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JANUARY 2017 Vol. 39, No. 1; p. 1-12

Freestanding EDs Can Have Special Compliance, Liability Concerns

As hospitals increasingly look to freestanding EDs (FSEDs) as a way to serve patients better while potentially increasing profits, legal and compliance experts caution risk managers that they may bring risks beyond the familiar concerns of a hospital-based ED.

There were 387 FSEDs operated by hospitals in 2016, a 76% increase from 2008 to 2015, according a recent report. There were another 172 independent FSEDs operated by for-profits. *(See the story on page 4 for more on the rise of freestanding EDs and how they operate.)*

Risk managers should approach the idea of FSEDs with extreme caution, says **Rodney K. Adams**, JD, a healthcare attorney with the law firm of LeClairRyan in Richmond, VA. Providing emergency care — not the minor treatment found in urgent care clinics — outside the confines of the hospital could create significant risk of both malpractice liability and compliance concerns, he says.

> "YOU HAVE A FREESTANDING ISLAND OUT THERE AND THE QUESTION IS WHETHER THEY HAVE THE RESOURCES THEY NEED FOR ANY EMERGENCY THAT CROSSES THEIR THRESHOLD."

While he has not seen an increase in claims related to FSEDs, Adams says he worries about the possibility every time a client opens a facility 10 or 15 miles from the hospital.

"You have a freestanding island out there and the question is whether they have the resources they need for

Financial Disclosure: Author **Greg Freeman**, Editor **Jill Drachenberg**, Assistant Editor **Jonathan Springston**, 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. Physician Editor **Arnold Mackles**, MD, MBA, LHRM, discloses that he is an author and advisory board member for The Sullivan Group and that he is owner, stockholder, presenter, author, and consultant for Innovative Healthcare Compliance Group.

AHC Media

HEALTHCARE RISK MANAGEMENT™

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

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

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

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

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

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ACCREDITATION: Relias Learning, LLC, is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. Contact hours [1.5] will be awarded to participants who meet the criteria for successful completion. California Board of Registered Nursing, Provider CEP#13791.

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any emergency that crosses their threshold," Adams says. "Every ED is sometimes going to be short on resources, but if you need to, you can pull an anesthesiologist, pulmonologist, or whatever you need in a hurry from the hospital. In a freestanding ED, the ED physician is it. The best you can do is arrange transport to the hospital, which is going to delay their care."

Trauma care is one scenario that Adams says should concern risk managers, as well as cardiac patients needing catheterization without delay. Many patients can be treated safely and effectively at an offsite ED, he says, but some will be at risk by delays in getting the patient from there to the hospital.

"You just don't have the resources available the same way you do in the hospital, so it's hard to say you're providing the same level of care," he says. "Most of the people coming to an ED don't require that immediate access to the highest level of care, technology, and specialists, but if you call it an ED then eventually someone is going to come in requiring resources you don't have."

One way to mitigate that risk is to have an ambulance at the FSED to immediately transport patients to the hospital. Some facilities use that option, but it is not economically efficient and can cut deeply into any profits from the freestanding ED, Adams notes.

Even variables such as traffic or weather could affect the ability to move a patient quickly to a higher level of care, Adams says. A good strategy, he suggests, is for the freestanding ED to implement protocols for which patients should and should not be taken there, perhaps instructing ambulance services to continue on to the hospital ED if the patient is suffering a stroke and needs thrombolytic therapy, for instance. The standard for accepting patients may be more restrictive when excessive traffic or inclement weather is expected to make transfers slower, he says.

Freestanding EDs also must consider the possibility that transferring a patient to its own affiliated hospital is not the best choice, says **Judith A. Eisen**, JD, a healthcare attorney with the law firm of Garfunkel Wild in Great Neck, NY. If a patient is in need of immediate advanced care and the FSED transfers him or her to its own hospital 20 miles away, a plaintiff's attorney might reasonably make the argument that the patient should have been sent to a competing hospital five miles away.

Such decisions should be considered in advance and protocols established to determine what is

EXECUTIVE SUMMARY

Many hospitals and health systems are opening freestanding EDs, which offer benefits to both the patient and provider. Compliance and liability issues with a freestanding ED are not necessarily the same as with the in-house facility.

- The availability of resources is a concern, because the freestanding ED will be held to the same standard as the hospital ED.
- Transportation delays could create a liability risk.
- EMTALA will apply to freestanding EDs in the same way as the traditional hospital ED.

in the patient's best interest, and the FSED should have necessary agreements with other facilities, she says.

The availability of specialist physicians is part of the concern about meeting the standard of care without all the resources of a hospital, Eisen says. Hospital EDs already struggle to put enough specialist physicians on call to provide timely care, and the addition of offsite EDs could exacerbate that problem.

"The expectations of what you can provide in your ED is going to be dictated in part by what your general capacity for care is, so a large academic teaching hospital might be expected to have more specialists available than a smaller acute care hospital," she says. "But with a freestanding ED — that's a different story. It's not at all clear that the freestanding ED would be held to a lower standard just because it's offsite. When the ED is part of the hospital, it most likely will be held to the same standards."

