and an ECG was

EXECUTIVE SUMMARY

Patients who refuse care and leave against medical advice pose significant liability risks to hospitals and other providers. There must be a protocol in place for addressing patients who wish to leave, and following up afterward.

- Avoid confrontations and respect a patient's right to refuse.
- Offer alternatives to the care being refused.
- Carefully document attempts to contact a patient who has left, including unsuccessful efforts.

performed at triage. The physician had not yet seen the patient, but the patient decided to leave. The abnormal ECG results were conveyed to the physician and patient, who followed up at a different facility the next day. That is the proper procedure, he says.

"Sometimes the staff gets the results back and since the patient is gone already, they see no reason to pass them on to the physician. Those positive test results just fall by the wayside," Klauer says. "There must be a protocol that says all test results are provided to the physician, who must act to notify patients about abnormal results even if they are no longer present at the facility."

At some hospitals, the staff removes AMA patients from the tracking board and the electronic tracking system once they leave the facility. This is bad practice, Klauer says.

"It's out of sight, out of mind. No one is aware that there are outstanding diagnostics for this patient, and no one is responsible for this patient anymore," Klauer says. "My recommendation to risk managers is that you have a policy in place that no one can be removed from the tracking boards or electronic records until all outstanding diagnostics have bene reconciled. That is a critical action item to avoid the failure to follow up on results for people who leave before completing treatment."

Reach Out After AMA

Second, the hospital must reach out to people who left and invite them to come back for care, Klauer says. The degree to which you try to convince them might vary according to what is known about the patient's health and how much intervention already took place.

"Those efforts will be greater for those who had care initiated already, and they certainly will be greater when you have a positive result. There have been more cases than I can count where the patient initiated care [and] then decided to leave, and the test results came back positive," Klauer says. "Those are the cases that are hardest to intervene in, because they're not in front of you anymore, giving you a chance to convince them about the right course of action. You have to do due diligence in trying to find them, and with some patients that is not a simple task."

> "IF A PATIENT IS DIFFICULT, ANGRY, AND UPSET, THE PATIENT CAN STILL HAVE THE MEDICAL CAPACITY TO CONSENT AND REFUSE."

Documentation is especially important when trying to contact patients who left AMA without discussing the matter or signing forms acknowledging their refusal of care, Klauer notes. Be sure to document every instance of trying to locate and contact the patient, including unsuccessful attempts.

Be specific, noting that someone called a certain phone number or sent an email to a specific address, and where you obtained that information. Note the result, such as the number being invalid or no one answering. If leaving a message on voicemail or talking to the patient, document what was said.

"What you often see in the record is only documentation of when the patient ultimately was contacted. That might be a day or two later, but in fact there might have been four or five attempts before that," Klauer says. "Those attempts are very important to show you were trying to do the right thing for the patient. If the final discussion is the only one documented, it looks like you waited a long time. Or if there was no successful contact and nothing is documented, it looks like there was no effort at all to contact the patient."

Avoid Confrontations

Even when the patient voices an intention to leave AMA but still is present, the physician and staff can face significant challenges, Klauer says. This can easily develop into a hostile confrontation, with well-meaning clinicians insisting the patient accept treatment or demeaning the patient's choice to refuse, while the patient gets angry and perceives his or her rights are not being respected. It should never escalate to that, Klauer says.

"If a patient is difficult, angry, and upset, the patient can still have the medical capacity to consent and refuse. If they know what day it is, who they are, they understand the risks and benefits of what you're offering and alternatives, they can leave. It is their right to leave," he says.

"If they will allow you to have a conversation prior to leaving so that you might convince them otherwise, all the better. But you can't detain a patient to have that conversation, unless you feel they do not have

the medical capacity for informed consent and refusal."

Klauer points out the informed consent documents also cover informed refusal. Whether someone wants to consent to treatment or refuse it, the ideal procedure is to document that decision in the same way, he says.

"If someone doesn't want to be treated for chest pain, and you are worried and think they need a diagnostic evaluation for that chest pain, you should offer them the opportunity to discuss it, and talk about alternatives like not being admitted but following up with your own physician tomorrow," Klauer says. "But you clearly state that our recommendation is to admit you because that is the best plan. Once the patient understands that and says, for whatever reason, that he or she doesn't want that plan, you must respect that decision."

Don't Show Patients the Door

However, that does not mean abruptly ceasing all treatment. Klauer notes that, too often, physicians or administrators grow frustrated and take the refusal personally, responding with an almost spiteful cessation of care. They may say, "Fine, if you don't want to be admitted, we'll just send you home," and then expedite getting the person outside the facility.

That is the wrong response, Klauer says. The patient's decision to refuse the best plan of care must be respected, but the physician still can suggest a second best plan.

"'If you don't want our recommended care, can I follow up with your cardiologist tomorrow? Can I do X, Y, and Z with your treatment plan as long as I still discharge you? I'll give you the same care I would give anyone else in this situation, but modified to what you want,'" Klauer says. "Even when patients don't want the plan you recommend, they are still entitled to care."

One of the most important things for clinicians to remember with AMA patients is to state that they are welcome to return for care, Klauer says. Actively refute any impression that patients have acted badly or made themselves unwelcome at the facility because they refuse care, he says.

"It doesn't matter if the patient has been unpleasant in refusing care — your obligation is still to tell that patient he or she is welcome to come back at any time for further care," he says. "There have been many, many malpractice cases where the patients said they didn't think they were welcome and didn't think they could come back, particularly when it was some negative interaction when they refused care."

Failure to properly handle AMA patients brings significant liability risk, Klauer says. The basis for a malpractice lawsuit is an unhappy patient with a bad outcome, the result of many AMA encounters, he says.

"People who decided to present to a hospital and then decided to leave, all too often, did so because their expectations were not met or they had some kind of negative interaction, like a delay in care, that made them change their mind. They left unhappy," Klauer says. "If they left unhappy, without a diagnosis and maybe with unresolved tests results, the consequences can be devastating for the patient and the hospital."

Klauer notes that in such litigation juries will resist any implication that the resulting injury is the patient's fault for leaving. The clinicians who offered care may feel strongly that they did their best and any poor outcome is strictly the patient's fault for refusing what was offered, but a jury is likely see the hospital and physician as having a greater responsibility than an individual who may not have understood the implications of that decision.

That makes it imperative to handle AMA patients carefully, going beyond what might at first seem necessary for someone refusing care, Klauer says.

"It is very, very difficult to convince a jury of laypeople that it was the patient's fault, and of course you would never say in those terms anyway," Klauer says. "Trying to convince them that it was anyone's fault but the hospital will be an uphill battle — very challenging."

AMA Form Not Enough

Even when clinicians and administrators do their best to counsel a patient who wishes to leave AMA and have signed documents acknowledging that exchange, the patient sometimes still will sue the hospital, says **Howard M. Merkrebs**, JD, an attorney with the Rivkin Radler law firm in Uniondale, NY.

"The form in and of itself does not prevent a lawsuit. The lawsuit would not be dismissed on a motion of summary judgment by the hospital just because the patient signed the form," he says. "If that were the case, there would never be any lawsuits in which the hospital has a signed form, and there certainly are."

That does not negate the value of those documents, but they should not be the sum total of the hospital's evidence showing efforts to provide care.

"The nurse can't just say, 'If you want to leave, here's a form. Sign it

and you can leave,'" Merkrebs says. "That's a problem."