Payment Issues Considered

State regulations will determine the limitations of freestanding EDs, and they vary widely, says **Rachel D. Ludwig**, JD, a healthcare attorney with the Jackson Kelly law firm in Charleston, WV. Some states impose no limitations, some have very specific licensure requirements, and other states prohibit them outright.

Payment issues also can be a concern, she says. Hospital-affiliated FSEDs would have to comply with the Medicare and Medicaid Conditions of Participation just like the rest of the hospital, she notes, but there could be difficulty in determining how to bill for reimbursement without submitting a false claim.

"It can get complicated with looking at transportation from your freestanding ED to your hospital, and maybe on to another hospital," she says. "Determining when a patient is inpatient and outpatient can be tricky, too, and these are issues that lead you to significant trouble if you get it wrong."

EMTALA is another concern because it applies in an FSED every bit as much as in a traditional hospital ED, Adams says. In some circumstances, EMTALA can even apply in an urgent care center, he notes. He recently had a healthcare client that wanted to ban a drug seeker from its urgent care center, but wondered if that could be an EMTALA violation. Adams explained that if the center holds itself out as a hospital facility, it is covered by EMTALA. The same reasoning would apply even more firmly for a freestanding ED promoted as part of the hospital or health system, he says.

> "YOU CAN'T TRY TO HAVE IT BOTH WAYS. THERE'S NO WAY TO PROMOTE THE ED AS PART OF YOUR HOSPITAL, BUT THIS ED IS JUST AN 'ED LITE' THAT DOESN'T DO EVERYTHING."

Ludwig agrees, noting that any potential EMTALA violation will result in scrutiny of not just the FSED, but the hospital's in-house ED as well. Investigators will look to the in-house ED and hospital to determine the capacity for care and whether the FSED met that standard, and the investigation could reveal deficiencies at the hospital ED as well, she says.

Eisen suggests that the staffing of an FSED also could come into question if there ever were a malpractice claim. Although the facility must be staffed by qualified physicians and nurses, there still could be some question as to the quality and experience of those working offsite as opposed to the in-house ED, she says, particularly if there is any perception that the in-house facility is the hospital's "real ED" or if residents and others work there because it offers them more experience with advanced care and technology.

Even without actively promoting the FSED as part of the hospital or health system, it will be reasonable for the public to make the association if there is any connection at all, Adams says. So there is no way to get around the EMTALA or standard of care obligations by being circumspect about the relationship, and most hospitals promote the affiliation strongly to give credibility to the freestanding ED, he says.

"You can't try to have it both ways. There's no way to promote the ED as part of your hospital, but this ED is just an 'ED lite' that doesn't do everything," he says. "You can't say it's an ED, but not really an ED." ■

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Freestanding EDs Growing in Popularity

Hospitals are opening freestanding EDs (FSEDs) at a rapid rate and mostly in states that allow them without meeting "determination of need" requirements, according to an article by **Nir Harish**, MD, MBA, at the Yale Department of Emergency Medicine; and **Jennifer L. Wiler**, MD, MBA, and **Richard Zane**, MD, both from the University of Colorado.

FSEDs may also be known as hospital outpatient department (HOPDs) or independent freestanding emergency centers (IFECs).

In 2016 there were 387 FSEDs operated by 323 hospitals, a 76% increase from 2008 to 2015, the authors reported. Most are found in Texas, Colorado, and Arizona because those states do not require a "determination of need" to be licensed. Other states require providers meet that requirement to protect other healthcare facilities from excessive competition and financial losses. In addition, there were 172 independently owned freestanding EDs, almost all in Texas, operated by 17 for-profit entities.

Unlike the hospital-owned EDs, the independent FSEDs cannot participate in Medicare, Medicaid, or TRICARE because they are not "outpatient departments of an acute care hospital," which means they are not subject to federal regulations required by those programs. The authors reported that there is growing interest from independent FSEDs to affiliate with hospital systems so they can participate in federal reimbursement programs.

FSEDs first appeared in the 1970s to serve rural areas without a hospital-based ED, but the idea has spread to other areas as technological innovations made them more cost effective, they wrote. Healthcare systems also look to FSEDs as a way to meet increasing demands for immediate care, and as a potential profit center, the authors said. *(The full report is available online at: http://bit.ly/1VpJFjl.)*

"The growth of FSEDs has been so fast in some states — more than tenfold within five years in Texas (Colorado is catching up) — that it's not uncommon to find two FSEDs within sight of each other," the authors noted.

> "THE GROWTH OF FSEDS HAS BEEN SO FAST IN SOME STATES — MORE THAN TENFOLD WITHIN FIVE YEARS IN TEXAS — THAT IT'S NOT UNCOMMON TO FIND TWO FSEDS WITHIN SIGHT OF EACH OTHER."

Capable of treating most illnesses, heart attacks, strokes, and minor trauma, FSEDs are different from urgent care centers or the immediate care clinics often found in retail locations. An FSED provides 24 hour/seven days a week access to an emergency physician, an emergency nurse, laboratory and radiology technicians, and more extensive, complex testing than can be found in the other settings. The ED also will provide radiological services not found in urgent care or immediate care clinics.