As with any medical malpractice case, the best way to avoid liability is with documentation, Merkrebs says. That documentation can show that you did everything in your power to inform the patient and offer the best care available, and that it was the patient's decision to leave. The patient may still sue, but that documentation is then your best defense, he says.

Establishing the patient's decision-making capacity is a crucial element in the process, he says. If the physician suspects the patient is not legally competent to make a decision about accepting care, it may be appropriate to call in a psychiatrist for a consult, he says.

The documentation also should detail the discussion with the patient regarding potential risks from leaving AMA, Merkrebs says. Do not rely on a form's general comment that "risks of leaving were discussed with the patient," he says.

"The chart should reflect what was told to the patient about exactly what could happen if he or she leaves the hospital without the care you're recommending," he says. "If there are family members present, use them to try to convince the patient to stay and document that you made that effort."

The biggest liability risk is posed in situations in which the healthcare professionals have an opportunity to explain the risks of leaving AMA, Merkrebs says. When a patient elopes without warning, it will be harder to prove that the hospital was negligent, he says.

"The hospital or medical facility is less likely to have liability in that situation. It is not up to the hospital to have a security guard standing at the bedside, preventing the person from leaving," he says. "That would be too high a bar. A hospital has an obligation to keep an eye on people, but not an obligation to have a security guard on every hallway making sure nobody pulls out an IV and walks out the door." ■

SOURCES

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Defending AMA Cases Costs Average of $400K

The number of patients who sue after leaving AMA is not clear, and hospitals can prevail when they have proper documentation, notes **Nicole Greene**, associate vice president for professional liability with liability insurer Burns & Wilcox in Farmington Hills, MI.

"Regardless of this, the hospitals still incurred significant defense costs through the litigating of these allegations, which in turn allows the hospital's reputation to be subject to scrutiny," she says. "Average defense costs for medical malpractice are approximately $400,000."

Three of the top five reasons for hospitalization among AMA stays were for mental health and substance abuse conditions, Green notes from research by the Agency for Healthcare Research and Quality. Patients hospitalized for alcohol- and substance-related disorders were 11.6 and 10.8 times more likely, respectively, to leave the hospital AMA than other patients.

Compared with patients discharged conventionally, readmission rates for patients discharged against medical advice are 20-40% higher, and their adjusted relative risk of 30-day mortality may be 10% higher, one study found. *(An abstract of that study is available online at: https://bit.ly/2MH0gkK.)*

In addition, patients who leave AMA tend to have an increased risk of bad medical outcomes, she says. A recent study looked at 1.9 million adult admissions and discharges over almost 20 years and found that the odds of death within 90 days were 2.5 times higher for patients who left the hospital AMA. *(An abstract of that study is available online at: https://bit.ly/2MbV2B6.)*

Formal Training on Communication

Hospital staff and physicians should undergo formal training on how to communicate with patients who express a desire to leave AMA, Greene says. The training should teach them how to collect and document, in detail, the mental state and physical condition of the patient throughout his or her stay at the hospital, she says.

The most common mistakes and oversights cited in lawsuits include poor communication, poor documentation, not providing care after a patient expresses a desire to leave, and not providing medication, medical instruction, or follow-up with patients after they have left, she says.

"Hospitals need to have policies

and procedures in place to help protect the hospital from AMA risks, and the staff absolutely need to be familiar with these policies and procedures through annual training and reviews," Greene says. "Within this training, they need to go over how to properly record the care of the patient."

Many clinicians, when asked how to protect against AMA exposure, will say they should document within the patient's chart the desire to leave, and note that the patient was informed of the potential risks of leaving. That is fine as far as it goes, Greene says, but it does not go far enough.

"This would provide little to no protection if the hospital was sued. The key is that the hospital needs to have communicated with precision and have thorough records," she says. "The burden on the hospital when litigating an AMA case is to establish that they took all the steps necessary to treat the patient. While documentation will help to establish this, it is critical for the notes to be detailed and specific."

In establishing that the patient's decision-making ability was intact, and he or she had the mental capacity to make reasonable decisions, staff should identify that the patient is not under the influence or intoxicated, Greene says. The patient also should demonstrate the ability to carry on a conversation with the staff about a variety of items, such as: How are you feeling? What are your symptoms? What were you doing prior to coming to the hospital?

"The staff will want to capture details of these conversations as these will help the hospital establish that the patient was of sound mind and had the capacity to make decisions," Greene says. "Doing this supports that they had the capacity to understand that the actions they were taking to leave AMA could potentially put them in harm's way."

If the patient does leave AMA, the hospital should do whatever is possible to limit a negative, adverse medical outcome, Greene says. Patients should be provided with any medications and medical instructions that they may presently need, and failure to do so will only increase the chance that the patient will have a bad outcome, thus increasing the hospital's risk of liability.

"Emergency physicians often wonder whether they should provide any care or treatment for patients who leave AMA, fearing lawsuits may arise from providing subadequate care," Greene says. "However, not doing so often strengthens the litigator's case and weakens the hospital's defense." ■

SOURCE

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Alarm Fatigue Still Serious, Solutions Slow to Come

Alarm fatigue still is a serious threat to patient safety and years of effort have yielded minimal improvement, experts say. Some effective strategies have been identified, but the problem could worsen before a real solution is found.

Diminishing the cacophony of alarms is proving to be more difficult than first imagined, says **Paul Dexter**, MD, research scientist with the Regenstrief Institute, an informatics and healthcare research organization, and associate professor of clinical medicine at Indiana University School of Medicine, both in Indianapolis.

"It's a very active issue. There have been efforts to improve the situation but it is likely, in many ways, to only get worse," Dexter says. "I don't think the rate of improvement is matching the influx of all the new alerts, reminders, and alarms coming our way. We have tried to improve the precision and specificity of the alarms, but so far that is not enough."

Most efforts involve trying to make the alarms and reminders more patient-specific, Dexter says. The patient history also can be factored in to the way alarms work, he notes, so that if a clinician has overridden an alert a number of times, that particular alert might be disabled or made less intrusive.

The adoption of such strategies is inconsistent across hospitals and health systems, Dexter says. Part of the problem is that device vendors tend to err on the side of safety, partly because of their own liability concerns, and encourage the widest use of their databases to detect allergy conflicts, for example, he says. It is up to the healthcare providers to tailor the use of the machine to their own needs, he says.

"You should take the vendor's package of drug interactions and

have clinicians assess what is right for your institution and your patients," Dexter says. "If you don't and you go with the vendor's default settings for everything, you can end up with an overwhelming number of alarms and reminders. That can prompt people to turn off the functionality entirely, which is the wrong solution."

Dexter urges hospitals to monitor and catalog alarms on particular units because you cannot effectively reduce the burden without knowing exactly what clinicians are subjected to on a daily basis.

"It's the only way to know what's really happening and to find a way to isolate those alarms that are most problematic," Dexter says. "You can find those alarms that are overridden on a regular basis, and then there should be a very good reason to keep that alarm as-is or else you need to stop that alarm from interfering with patient care."

New Guidelines Can Help

The American Association of Critical-Care Nurses (AACN) in Aliso Viejo, CA, recently issued a Practice Alert on the issue, titled "Managing Alarms in Acute Care Across the Life Span: Electrocardiography and Pulse Oximetry," which outlines evidence-based protocols and clinical strategies related to alarm management. *(See the story on page 104 for more on the Practice Alert.)*

Alarms can be detrimental to patient safety if they are not managed properly, says **Nancy Blake**, PhD, RN, NEA-BC, CCRN, FAAN, former nursing director at Children's Hospital in Los Angeles, former board member with AACN and a member of the Association for the Advancement of Medical Instrumentation Alarm Coalition.