More than 95% of FSED patients are walk-ins, compared to hospital EDs that often receive nearly half of their patients by ambulance, the authors reported. Fewer FSED patients are admitted to a hospital, less than 5% rather than the typical 15-35% for hospital-based EDs, the authors said.

"It is a rare FSED that can observe a patient overnight; most transfer patients to a full-service hospital for any emergent subspecialty need, an operation, or hospitalization," according to the report.

When freestanding EDs surged in 2014, the American College of Emergency Physicians (ACEP) developed standards and expectations for their patient care and management.

ACEP notes that freestanding EDs owned and operated by medical centers or hospital systems must comply with the same rules and regulations of the Centers for Medicare & Medicaid Services (CMS) as the ED of the medical center or hospital, and must comply with all CMS Conditions of Participation (CoPs). For those facilities that do not seek CMS approval for Medicare/Medicaid reimbursement, ACEP cautions that state licensing rules and regulations for the technical component of their services are often "inconsistent, unclear, or nonexistent."

ACEP established the following seven qualifications that facilities should meet to qualify as a freestanding ED:

1. It must be available to the

public 24 hours a day, seven days a week, 365 days per year.

2. It must be staffed by appropriately qualified emergency physicians.

3. The ED should provide adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

4. A registered nurse with a minimum requirement of current certification in advanced cardiac life support and pediatric advanced life support should be present at all times.

5. There must be policy agreements and procedures in place to provide effective and efficient transfer to a higher level of care if needed.

6. FSEDs must follow the intent of the EMTALA statute. All individuals arriving at an FSED should be provided an appropriate medical screening examination by qualified medical personnel, including ancillary services, to determine whether the individual needs emergency care. The ED should provide stabilizing treatment within the capability of the facility, or transfer the patient as necessary, regardless of the patient's ability to pay or method of payment.

7. FSEDs should operate under the same standards as hospital-based EDs for quality improvement, medical leadership, medical directors, credentialing, and appropriate policies for referrals to primary and specialty physicians for aftercare. ■

Report Overpayments to CMS Carefully to Avoid More Trouble

CMS expects hospitals and healthcare systems to report overpayments within 60 days of discovery to avoid false claims allegations, but knowing when and how to report is not always easy. Attention to the process is crucial to avoid creating additional liability or inviting investigations.

A good compliance program will include processes for discovering overpayments, says **Mark Bogen**, senior vice president of finance and chief financial officer at South Nassau Communities Hospital in Oceanside, NY. He notes that overpayments are not necessarily any indication of error, much less fraud, by the hospital because it is common for Medicare to pay and the hospital finds a primary insurer that should have paid. In those cases, the Medicare payment must be returned.

"We have regular audits to detect situations like that and our staff are trained to look for them and respond," Bogen says. "We then review the credit balances report on a monthly basis to look for instances in which the amount credited was greater than the value of the account. Sometimes that is a clerical issue or an incorrect initial valuation of the account, but in most cases it's because you received more cash than you were entitled to."

Those overpayments can be clear-cut, obvious overpayments once identified. Other situations can be more murky, such as whether documentation of the nature of the service provided accurately supports what was billed, Bogen says. When those cases are identified, they are sent to the hospital's compliance group for further investigation. The compliance group and the hospital's internal auditor also proactively search for such cases.

Bogen notes that regulators often work under the impression that their extensive, detailed regulations clearly address every possible situation, when in reality there can be many gray areas. In those situations it is best to take a conservative approach and try to view the case as regulators might, he says.

But at the same time, he says, you can't be so fearful that you return funds unnecessarily.

"The goal I have is staying within the boundaries of compliance, because as CFO I'm usually the first one they start measuring for a striped

EXECUTIVE SUMMARY

Report overpayments to CMS properly to avoid creating liability. Know when reporting is necessary, and report without inviting further investigations.

- CMS requires overpayments to be reported within 60 days.
- Failure to report can result in False Claims Act allegations.
- Document decision-making when deciding not to report.

suit," he says. "But if you get so bullied by the process and so fearful of trying to stay in compliance, you can be legitimately leaving hundreds of thousands, if not millions, of dollars on the table as a result of this battle between black and white and gray."

Invest in Technology

For those cases that are not so clear, South Nassau sends them to the hospital's compliance group for further investigation. If they determine that the services were not appropriately billed, the compliance counsel helps prepare a letter to the fiscal intermediary, Bogen says. The letter would include a listing of the accounts that were identified as overpaid, a dollar amount, and a check to return the funds.

An effective compliance program will require some investment in technology and administrative overhead to detect and respond to overpayments, Bogen says.

"It's also all about the culture. This idea of prompt discovery and investigation is part of our revenue cycle culture," Bogen says. "Regulators say that effective self-reporting is one of the best signs of a good compliance program, so we make that our goal. We have a definitive compliance culture ingrained in our institution, but I struggle sometimes to make sure that culture doesn't overwhelm a system where we all believe there is plenty of gray left in the interpretation of hundreds of thousands of regulations."

Regulators will look to see if you exercised reasonable diligence in determining whether a claim was overpaid, says **Gejaa T. Gobena**, a partner with the law firm of Hogan Lovells in Washington, DC. A particular area of risk lies in determining the scope of overpayments, he says.

"That's an area where providers can get into trouble. They don't do extensive enough review of related or similar claims to determine the extent of the overpayment," Gobena says. "If you have an overpayment that could possibly be linked to others and you choose not to conduct a thorough investigation, you should at least document your reasoning carefully with memos to file. Potential whistleblowers are always lurking in the background, so you want to make sure you document your decision-making later on to show why you did what you did and shouldn't be subject to False Claims Act liability."

> "CMS SAYS IF YOU ARE EXERCISING REASONABLE DILIGENCE AND MOVING FORWARD IN A TIMELY MANNER, THE 60-DAY TIMER WON'T START UNTIL YOU HAVE COMPLETED YOUR INVESTIGATION."

Document Decision-making

The provider's decision whether to report must be clear and defensible, says **George B. Breen**, JD, an attorney with the law firm of Epstein Becker Green in New York City. It is critical to be able to demonstrate and document, through an established process, that there was a reasonable and good faith determination of whether to report an overpayment, he says.

"Providers must have a carefully thought-through process in place to investigate potential overpayments, and that process needs to be delineated before a potential overpayment is identified. The organization needs to be able to demonstrate that it is making efforts to identify any situation in which it has received money to which it is not entitled, and has implemented a process to return those funds determined not rightfully in its possession," Breen says. "While the government may not agree with the entity's assessment that there was not an overpayment to report, that does not mean that liability attaches merely as a result of that disagreement — and any government effort to make that contention should be resisted vigorously."

Recent information from CMS clarifies when the 60-day clock starts running for returning overpayments, says **Peter M. Hoffman**, JD, a healthcare attorney with the law firm of Garfunkel Wild in Great Neck, NY. CMS expects the provider to proceed in good faith when there is credible information suggesting an overpayment, he says, but that moment is not necessarily when the 60-day timer starts running. CMS allows for a period of investigation lasting no longer than six months.

"CMS says if you are exercising reasonable diligence and moving forward in a timely manner, the 60-day timer won't start until you have completed your investigation,"

Hoffman says. "But the time you have for that period of reasonable diligence is, at most, six months from the time you receive credible information, unless there are extraordinary circumstances."

CMS allows many methods for returning overpayments, Hoffman says, including claims adjustments, and returning funds directly to an intermediary.

Decide Who Will Receive Report

When there is an overpayment, the provider must decide to which government entity to report and the mechanism through which to do so, Breen says.

For example, is this a straightforward repayment to a contractor resulting from an error? Or is there a reason to be concerned about potential False Claims Act liability? If so, a report to a U.S. Attorney's Office is the right venue, given that only the Department of Justice can offer a False Claims Act release, Breen says. Caution must be exercised so the report is given to the entity that can address the specific concerns the provider may express as a result of the identification of the overpayment, and for the provider to obtain the greatest potential protection from the report, Breen says.

If there is concern about potential False Claims Act liability, reporting to a contractor will not be sufficient and there is risk of further investigation, Breen says.

"It is important to recognize that reporting and acceptance of a voluntary refund in no way affects or limits the rights of the federal government or any of its agencies or agents to pursue an appropriate criminal, civil, or administrative remedy arising from or relating to the claims subject to the voluntary refund," Breen says. "As a result, it is critical to make the right determination of the entity to which an overpayment should be reported." ■

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Understand Discovery Rule, How to Avoid its Effects

The statute of limitations discovery rule can make or break a malpractice case, so it is important for risk managers to understand exactly how it works and how to respond when plaintiffs try to use it to their advantage.

The discovery rule puts a time limit on how long a patient can wait before filing a malpractice claim, but defining that deadline is not always clear.

Generally speaking, the limitation on the time period a plaintiff patient can file a lawsuit against the healthcare provider hospital is defined by state law, and those laws vary, says **Catherine J. Flynn**, JD, partner with the law firm of DeCotiis, FitzPatrick & Cole in Teaneck, NJ. The discovery rule allows for a "tolling" or delaying of the statute of limitations to a date when a patient knew or should reasonably be expected to know they were injured due to someone's negligence.

The "reasonably expected to know" leaves some room for interpretation, but it is necessary because the patient might not be able to determine that an injury occurred at the time of treatment based on the subsequent medical circumstances involved, Flynn explains.

Courts have held that to be "equitable" or fair to the parties, the statute of limitations should begin to run when the facts presented would alert a reasonably diligent person that they were injured by a healthcare provider, says **Michael A. Moroney**, JD, also a partner with the law firm.

"At times, the patient might not be aware until some time has lapsed between when the condition for which they were treated and a medical problem has arisen as a result of the provider's treatment," Moroney explains. "The court will review the medical circumstance regarding when the injury becomes apparent to

determine when a reasonable patient knew or should have known that someone did something negligently, resulting in the injury."

Date of Discovery Critical

Flynn and Moroney offer this factual scenario that illustrates how the discovery rule works: A patient underwent surgery on Jan. 1, 2014, and an instrument was left inside the operative field. The operating room team (surgeon, nursing staff, surgical techs) did not conduct an instrument count. The patient was discharged and returned later for a post-op visit with the surgeon. The patient began to experience pain, reported it to the surgeon, and an X-ray conducted on July 1, 2014, revealed the retained instrument.