"While clinical alarms are meant to alert the clinician to a potentially harmful event for the patient, they are not without problems. If any of the monitors with integrated alarms aren't used properly, they can become more of a hindrance to the clinician in performing their patient care duties," she says. "Over the years, the growing number of alarms have contributed to sensory overload, and the clinicians have become desensitized to the alarms because of alarm fatigue. This alarm fatigue has contributed to delayed response to the alarms, which is a patient safety issue as clinicians could be missing a potentially critical event that triggered the alarm."

Research has indicated that a range of 89% to 99% of alarms are false or clinically insignificant, Blake says. There are alarm parameters that are unique to every patient population, so it is important to look at the issue across the lifespan of the patient, she notes. It is important to ensure that the alarm settings are appropriate for the patient population.

The Joint Commission developed a leadership standard that requires the organization's leadership to work with clinicians to develop structures and processes to manage alarms, Blake notes. This standard reinforces that alarm management affects the entire organization and is not an individual clinician problem.

"The Joint Commission realized that without a comprehensive approach, bedside clinicians alone are unable to fix this issue in organizations. It also ensures that the key decision-makers, when it comes to equipment, policies, and procedures, fully understand and are actively involved in solving this issue together as part of the team," she says. "This has made alarm management an organization priority over the last few years, causing organizations to change the way they manage alarms from an organizational perspective and making it a high priority patient safety issue."

Find Best Practices

By setting up teams to work on this issue and making this a joint problem to solve, an organization can truly examine its own issues and events and create a unique process based on evidence to help decrease or eliminate alarms that may be clinically insignificant or not actionable, Blake says.

The AACN Practice Alert also looks at best practices from using the equipment correctly or as

EXECUTIVE SUMMARY

Clinicians are still overwhelmed with excessive alarms. There has been little progress in reducing the threat to patient safety.

- The rate of improvement is not keeping up with the increasing number of alarms.
- The vast majority of alarms are false or not clinically significant.
- Hospitals must address alarm fatigue so clinicians do not ignore the alarms.

intended by the manufacturer, to how the skin is prepped prior to placing the ECG electrodes, Blake notes. It suggests how often the electrodes must be changed daily to decrease the number of false alarms and technical alarms that are not due to a patient event.

"As hospitals strive to be high-reliability organizations and decrease patient harm while in the hospital, the AACN Practice Alert can assist in not only changing organization practice, but also developing unit-specific practices, organizational policies and procedures, ongoing education, and safe bedside practices to check the alarms at patient handoff, which supports excellence in practice," Blake says. "Implementing the recommended practices and understanding the entire issue around managing clinical alarms will improve patient safety."

The very high rate of false or clinically insignificant alarms is difficult to reduce, notes **Bette McNee**, RN, NHA, clinical risk management consultant at insurance broker Graham Company in Philadelphia. From the 89% to 99% found in research, even a concerted effort to address alarm fatigue typically reduces that number only about 50%, McNee says.

"Any nurse working in this area will still tell you that these alarms are still a diversion in their efforts to

Practice Guidelines Address Alarm Fatigue

The American Association of Critical-Care Nurses (AACN) in Aliso Viejo, CA, recently issued new guidelines for reducing the burden of alarms involving ECG monitoring.

The Practice Alert, "Managing Alarms in Acute Care Across the Life Span: Electrocardiography and Pulse Oximetry," addresses an area in which repeat alarms are particularly common and may be reduced with specific strategies, says **Nancy Blake**, PhD, RN, NEA-BC, CCRN, FAAN, former nursing director at Children's Hospital Los Angeles, former board member with AACN, and a member of the Association for the Advancement of Medical Instrumentation Alarm Coalition.

The AACN Practice Alert gives guidance to the team on what the leaders and the bedside care providers should do. It provides the most recent information to guide evidence-based practice, which is important to safe, quality, patient-centered care, she says.

"Many clinical areas did not know where to begin, and the AACN Practice Alert brings the current evidence and current best practices together in one place. It also encourages nurse leaders to establish an interprofessional team to address alarm issues," she says. "It is important that the physicians, nurses, leaders, risk managers, and biomedical technicians come together to bring their own expertise and knowledge to the table to address issues as a team and allocate the appropriate resources to address this problem as a systems issue which can improve patient safety if done right."

The Practice Alert encourages hospitals to assess who should be monitored and to follow the American Heart Association's Update on Electrocardiographic Monitoring in Hospital Settings, which is a current best practice released in 2017.

The following are some of the recommended interventions:

- Provide proper skin preparation for and placement of ECG electrodes.
- Use proper oxygen saturation probes and placement.
- Check alarm settings at the start of every shift, with any change in patient condition and with any change in caregiver.
- Customize alarm parameter settings for individual patients in accordance with unit or hospital policy.

These strategies are for nursing leaders:

- Establish an interprofessional team to gather data and address alarm-related issues.
- Develop unit-specific default parameters and alarm management policies.
- Provide initial and ongoing education on monitoring systems and alarm management for unit staff.
- Develop policies and procedures for monitoring only those patients with clinical indications for monitoring.

The Practice Alert is available online at: https://bit.ly/2xP6hc1. ■

provide good patient care," McNee says. "They have to keep their sensitivity up and respond to these alarms, even when a far majority of them are false. They have to step away from documentation and other patient care to check them out."

In terms of improvements, the low-hanging fruit includes things like setting parameters specific to each patient, rather than having a machine default to a generic range of readings for all patients, she says. That kind of improvement is necessary, but only gets you so far in tackling the problem, she says.

Real improvement will come with building algorithms that consider various vital sign readings before triggering an alarm, McNee says. The goal should be to get the technology to work for the healthcare staff, having the machine do some of the initial thinking to realize that the one abnormal reading does not actually require the nurse's intervention, she says.

"We've seen hospitals trying to go more toward wireless and silent alarms, and we're seeing hospitals involve IT more to address technical alarms," she says. "Some of these alarms are for technical issues like loss of Bluetooth connectivity or a low battery, so hospitals are diverting those nonclinical alarms to the IT department, which helps relieve some of the fatigue for nurses."

Hospitals must continue to seek solutions, McNee says, because otherwise nurses will be tempted to silence the alarms instead of responding to each one, which can be deadly.

"Unfortunately, when people don't know how to adjust them or nothing is done to reduce the alarms, nurses have been known to silence them. There have been deaths attributed to nurses silencing alarms because they just had so many alarms they didn't know what else to do," McNee says. "Unless hospitals put in some innovative solutions, the risk is still there to silence the alarm and move on." ■

SOURCES

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Closed Radiology Claims Show Most Common Risks

Radiology is the second most common source of diagnosis-related malpractice claims, behind general medicine, according to a recent analysis from Coverys, a medical malpractice insurer based in Boston.

Radiology claims are common and can be costly, says **Robert Hanscom**, JD, vice president of business analytics with Coverys. For radiology, misinterpretation of clinical tests is the most likely allegation in lawsuits.

The analysis examines 10,500 closed medical professional liability claims across a five-year period from 2013-2017. Claims naming a radiologist often involve significant patient harm and can delay the accurate diagnosis of a patient's condition, Hanscom notes.