Although the surgery — the negligent act — was performed on Jan. 1, 2014, the "discovery" of the injury was not until July 1, 2014. Under these circumstances, the court would likely hold that the statute of limitation began to run on July 1, 2014; the date the retained instrument was discovered and when a reasonable patient would be aware of the injury resulting from a negligent act. Thus, in a state with a two-year statute of limitations, the patient would have until July 1, 2016, to file the lawsuit.

In many cases, plaintiffs will wait until just before that deadline to file the malpractice lawsuit. That's because they can take their time preparing the case while the defendant hospital isn't even aware there will be a case.

"The strategic advantage to a plaintiff in waiting to file suit until right before the statute of limitations expires is that they can conduct their pre-suit investigation up to that date. They can get their case organized, get their collection of factual information done, and have the case reviewed by experts," Moroney says. "The longer the delay in filing, the greater the chance of prejudicing the defendants as they likely do not know of the impending lawsuit."

Rule Often Hurts Defense

Once suit is filed, the defendant healthcare providers must conduct factual discovery to ascertain when the plaintiff knew or should have known of the injury and negligence, Moroney says. Based on what is discovered by way of depositions and medical records reviewed, a motion to dismiss might be filed based on the plaintiff's lack of diligence in pursuing the lawsuit. For example, if the plaintiff in the scenario above was advised by a different treating doctor that the pain she was experiencing since the surgery was likely due to a retained instrument during the surgery, and the physician's records reveal she was told this on Feb. 1, 2014, a strong argument can be made that the statute of limitations expired within two years of that date, or Feb. 1, 2016, if they waited to file suit, he explains. If the suit was filed after the February date, the patient's case should be dismissed. For this reason, it is not always advantageous for the plaintiff to wait out the expiration of the statute of limitations.

Defendants often are put at a disadvantage by the tolling of the statute of limitations based on the discovery rule, Flynn says. In the time before the lawsuit is filed, records are subject to change or could potentially be subject to destruction. Witness memories are more likely to fade over the course of time. However, the lapse of time also could be used to impeach a plaintiff patient's credibility due to the fading recollection of the events involved — which would be to the defendant's benefit, she notes.

"Risk managers in a hospital setting can be proactive by ensuring that the medical records are secured in those matters where they have some idea that there exists the potential for a suit. Privileged interviews of key facts with witnesses conducted in cooperation with counsel will serve to preserve the recollections of those involved, which might otherwise fade over time to the prejudice of the defense," Flynn says. "These privileged interviews would be helpful to witnesses in the future, should the lapse of time affect recollections."

Knowing your own state's discovery rule statute is important, says **Robert Ryan**, JD, a plaintiffs' attorney with Kuzyk Law in Lancaster, CA. In California, for example, the statute of limitations

EXECUTIVE SUMMARY

The discovery rule can determine whether a potentially costly malpractice case will proceed, so understanding how it works is important for risk managers. Determining when the time period starts is especially important.

- The discovery rule varies from state to state.
- Secure relevant medical records immediately.
- The clock does not necessarily begin with the time of injury.

on filing a malpractice lawsuit is three years, but only one year after the plaintiff discovered or through reasonable diligence should have discovered that he or she was harmed by professional negligence. That means the actual time limit could be one year from the date of injury, if the plaintiff knew about it immediately, or it could be as long as three years.

"Most states have statutes that work in the opposite way, allowing the plaintiff to extend the time period beyond the initial statute of limitations," he says.

No matter the particulars of state statutes, the goal for risk managers will always be to get the clock running as soon as possible, Ryan explains. The discovery rule usually is seen as a benefit to the plaintiff because it can allow a longer time for filing suit than the statute of limitations allows, but Ryan says risk managers can use the rule to their benefit, too.

If the discovery rule is invoked to make a malpractice lawsuit possible beyond the statute of limitations, the defendant hospital should thoroughly explore documentation that might reveal the patient knew, or should reasonably have known, of an injury through professional negligence, Ryan says.

"You want to explore all prior interactions with healthcare professionals that could have revealed their current condition, or information that if a reasonable person followed up on, would have revealed their condition," Ryan says. "You don't necessarily have to prove that someone said to the plaintiff, 'You were injured through professional negligence in your surgery three weeks ago.' If the plaintiff had information available to them that a reasonable person would explore and then realize the injury had occurred, that can be enough to get the clock rolling."

Defense attorneys sometimes use the discovery rule to their advantage when deposing the plaintiff. They will ask when the injury first started bothering the plaintiff, and whether he or she sought medical help. Then the defense attorney might ask if the plaintiff thought from the beginning that the surgery was successful. If the plaintiff replies "no" because he or she experienced constant tingling and pain in one leg afterward, the defense can search through any prior healthcare documentation for evidence that the plaintiff said that to a medical professional.

> "HOW WELL YOU RESEARCH THE CASE AND WHEN THE PLAINTIFF SHOULD HAVE KNOWN OF THE INJURY CAN MAKE ALL THE DIFFERENCE IN THE WORLD."

"If a doctor put that in his notes that the plaintiff said the tingling started after the surgery and was ascribing it, at least subjectively, to the possibility that something had gone wrong, that could trigger the statute running," Ryan says. "The plaintiff now has the responsibility to pursue due diligence to establish whether the condition was the result of professional negligence."

Physicians can be reluctant to document their suspicions, or a patient's comments, that a patient's condition is the result of negligence, not wanting to indict a fellow doctor and also not eager to be called for testimony in a malpractice lawsuit. But Ryan says that approach can be misguided. In fact, risk managers may want to encourage more documentation of such concerns because it can work to the accused physician's favor in many cases, establishing that the plaintiff knew of the injury earlier than claimed, he says.

"Far from harming that earlier doctor, that kind of documentation can be what gets the case thrown out for being too late," Ryan says.

The defense also can interview spouses and other family members to ascertain whether the plaintiff ever ascribed the condition to professional negligence, Ryan says. Recollections that the plaintiff said, "I think they did something wrong during the surgery," or "I think there's something wrong at that hospital," might be used to convince a judge that the statute began running at that date.

"How well you research the case and when the plaintiff should have known of the injury can make all the difference in the world," Ryan says. "It is always a mistake to just accept the other party's assertion as to when the injury was known. You could be proceeding with a costly lawsuit that would have been dismissed if you had looked a little deeper." ■

SOURCES

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Radiology Practice Settles FCA Claims for $8 million

A radiology group in New York has agreed to pay $8 million to settle claims that it knowingly submitted false claims to Medicare and Medicaid. Federal prosecutors claimed that the provider billed for services provided by physicians not enrolled in the government programs and for services not ordered by a physician.

X-rays, Ultrasounds Not Ordered by Physician

Some of the false billings resulted from a policy of automatically performing X-rays and ultrasounds on patients without a physician specifically requesting them.

Attorney General **Eric T. Schneiderman** and United States Attorney **Robert L. Capers** recently announced the settlement with Zwanger-Pesiri Radiology Group, headquartered in Lindenhurst, NY. The radiology group and **Steven Mendelsohn**, MD, will pay $8,153,727 to resolve allegations that from Jan. 1, 2003, through Oct. 26, 2015, Zwanger submitted claims for services provided or supervised by physicians, or at a Zwanger location, that were not enrolled in Medicare and/or Medicaid and therefore ineligible for payment.

"Zwanger falsely claimed that Dr. Mendelsohn, who was a Medicare- and Medicaid-enrolled provider, had, in fact, performed the procedures," the prosecutors said in a statement announcing the settlement. *(The statement can be found at: http://on.ny.gov/2gIrFXB.)*

Prosecutors also alleged that the group submitted false claims to Medicare and Medicaid for procedures, including the automatic performance of certain types of X-rays and the automatic performance of ultrasounds in female patients, even though the procedures were not ordered by a treating physician.

The government investigated after whistleblowers filed a *qui tam* lawsuit under provisions of the state and federal False Claims Acts. The whistleblowers will receive $221,802 from New York's $1.2 million share of the total settlement. ■

UMass Settles HIPAA Violations After Malware Infection

A malware infection cost the University of Massachusetts Amherst (UMass) $650,000 for potential HIPAA violations, and the school must comply with a corrective action plan.

The breach was blamed, in part, on the university's failure to consider the location of its healthcare facilities, which left it without the HIPAA security provided to other sites on campus.

UMass reported to the U.S. Department of Health and Human Services Office for Civil Rights (OCR) on June 18, 2013, that a workstation in its Center for Language, Speech, and Hearing was infected with a malware program that compromised the electronic protected health information (ePHI) of 1,670 individuals, including names, addresses, Social Security numbers, dates of birth, health insurance information, diagnoses, and procedure codes. The university determined the malware was a generic remote access Trojan that infected the system because UMass did not have a firewall in place.

Misclassified Areas

In addition to lacking a firewall, the OCR investigation revealed that the university had misclassified the language center as outside the scope of HIPAA requirements. UMass failed to designate all its healthcare components when hybridizing, OCR concluded, incorrectly determining that while its University Health Services was a covered healthcare component, other components, including the center where the breach of ePHI occurred, were not covered components.

"Because UMass failed to designate the center a healthcare component, UMass did not implement policies and procedures at the center to ensure compliance with the HIPAA Privacy and Security

Rules," according to the OCR report.

Risk Analysis Lacking

The HIPAA Privacy Rule permits legal entities that provide some functions that are covered by HIPAA and some that are not to elect to become a "hybrid entity." To successfully "hybridize," the entity must designate in writing the healthcare components that perform functions covered by HIPAA and assure HIPAA compliance for its covered healthcare components, the OCR report explains.

OCR also noted that UMass did not conduct an accurate and thorough risk analysis until September 2015.

In addition to the monetary settlement, UMass agreed to a corrective action plan that requires the organization to conduct an enterprise-wide risk analysis, develop and implement a risk management plan, revise its policies and procedures, and train its staff on these policies and procedures. The Resolution Agreement and Corrective Action Plan is available online at: http://go.cms.gov/2geW3DL. ■

Caution: Fake HHS HIPAA Email Is Phishing Scam

The Office for Civil Rights (OCR) has issued an alert warning healthcare providers about a phishing scam disguised as an official communication from the Department of Health and Human Services.