The analysis includes these findings:

• About 15% of malpractice claims with a diagnosis-related allegation involve radiologists.

• Within diagnosis-related claims, 80% result from the misinterpretation of clinical tests.

• More than 80% of claims involved permanent injuries to the patient, or death.

• Among diagnostic failure claims involving radiology, the largest number of cases involve a missed or delayed diagnosis of cancer.

EXECUTIVE SUMMARY

Radiology is responsible for a large number of diagnosis-related malpractice claims. Clinical tests are most often involved.

- Most diagnostic radiology cases involve cancer.
- Malpractice cases involving fast-moving cancers are particularly difficult.
- Hospitals must have a system for tracking diagnostic results.

• The types of cancer most often associated with misinterpretation of diagnostic tests are breast, lung, pancreatic, and ovarian.

Diagnosis-related allegations are the most common malpractice claims, and the most expensive. General medicine accounts for the most cases, but radiology is not far behind, Hanscom says.

"Radiology is uncomfortably high. We were surprised by that and thought radiology might be lower in the prevalence of these claims because there has been a lot of work done over the last decade," Hanscom says.

"Radiologists are still being named in these suits, either the primary defendant or just involved, and may bear some responsibility for what happened. The ones where radiologists are being pulled in are the cancer diagnoses, and that's no surprise."

Pancreatic and ovarian cancer cases are particularly difficult and costly, Hanscom says, because those cancers are so fast-moving.

"A delay in diagnosis with those cancers can mean the difference in the patient living or not, so those are very serious cases," Hanscom says. "Breast and lung cancer don't always mean that, but they do involve a great deal of radiologist involvement. These are all high-severity injury cases, as opposed to other malpractice cases like surgical injury cases that might fall into medium severity."

One of the key lessons from the data is the need for a closed-loop tracking system to identify critical test results, Hanscom says. Communicating test results during transitions of care also is critical, he says.

"That often is a phase of care where things get lost and things that are critical don't get to the person who needs to receive it," he says.

"Also, there must be a system in place that identifies situations that need attention. Radiology reports tend to go on at length and everything can seem like it has equal importance, so there must be a way for physicians to recognize that this particular paragraph needs your attention and focus." ■

SOURCE

- **Robert Hanscom**, JD, Vice President of Business Analytics, Coverys, Boston. Phone: (800) 224-6168.

Beware Exposure if 'Bouncebacks' Don't Return to Same ED

Most EDs track return visits — cases in which patients come back with new or worsening symptoms. But what if that patient goes to a different ED? Investigators recently examined this question.[1]

"Our research group undertook this study to better understand how patients moved between different hospitals after an initial ED discharge," says **Bradley Shy**, MD, the study's lead author. Researchers analyzed more than 12 million return visits (sometimes called "bouncebacks") occurring within 72 hours of initial presentation at 31 EDs over a five-year period. These included 841,259 same-site visits and 107,713 different-site return visits.

"This work may raise important malpractice implications for the second ED involved in a two-hospital bounceback," says Shy, associate medical director and director of quality assurance and process improvement in the department of emergency medicine at Mount Sinai School of Medicine in New York City.

The data showed "a huge variability" in how frequently patients from any particular ED will return to a different hospital within 72 hours, Shy says. The ED most likely to have patients return to another site saw a 52% increase in the number of 72-hour returns identified when other hospitals were included in this analysis.

"This work highlights the perils of using 72-hour return frequency as a surrogate measure for quality of care," Shy notes.

Health information exchanges could allow ED physicians to learn in real time the nature of a patient's recent visit to an outside hospital. "There are countless examples — access to blood culture results, avoiding redundant CT scans, knowledge about patients' allergic drug reaction history — of how this technology can be potentially life-saving," Shy says.

As health information exchanges grow, ED physicians could conceivably be liable for not reviewing data from outside hospitals. "If EDs have access to these records from outside hospitals and do not access these, these physicians and hospitals could be taking on significant risk," Shy warns.

Shy stresses that EPs should look for ways that this can improve their patient care. "It is very likely health information exchanges will become

substantially larger and more robust over the next decade."

The traditional understanding of a 72-hour bounceback was based on identifying patients who had returned to the same facility. "But it is logical to consider the possibility that if the initial visit resulted in a return, the patient may want their repeat evaluation to be done by a different center," says **Michael B. Weinstock**, MD, co-author of *Bouncebacks! Emergency Department Cases: ED Returns*.

Investigators did not seek to determine if there was a medical error resulting in the return. "In fact, there are some patients who will have a progression of their disease or new symptoms. We want these patients to return," says Weinstock, associate program director of Adena Emergency Medicine Residency and director of medical education and research at Adena Health System.

Factors that increased the likelihood that the patient would return to the same ED included age of 65 years or older, and the existence of an emergency medicine residency program at the hospital.

"Risk management factors to consider when discharging a patient are to anticipate patients who may have progression of disease and to ensure they understand the importance of returning for a recheck," Weinstock says, noting that patients should know they are welcome to return to the ED any time. "But going to the closest ED, even if a different ED, should not be discouraged."

The need to return to the ED is not always clear to patients. "A patient's presentation is a question that sometimes only we understand — for example, a thunderclap headache or left lower quadrant pain in an amenorrheic woman," Weinstock offers. It is important that both the ED provider and the patient understand the question that needs answering. "This will help with encouraging the patient to return if their symptoms progress or change," Weinstock notes.

When seeing a bounceback patient, there is a risk EPs will fall into "diagnosis momentum," according to Weinstock. "One of the biggest impediments to making an accurate current diagnosis is to attribute undue importance on the previous diagnosis," he says.

When a patient returns to a different ED, Weinstock says, "the previous ED visit should be explored for complaints not explored, lab abnormalities not acted on, and abnormal vital signs not recognized."

Some EPs may be inclined to blame the initial doctor for a misdiagnosis. "This may prompt the patient to initiate a lawsuit," Weinstock warns.

The presentation may seem obvious on the return visit, but the diagnosis may have not been so clear at the time of the first ED visit. A common example is a patient presenting with the earliest symptoms of appendicitis (mild nonfocal abdominal pain and nausea). If the patient feels better with conservative treatment, exhibits good vital signs, and shows improvement during a follow-up physical exam, discharge may be indicated, provided that good ED return precautions are understood by the patient.

"Although appendicitis would be possible at this point, other diagnoses, such as gastritis, may be more likely," Shy says. On a return visit to the same or different ED, symptoms may be more severe and consistent with appendicitis. "At this point, this diagnosis can be readily made," Shy adds.

EPs should keep in mind that the previous ED evaluation and management might have been entirely appropriate based on the information available at the time. "We should never cast blame on a previous provider," Weinstock advises.

For example, a patient with complaint of headache may have told the initial provider that it was identical to past headaches. But with the additional information of unintentional weight loss given to an EP at the second ED, now primary or metastatic malignancy moves up on the differential.

"Keep the encounter focused on the patient's symptoms and making a diagnosis and management plan," Weinstock offers. "Leave litigation for someone else." ■

REFERENCE

1. Shy BD, Loo GT, Lowry T, et al. Bouncing back elsewhere: Multilevel analysis of return visits to the same or a different hospital after initial emergency department presentation. *Ann Emerg Med* 2018;71:555-563.

SOURCES

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- **Michael B. Weinstock**, MD, Associate Program Director, Adena Emergency Medicine Residency; Director, Medical Education and Research, Adena Health System; Professor, Emergency Medicine, Department of Emergency Medicine, Wexner Medical Center, The Ohio State University, Columbus. Phone: (614) 507-6111. Email: mweinstock@mweinstock.com.

HEALTHCARE RISK MANAGEMENT™

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CE QUESTIONS

1. **According to Kevin Klauer, DO, EJD, FACEP, chief medical officer for hospital-based services and the chief risk officer for TeamHealth, what should happen with test results after the patient leaves the facility AMA?**
   a. They must still be provided to the physician, and abnormal results must be addressed.
   b. They can be ignored.
   c. They should be set aside and provided to the physician if the patient returns.
   d. They should be held in a grouping of AMA results and reviewed monthly.

2. **When trying to contact a patient who left AMA, what should be documented?**
   a. Only successful attempts to reach the patient, and what information was conveyed then.
   b. Details of both unsuccessful and successful attempts to reach the patient, along with what information was conveyed.
   c. Only a notation that an effort was made to reach the patient.
   d. Nothing needs to be documented in this regard.

3. **Why does Paul Dexter, MD, research scientist with the Regenstrief Institute, say the issue of alarm fatigue may get worse?**
   a. Healthcare providers are making little effort to address the problem.
   b. The rate of improvement may not match the increase in alarms and alerts introduced by new devices.
   c. Healthcare employees are resistant to strategies that address the issue.
   d. Physicians are concerned about liability related to reducing alarms.

4. **According to a recent analysis from Coverys, a medical malpractice insurer, most diagnostic-related radiology claims involve which of these?**
   a. Pediatrics
   b. Cancer
   c. Orthopedics
   d. Neurology

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

Canceled HIV Test Results in $18 Million Verdict

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News: In late 2006, a man was seen at a hospital for multiple conditions, including major depression, joint stiffness, a scattered maculopapular rash, dysarthria, gait difficulties, and neurological deficits (a facial droop). After returning to the hospital seeking treatment for additional ailments, the patient was admitted to the hospital's ED with flu-like symptoms. He was told that he suffered from an unnamed viral infection, but that he had no risk of HIV.

In 2007, the patient was told by an outside physician that his symptoms were indicative of HIV, and the physician recommended testing. The patient returned to the hospital and signed a form permitting the hospital to test him, but no testing was performed. After returning to the hospital over the next three years for different ailments, the patient was again informed that his symptoms were indicative of HIV. However, the patient informed the physician that he had already been tested and received a negative result. After a retest, it was discovered that the patient did in fact suffer from HIV, prompting him to file suit against four physicians. A jury awarded the patient $18.4 million in damages.

AFTER RETURNING TO THE HOSPITAL OVER THE NEXT THREE YEARS FOR DIFFERENT AILMENTS, THE PATIENT WAS AGAIN INFORMED THAT HIS SYMPTOMS WERE INDICATIVE OF HIV.

Background: In November 2006, a man was treated at a hospital for multiple ailments including major depression, joint stiffness, a scattered maculopapular rash, dysarthria, gait difficulties, and neurological deficits (a facial droop). He was seen by four different physicians. While undergoing treatment, the patient attended law school and thereafter secured a position working at a probate court as an attorney.

In 2007, the patient was tested for diseases and conditions, including Lyme disease, strep, syphilis, Epstein-Barr virus, Guillain-Barré syndrome, cytomegaly, and parvovirus. Following a battery of tests, the patient was diagnosed with cranial neuropathy of uncertain etiology and Bell's palsy. In May 2007, he was admitted in the hospital's ED for flu-like symptoms and was informed he was suffering from a viral illness, given Z-pack antibiotics, and sent home. One of the physicians noted in the medical record that "There is no risk of HIV, but testing will be considered."

Later that month, an outside physician advised the patient that his symptoms were highly suggestive of HIV and recommended testing. The patient returned to the hospital and signed a consent form to undergo testing. During the next month, another physician saw the patient and informed him that his test results "looked good."

In June 2007, one of the patient's physicians noted that the patient's bilateral facial weakness was improving and that there was no specific explanation for the symptoms or any known etiology. The physician informed the patient that his neurological and lab tests were negative. Based on

the consent form executed the month before, the patient believed that HIV tests were also performed and also returned a negative result. No hospital staff member informed him that the test had not been performed, and the physician noted that he did not need to see the patient again.

From 2008 through 2010, the patient saw different physicians and underwent different tests as a result of his ailments. One physician noted the patient's HIV factors and recommended testing. The patient mentioned that he had been previously tested and had a negative result, but nevertheless consented to retesting — which returned a positive result.

The patient brought a medical malpractice action in January 2013 against the four physicians who were involved in his initial testing. The district court partially limited the patient's claims as a result of the statute of limitations, which bars claims if too much time has elapsed. The defendants also claimed that the patient assumed the risk and claimed that he refused HIV testing on at least one occasion, and that his symptoms did not warrant HIV testing.

A jury awarded the plaintiff $18.4 million against two of the physicians; the jury further determined that one physician was not negligent and the other was negligent but did not cause injuries.

What this means to you:
This case demonstrates how clear communications are critical for hospitals and physicians to correctly inform patients of test results, and the importance of timely diagnosis and treatment.

If the CD4 count in an HIV-positive person's body drops below 200, the infection has progressed into AIDS. AIDS is characterized by an inability to fight off certain infections and cancers, such as PCP, Kaposi sarcoma, wasting syndrome, memory impairment, and tuberculosis. Most patients who are diagnosed with HIV early and treated properly will not develop AIDS.

When a patient presents with symptoms that suggest HIV, physicians should inquire about the patient's personal interactions and other relevant background information that enable the physician to better diagnose and determine whether testing for HIV is appropriate.

In this case, the patient exhibited several risk factors for HIV, such as previously working as an EMT and homosexuality. Other risk factors physicians should inquire about for HIV include whether the patient engages in unprotected sex or sexual relations with an HIV-positive individual, uses intravenous drugs, the presence of a sexually transmitted infection, or for males, being uncircumcised.

Since HIV progresses through a series of stages, it is critical to diagnose and treat it as soon as possible in order to minimize harm to the patient. While a complete failure to diagnose is more likely to give rise to injuries and a subsequent medical malpractice action, a delayed diagnosis — combined with the resulting delayed treatment — can cause equal injury.

A patient who receives treatment in the earliest stage of primary infection, also known as acute HIV, may remain at this stage and avoid becoming symptomatic. However, if a physician does not timely identify the patient's symptoms and order an HIV test, that failure may constitute medical malpractice if a reasonable physician in the same or similar circumstances would have done so. Such a failure may be directly responsible for the patient's HIV progressing to a more serious stage and cause significant harm.

While the symptoms above can indicate an HIV infection, the only method to verify is by testing for HIV. One method to test for the infection is to test blood or saliva for the HIV antigen. This method can indicate the presence of the virus shortly after infection, unlike testing for HIV antibodies, which can take up to 12 weeks to appear. It is advisable to test for other comorbid infections and complications in addition to directly testing for HIV, such as tuberculosis, hepatitis, toxoplasmosis, other sexually transmitted infections, liver or kidney damage, and urinary tract infection.

One complication that physicians must be conscious and sensitive about is the stigma surrounding HIV and AIDS, which extends to all aspects of the disease and its diagnosis, testing, treatments, and even conversations relating to symptoms, risk factors, and lifestyle choices that increase those risks.