Scam artists are circulating the email on fake HHS letterhead with the signature of **Jocelyn Samuels**, OCR's director. It is aimed at covered entities and business associates, appearing to be an official government communication. The email prompts recipients to click a link regarding possible inclusion in the HIPAA Privacy, Security, and Breach Rules Audit Program, but the link directs individuals to a non-governmental website marketing a firm's cybersecurity services.

Be Wary of Email Address

"In no way is this firm associated with the U.S. Department of Health and Human Services or the Office for Civil Rights," OCR states in the alert. "We take the unauthorized use of this material by this firm very seriously."

The phishing email originates from the email address OSOCRAudit@hhs-gov.us and directs individuals to a URL at http://www.hhs-gov.us. OCR points out the subtle difference from the official email address of the HIPAA audit program: OSOCRAudit@hhs.gov.

"Covered entities and business associates should alert their employees of this issue and take note that official communications regarding the HIPAA audit program are sent to selected auditees from the email address OSOCRAudit@hhs.gov," according to the alert. ■

CMS Offers New Settlement for Billing Denials

CMS is offering a new settlement deal for disputed billing denials, offering 66 cents on the dollar in exchange for hospitals dropping their appeals.

CMS outlined the settlement deal on its website and in slides posted online (http://go.cms.gov/2geW3DL). The offer began Dec. 1, 2016, and applies to acute care hospitals and critical access hospitals (CAHs) that have appeals at the administrative law judge (ALJ) and departmental appeals board (DAB) levels.

"CMS has decided to once again allow eligible providers to settle their inpatient status claims currently under appeal," according to CMS. The new offer follows a 2014 deal that was intended to help clear a large appeals backlog. That deal settled about 346,000 disputed claims with 2,022 hospitals, but there still were more than 884,000 Medicare claims at the ALJ level for the federal fiscal year ending September 2015. ■

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HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **What does Rodney K. Adams, JD, a healthcare attorney with the law firm of LeClairRyan, say is a primary liability risk with freestanding EDs?**

   A. They have access to fewer resources than an in-house hospital ED.
   B. They are not staffed at all times by emergency physicians.
   C. They are not allowed to accept ambulance transfers.
   D. They typically have a higher patient volume than an in-house hospital ED.

2. **What does Adams advise regarding the applicability of EMTALA to freestanding EDs?**

   A. It does not apply.
   B. It applies every bit as much as it applies to in-house hospital EDs.
   C. It applies only if the hospital's name appears in the name of the freestanding ED.
   D. It applies only after the freestanding ED reaches a patient volume 50% or more of the in-house hospital ED.

3. **When does the CMS 60-day limit for returning overpayments begin?**

   A. When the overpayment is first suspected.
   B. When an investigation is initiated.
   C. When the investigation is completed, but no later than six months after it starts.
   D. When the overpayment is received.

4. **In most states, when does the discovery rule time limit begin?**

   A. When the injury occurs.
   B. When the plaintiff first knew of the injury or should have known through reasonable diligence.
   C. When the malpractice case is certified.
   D. When the patient obtains an attorney.

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

Untreated Blood Clot Leads to Leg Amputation and $25 Million Verdict

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News: An 18-year-old woman was admitted to a hospital for an asthma attack. At the hospital, she experienced numbness and pain in her leg, and her physicians consulted a vascular surgeon via telephone. Tests revealed a blood clot in the leg, but the vascular surgeon recommended the patient be discharged. He also recommended she come into his office three days later for a follow-up. The patient's condition deteriorated so drastically within those three days that part of her leg had to be amputated. The patient filed suit against the hospital, her primary physicians, and the vascular surgeon. The five-week trial resulted in a $25 million verdict against the surgeon.

Background: In November 2009, an 18-year-old woman was admitted to a hospital following an asthma attack. While undergoing treatment for her asthma attack, the patient informed physicians of pain and numbness in her left leg. Subsequent tests revealed a blood clot in her leg. The hospital contacted an on-call vascular surgeon for advice.

IN THE ENSUING DAYS, THE PATIENT'S CONDITION WORSENED AND HER LEFT LEG EVENTUALLY WAS AMPUTATED BELOW THE KNEE.

Allegedly, there was miscommunication between the vascular surgeon and another physician at the hospital regarding the physician's two-part report. The vascular surgeon ordered additional testing, but ultimately concluded, and communicated to the hospital via telephone, that the patient ought to be sent home. He told the patient to come to his office three days later for a follow-up visit. In the ensuing days, the patient's condition worsened and her left leg eventually was amputated below the knee.

The plaintiff filed suit against the hospital, her primary physicians, and the vascular surgeon. The hospital and primary physicians settled with the patient before the trial began against the vascular surgeon. The surgeon's motion for summary judgment was denied by the trial judge because a genuine issue of material fact existed as to whether there was a causal connection between the surgeon's communication and the later injury. The trial lasted five weeks, during which time the jury was given "a window into what it is like to be a 25-year-old amputee."