Physicians discussing these sensitive issues with patients should notify patients of the various state and federal laws that are designed to protect the privacy of those being tested for the virus or diagnosed with the virus while requiring notification to those who may have been exposed to the virus by an infected individual. Hospitals and care providers must ensure that their staff are trained and educated concerning these issues in order to fully inform patients.

These laws can be complicated for patients to understand, yet patients look to physicians for guidance. Healthcare providers should be cautious and consult risk management and legal professionals to ensure all procedures are current, especially for responsibly managing HIV and HIV/AIDS patients.

If the patient here had actually received HIV testing in 2007, as he expected, he would have promptly received treatment and his quality of life would have been significantly increased. While there is no cure for HIV, antiretroviral therapy exists, which can block the virus in various ways depending on the class of drug. The classes of these drugs include non-nucleoside reverse transcriptase inhibitors, nucleoside or nucleotide reverse transcriptase inhibitors, protease inhibitors, entry or fusion inhibitors, and integrase inhibitors. It is advisable to combine three drugs from two different classes to avoid the creation of drug-resistant strains of HIV.

In this case, clear communications and timely diagnosis and treatment did not occur. With follow-through and adequate testing procedures, this patient's injuries and an $18.4 million verdict could likely have been avoided. ■

REFERENCE

Decided on June 18, 2018 in the U.S. District Court for the District of Massachusetts; case number 1:13-cv-10103-RGS.

Physicians' Failure to Diagnose Cardiac Condition Not Hospital Negligence

News: A man presented to a physician several times for the treatment of pain in both shoulders. He received medications that failed to alleviate his pain. One morning, the patient called the health center that prescribed the medications and informed the receptionist that he was experiencing shoulder pain and requested an appointment, which was scheduled for 45 minutes thereafter.

While being driven to the health center, the patient experienced shortness of breath and suffered a heart attack. Fortunately, his nephew was driving and was able to pull over and call 911. The patient passed away shortly thereafter. His sister brought suit on behalf of the man's estate against the physician and the hospital. The plaintiff and the physician settled, but the case against the hospital proceeded to trial, where the jury found in favor of the hospital.

Background: In May 2014, a 52-year-old security guard presented to a family medicine physician at a health center for treatment of bilateral shoulder pain. The physician performed a normal examination, diagnosed musculoskeletal pain, and prescribed pain medications. A few days later, the patient returned to the health center with continued pain and increased pain in his left shoulder. The patient told the physician that the medications failed to reduce the pain, and the physician prescribed different pain medication. The physician also told the patient to apply heat to his left shoulder and to return if needed.

Three days later, the patient called the health center and requested an appointment for further treatment of shoulder pain; an appointment was scheduled for 45 minutes later. As the man felt he was unable to drive safely, his nephew drove him to the medical center. During the drive, the patient experienced shortness of breath and chest pain, and the nephew pulled over to call 911. The patient lost consciousness and was transported by ambulance to a hospital. Resuscitation efforts were unsuccessful, and he was pronounced dead as a result of a myocardial infarction.

The man's estate, represented by his sister, sued the physician, alleging that he failed to diagnose a cardiac-related issue when he saw the patient. The estate also sued the health center, claiming that the receptionist failed to refer the patient to emergency services. The patient's nephew also filed suit against the physician, alleging negligent infliction of emotional distress. The plaintiffs settled with the physician, and the case against the health center proceeded to trial.

At trial, the estate's expert in family medicine opined that when a patient calls a medical practice complaining of unexplained arm pain, even if the symptom is generic, the staff taking the call has a responsibility to elicit additional information. The estate argued that the receptionist should have inquired as to which arm was painful and if he had other symptoms. If she was uncertain whether he needed to be seen by a health center physician or present to an ED, she should have transferred the call to a nurse qualified to make that determination. The expert concluded that the receptionist's failure to ask follow-up questions, or in the alternative direct the man to call 911, breached the standard of care.

Defense counsel maintained that the receptionist did not breach the standard of care. The receptionist, who had worked in previous hospital and medical settings, testified that if she had sensed the man was in

distress or was experiencing a medical emergency, she would have directed him to call 911. She further testified that it was her usual practice to type into the office telephone log a patient's complaints, which in this case simply read "arm pain." The receptionist testified that the man's demeanor and the symptoms he described led her to believe it was appropriate to schedule an appointment with a health center physician.

The defense's internal medicine expert opined that the receptionist's conduct, without knowing the patient's background other than his arm pain, did not fall below the standard of care. The defense also cited the patient's 2009 records that indicated that he was a heavy, longtime cigarette smoker, and that the physician instructed him to stop smoking. In 2014, he was still smoking; moreover, he had not undergone any medical evaluations during that five-year period.

The jury returned a verdict in favor of the defense after a four-day trial.

What this means to you: This case illustrates the importance of providing adequate training for nonmedical personnel in healthcare facilities. To the extent an employee has contact with a patient, that employee must have basic training to evaluate the urgency of a patient's symptoms. As the receptionist testified in this case, if she had sensed the man was in distress or was experiencing a medical emergency, she would have directed him to call 911. In part, her experience with hospitals and medical settings helped prevent liability for the health center.

Hospitals and other healthcare facilities should similarly be trained to be wary of patient conditions and symptoms so as to avoid unnecessary malpractice suits. The patient's estate here argued that the receptionist should have inquired further as to the patient's status, given his stated arm pain. Most physicians' offices, urgent care centers, and even hospital EDs are staffed with medical assistants who have basic training in simple procedures. These staff members may also function as receptionists greeting patients, answering phones, and scheduling appointments.

What is essential is that individuals can recognize what they do not know and when to elevate the patient's concerns to a nurse, physician, or another individual better qualified to assist. No matter who is interacting with the patient, the critical question that must be asked of all callers is whether he or she is experiencing an emergency.

THIS CASE ILLUSTRATES THE IMPORTANCE OF PROVIDING ADEQUATE TRAINING FOR NONMEDICAL PERSONNEL IN HEALTHCARE FACILITIES.

A safe response is to tell callers to call 911 or go to the nearest ED if they need to be seen right away. Another option is to ask the caller to speak to a licensed nurse if one is readily available. In general, diagnosing a patient over the phone is problematic, even for a physician. Nevertheless, patients do call and may express concerns about their symptoms, so care providers must be prepared for this eventuality and be able to calmly respond and advise patients to seek emergency care when appropriate.

Similarly, healthcare facilities without EDs should implement procedures to deal with patient emergencies. The foundation of such procedures should include a duty to inquire into patients' symptoms. In a situation where a patient appears to require emergency medical attention, staff members should be instructed to contact 911 promptly and prepare for an immediate transfer to a nearby hospital. Coordination with hospitals is essential for smooth patient transitions. Healthcare facilities should foster relationships with nearby hospitals and train medical personnel accordingly.

The patient in this case suffered from a myocardial infarction, which is a common and well-understood urgent medical condition. With a condition such as this, the symptoms (chest tightness, shortness of breath, chest or arm pain, etc.) are generally known, and care providers must be trained to recognize them — and to promptly act. Once diagnosed, treatment of myocardial infarctions commonly involves an angioplasty, which breaks up the blockage preventing adequate blood flow.

Other treatments may include the use of stents or coronary artery bypass grafts. Medications also can be used to assist with treatment of heart attacks, including blood thinners, thrombolytics, antiplatelet drugs, nitroglycerin, beta-blockers, ACE inhibitors, and pain relievers.

While the man in this case did suffer from a serious and emergent condition, the jury determined that the care provider was not liable based on the limited information provided by the patient and the provider's appropriate response. ■

REFERENCE

Decided on May 29, 2018, in the Lancaster County Court of Common Pleas; case number CI-15-398.

HIPAA REGULATORY ALERT

CUTTING-EDGE INFORMATION ON PRIVACY REGULATIONS

Educate Staff on Criminal Prosecution Risk

Criminal prosecutions for HIPAA violations appear to be increasing, putting both individuals and healthcare organizations at risk for more than just monetary penalties and regulatory burdens.

The criminal penalties for HIPAA violations can be severe: a fine of up to $50,000, imprisonment for up to a year, or both. Additionally, if the offense is committed under false pretenses, there can be a fine of up to $100,000, imprisonment for up to five years, or both.

If the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, the offender can be fined up to $250,000 and imprisoned for up to 10 years, or both.

Those criminal prosecution options are not as well known to healthcare professionals as the civil penalties that are reported often, notes **William P. Dillon**, JD, shareholder with the Gunster law firm in Tallahassee, FL. Office for Civil Rights (OCR) has made 688 referrals to the Department of Justice (DOJ) since the law was enacted. "I think the number of referrals is going to grow as the government focuses more on identity theft," Dillon predicts. "There hasn't been a ton of referrals to DOJ since the process has been in place, but there is reason to think that is going to increase. Covered entities have to have the right processes in place to stay away from that kind of risk."

The criminal sanctions for violating HIPAA were part of the initial public law and are codified at 42 USC 1320d-6, explains **Darci L. Friedman**, JD, CHPC, CSPO, PMC-III, director of content strategy for healthcare compliance and reimbursement within Wolters Kluwer Legal & Regulatory U.S.

There are three prohibitions under the statute. Criminal liability may flow when a person knowingly uses or causes to be used a unique health identifier, or obtains individually identifiable health information relating to an individual, or discloses individually identifiable health information to another person. A person is considered to have obtained or disclosed individually identifiable health information if the information is maintained by a covered entity and the individual obtained or disclosed such information without authorization, Friedman explains.

"Initially, there was some ambiguity as to whether an individual could be criminally liable under the statute and as to whether the term 'knowingly' required proof of knowledge that the conduct was contrary to the statute," Friedman says.

Regarding individual liability, the DOJ concluded that both covered entities and individuals, including directors, officers and employees, may be prosecuted directly under section 1320d-6, Friedman notes.

Concerning the "knowingly" requirement, the DOJ concluded that the element should be read with ordinary meaning to require only proof of knowledge of the facts that constitute the offense and not knowledge that the conduct was contrary to the statute, she says.

"The criminal prosecutions we have seen to date indicate that prosecution is likely where the facts of the case are particularly egregious or where the violation is discovered or prosecuted as part of a larger case involving other kinds of wrongful deeds, like Medicare or tax fraud," Friedman says.

One of the first cases of a HIPAA privacy prosecution involved a cardiothoracic surgeon from China working at a U.S. hospital in 2010, Friedman notes. After receiving a notice of dismissal, the surgeon accessed and read his immediate supervisor's medical records, those of other co-workers, and various celebrities. The surgeon was the first defendant in the nation to receive a prison sentence (four months) for a HIPAA violation.

In 2013, a former nursing assistant at a Florida assisted living facility pleaded guilty to selling HIPAA-protected patient information, including Social Security numbers,

and tax fraud. She was sentenced to 37 months in prison. The crime was discovered when local police executed a narcotics-related search warrant, Friedman notes.

"Most recently, a Massachusetts physician was convicted of a HIPAA violation for her role in a scheme whereby she shared patient information with a pharmaceutical company representative so that the company could target patients with specific conditions," Friedman says. "This case illustrates not only a criminal HIPAA prosecution but the DOJ's ongoing focus on pharmaceutical company marketing practices and their relationships with doctors."

It is important to note that all three cases noted were pursued against insiders, Friedman adds.

"Healthcare providers must ensure, among other things, that employee access to records is limited to the minimum necessary," she says. "Limited access should be paired with following the administrative requirements of the HIPAA security rule regarding the management of the conduct of the workforce in relation to the protection of the information."

Even when criminal prosecution falls on the individual, there still can be significant damage to the healthcare organization, Friedman says. Prosecution of an individual could be a potential flag to enforcement agencies to explore organizational liability.

"Let's not forget that covered entities may be held criminally liable for HIPAA violations as well. When the covered entity is not an individual, principles of corporate criminal liability determine when a covered entity has violated HIPAA," Friedman says. "Even if a case does not implicate the covered entity organization criminally, civil and administrative sanctions, up to and including exclusion from participating in the Medicare program, could come into play. If the organization is a focus, in addition to an individual, it is important that it cooperate in the investigation with regard to the individual in order to be eligible for 'cooperation credit' under the Principles of Federal Prosecution of Business Organizations."

The apparent increase in criminal prosecutions likely is the result of several factors, Friedman says. One factor may be the continuing rise in medical identity theft, and another may be the "Yates Memo," issued by the DOJ in 2015.

In the Yates Memo, then-Deputy Attorney General Sally Yates announced a policy on seeking accountability from the individuals who perpetrated wrongdoing to combat corporate misconduct. The guidance provided in the Yates Memo suggests that U.S. attorneys focus on individuals from the inception of the investigation, Friedman explains.

"Another factor in the increase may be simply that the DOJ is getting used to flexing their HIPAA criminal muscles," Friedman offers. The DOJ memo was issued in 2005, and the first prison sentence came in 2010. Since then, we have seen prosecutions in federal districts in Florida, New York, Texas, Ohio, and Massachusetts."

HIPAA should be a cornerstone of the educational training program for all providers, Friedman says. The training should start when an individual is onboarded and continue throughout the course of their work for the provider organization.

Include in that training information of individual liability, and use recent cases to highlight that liability may include jail time. Criminal prosecution is most likely when an employee in a physician practices knowingly violates HIPAA and the data obtained are used for monetary gain or other illegal acts, **Kyle Haubrich**, JD, an attorney with Sandberg Phoenix in St. Louis.

"It is rare that criminal penalties are handed down by HHS," he says. "Most of the time, the person violating HIPAA does so without knowing that what they did, or didn't do, was a violation. Therefore, you see more civil penalties than criminal ones."

The employer could be held liable in a *respondeat superior* situation, if the employee who was prosecuted was acting on a request to violate HIPAA by his or her employer, Haubrich explains. If the employee acted on his or her own and the employer had no idea the employee was violating HIPAA in a way that caused criminal penalties to be sought, the effect to the employer is reputation-based.

Lack of training and understanding of HIPAA could be contributing to a rise in criminal prosecutions, Haubrich says.

Another cause may be that physicians, healthcare providers, their staff, and even business associates can access multiple records easily with the implementation of electronic medical record software, Haubrich says.

The ability to use the information in a way that could result in criminal penalties (e.g., the temptation to retaliate) is higher.

"Say a physician is fired from a medical practice. However, the practice fails to [revoke] his username and password, allowing him to continue to access the medical records on the EMR software of the practice," Haubrich says. "If that doctor wanted to retaliate against that group for firing him, he could cause all kinds of problems to a

patient's medical record, including changing diagnosis, or worse, using the patient information to open credit cards in the patients' names."

The best way to educate employees about the risk is to educate them on what would cause criminal penalties to be sought, Haubrich offers. If employees know that if they access medical records for no legitimate reason, they could be criminally prosecuted for such access. Employees would be less likely to violate HIPAA because they would know the consequences of doing so, Haubrich argues.

"The best defense is making sure the employees know the risk of violating HIPAA, what criminal and civil penalties could be sought based off of violations committed, and that they, too — not just the physician — can be criminally liable for committing certain violations," Haubrich says. "That can go a long way to helping an employer mitigate the risk of any penalties being handed down."

Dillon suggests emphasizing to employees the significantly increased risk from intentional violations of HIPAA.

"Criminal prosecutions are reserved for intentional acts that cause harm. If you have a nurse who mistakenly faxes a document to the wrong number — that's not a criminal act," Dillon says. "But people who knowingly misuse patient identification need to know that there is this risk, that the government looks on those situations very differently."

The relatively low number of criminal prosecutions may be due to the overall HIPAA caseload facing the government, says **Iliana L. Peters**, JD, shareholder with Polsinelli. Prior to joining the firm, Peters spent more than a decade at OCR, most recently as the acting deputy director and as the senior advisor for HIPAA compliance and enforcement. OCR enforces civil violations of HIPAA, and investigates complaints, breaches, and other HIPAA-related matters that come to its attention.

"OCR expects to receive 24,000 HIPAA complaints in 2018. Further, OCR has received almost 2,400 reports of breaches affecting 500 or more individuals, all of which are posted to OCR's website, as required by the HITECH Act, and investigated," Peters explains.

From there, Peters says OCR refers any complaints or breach reports that may implicate the criminal provisions of HIPAA to the DOJ.

In potential criminal cases, DOJ must prove that an individual knowingly and in violation of HIPAA used, obtained, or disclosed HIPAA-protected information, Peters notes. Although there are penalties for lesser offenses, DOJ likely would take a case in which the agency would have to prove that the individual intended to use the information for personal gain or malicious harm, particularly for identity theft, fraud, or sale of such information. In such cases, DOJ typically adds HIPAA violations to other violations for which DOJ is prosecuting the individual, Peters says.

"Ultimately, healthcare entities themselves can be liable for millions of dollars of civil money penalties after an investigation from OCR. Individuals, including their employees, can be on the hook for criminal penalties of up to 10 years in prison, in addition to a fine," Peters says. "Even if criminal behavior by an employee or an outsider is at issue in a particular case, healthcare entities must be vigilant to protect against such potential criminal behavior by ensuring they implement the administrative, physical, and technical safeguards required by HIPAA, given that they are liable for not doing so."

It is important to remember that criminal prosecution may not start with a standard OCR investigation, says **Patricia Wagner**, JD, an attorney with Epstein Becker Green. In addition to the OCR referral process, it is possible that a HIPAA violation will come to light when the DOJ is investigating or prosecuting another crime and decide to include the HIPAA prosecution as part of the other matter.

When educating employees on the risk of criminal prosecution, Wagner says leaders can describe real incidents in which people have gone to prison for their actions. This makes the risk more than theoretical, she says.

"Often, it is useful to include examples of when penalties have been applied so that employees have a better understanding of the risk," she says. "Of course, it is more important to train employees on and to have a culture of compliance for HIPAA and other laws so that the focus of the organization and employees is on performing tasks in an appropriate manner."

The DOJ memo emphasizes the fact that criminal penalties are reserved for limited and specific violations of HIPAA, notes **Elizabeth Litten**, JD, HIPAA privacy and security officer with Fox Rothschild.

The memo states that such punishment is reserved for violations involving "unique health identifiers' and individually identifiable health identifiers [IIHI]. Thus, the statute

reflects a heightened concern for violations that intrude upon the medical privacy of individuals," the memo reads.

The DOJ memo focuses on violations by covered entities and notes that when a covered entity is a corporate entity, the conduct of agents may be imputed to the entity when the agents act within the scope of employment.

Criminal liability of a corporate entity may be attributed to individuals in managerial roles, Litten explains.

Once a HIPAA violation is referred for criminal prosecution, the case may be easy for prosecutors.

"It may be that a DOJ conviction for a knowing violation of HIPAA is more easily obtained than a conviction for a violation of other federal laws governing healthcare providers, such as Anti-Kickback Statute violations," Litten says. "In addition, where a healthcare entity, like a large hospital system or health plan, has deep pockets, the OCR may pursue very high civil monetary penalties and rely on the financial implications as a deterrence message sent to the regulated community. DOJ may seek to deter behavior associated with a wider range of criminal activities by pursuing jail time for a HIPAA violation. I expect HIPAA will be used as the basis for criminal prosecution where other, less easy-to-prove criminal conduct is involved, similar to convicting mafia members for tax evasion." Although criminal prosecution may seem extreme to those accused of HIPAA violations, it may be far more mundane to prosecutors, Litten says.

"Be aware that a HIPAA violation involving disclosure or breach of IIHI may be the low-hanging fruit for criminal prosecutors originally focused on other violations of law," Litten warns. "In particular, covered entities should carefully evaluate arrangements with third parties that involve the sharing of IIHI with third parties for commercial/personal gain or commercial harm, since the highest criminal penalties under HIPAA are for violations committed with the intent to use or disclose IIHI for these purposes." ■

Federal Court Affirms No Private Right of Action

A federal judge recently affirmed that HIPAA does not provide a mechanism for individuals to sue when they believe their privacy rights have been violated. However, the decision probably will not stop individuals from thinking they have the right to sue.

The supposed private right to action under HIPAA has confused people since the law's inception, explains **Nathan A. Kottkamp**, JD, a partner with McGuireWoods.

The case involved a plaintiff who had been treated at a Washington, DC, hospital in 2017, during which staff instructed her to complete an online form at a computer workstation. The plaintiff thought the information could be seen by other patients in the area. She filed complaints with HHS, the hospital, the laboratory testing company the hospital used, and the District of Columbia Office of Human Rights. She claimed that the hospital and lab company failed to make proper public accommodations for patients.

The federal court recently followed the pattern of previous courts by telling the plaintiff HIPAA does not allow such lawsuits from individuals. The courts have been clear in confirming there is no private right of action, which means a healthcare entity cannot be sued for a HIPAA violation by a patient, Kottkamp explains.

"That is often a huge surprise to members of the public. They see HIPAA information all the time, and they often are shocked to think that if this is such a big, important federal law, why can't I sue if I believe my rights have been violated?" Kottkamp says. "I probably get an average of a call a month from people who believe their HIPAA rights have been violated, and they want to sue. I have to tell them, 'Sorry, there's nothing you do can other than filing a complaint with the OCR.'"

Plaintiffs also have tried to use HIPAA violations as a starting point for other lawsuits related to privacy matters, essentially saying HIPAA represents the most fundamental level of privacy patients should expect. If there were HIPAA violations, plaintiffs often believe there were de facto violations of more strict state privacy regulations. Those cases have not been very successful, either, Kottkamp says.

"Providers need to know that a patient's inability to sue over HIPAA violations is no reason to be lax about compliance. Sometimes, the reputation damage and exposure in the media can be more costly than any civil penalties you might have incurred," Kottkamp warns. "If someone goes on social media and says you don't care about patient privacy, that could be very costly." ■