The patient's attorney argued that the surgeon should have indicated the patient required immediate care to avoid future injury. Thus, she contended, it was unsafe for the patient to be released.

A point of contention between the parties existed regarding the formation of a doctor-patient relationship through the phone call. The plaintiff's attorney argued that because ED physicians are generalists, the expertise of the specialist plays an important role in the care of a patient, lending itself to the formation of a doctor-patient relationship. The attorney leveraged the emotions of the jury by representing to them that her client was a highly

active and athletic person before this life-altering injury.

In response, the defense argued that the surgeon had only minimal influence on the patient's care, and therefore did not cause her injury. Defendant's counsel contended there was no doctor-patient relationship since the surgeon merely consulted on her case over the phone. Thus, the defense attempted to shift blame onto the co-defendants, who had already settled out of court.

On Oct. 14, 2016, after fours of hour deliberation, the jury returned a verdict in favor of the patient for $25 million. The jury assigned 60% of the liability to the vascular surgeon and 40% liability to the hospital and other physicians, but as the co-defendants previously settled, this portion of liability was moot.

What this means to you: This case demonstrates the need for physicians to proceed with care when communicating with a potential patient. Creating a doctor-patient relationship opens physicians up to medical malpractice; therefore, it is imperative that physicians consciously evaluate communications with patients to determine whether a relationship has been formed. Additionally, like attorney communications with potential clients, it may behoove physicians to communicate that preliminary conversations are not intended to form a professional relationship with the patient. Of course, simply suggesting to a patient that there is not yet a doctor-patient relationship will not suffice if a reasonable person would still conclude that the relationship existed.

A rather large issue in this case was the miscommunication between the primary physician at the hospital and the vascular surgeon. This stemmed from a two-part report the primary physician sent to the surgeon: the preliminary report, which stated the patient's "arterial structures enhance normally," and the addendum, which reported "a possible short segment occlusion, emboli." The vascular surgeon testified that if he had received the addendum, he would have changed his treatment of the patient; i.e., he would have admitted the patient rather than discharging her. This miscommunication illuminates a need for effective and efficient modes of communication within the medical profession. This need ranges from the relatively limited scope of communications between physicians relating to an individual patient to communications regarding interhospital patient transfers. Without a medium to relay information quickly about a patient, hospitals and medical professionals alike expose themselves to negligence claims.

A PHYSICIAN CALLED ON TO CONSULT ON ANOTHER PHYSICIAN'S PATIENT IS DUTY-BOUND TO SEE THE PATIENT BEFORE FORMING ANY OPINIONS.

A physician called on to consult on another physician's patient is duty-bound to see the patient before forming any opinions. To recommend discharging the patient without performing a physical examination can be considered negligent even without a negative outcome triggering actual negligence liability. Additionally, the patient's primary physician, knowing of the venous abnormality described in the patient's test result, should have had a conversation with the consulting physician to understand the rationale behind the decision to discharge the patient. This would also give the primary physician the opportunity to call in an additional expert for a second opinion.

The litigation portion of this case illustrates what can be strong strategy. The majority of the parties to this case settled out of court — only the vascular surgeon remained at trial. This allowed the surgeon to shift blame onto the parties who already settled, presumably easing his financial burden. This method obviously only applies to multiparty litigation, but its utility for defendants has high potential. This method allows a negotiator to leverage the plaintiff's ability to recover from other co-defendants in the out-of-court settlement, then shift blame back onto the settlers at trial, effectively reducing the damages paid. However, settling parties may have to prove to the remaining defendant(s) and the court that settlements prior to trial are made in good faith. Finally, the settlements out of court ought to contain confidentiality clauses, if they are reached in jurisdictions where such a clause would be appropriate.

This case also presents an interesting procedural issue: the choice to pursue a motion for summary judgment (i.e., a motion to convince the court that the discovery and depositions taken thus far in the case prove one side or the other should win, without the need for a trier of fact to resolve remaining

factual disputes). While this step should be at least considered by all defendants during the litigation process, negligence defendants in certain jurisdictions may find these motions to have unacceptably high costs relative to the probability of their success. This is not to say that motions for summary judgment in negligence cases are impossible in all circumstances, but the decision to file such a motion should be made only after serious consideration of the likelihood of its success. Exercising caution in filing motions that have low chances of being granted will cut costs long-term.

Along the same lines as the choice of whether to file a motion for summary judgment is the decision of whether to file an appeal. If the current state of the law supports a conclusion that the vascular surgeon did not form a doctor-patient relationship with the patient in this case, an appeal would likely be very worthwhile. The surgeon here could appeal this decision based in part because the jury did not receive a full instruction on the issue of doctor-patient relationships. Not only could an appeal benefit this particular surgeon (and his insurance provider), but it could also deter patients from pursing negligence actions in similar situations in the future. While appeals are often costly, the long-term net benefit may very well outweigh the upfront costs. ■

REFERENCE

Superior Court of Connecticut, Judicial District of Fairfield at Bridgeport Case No. FBTCV126037222.

Jury Awards $10 Million for Wrongful Death of Newborn

News: On Dec. 26, 2013, a pregnant woman in her mid-20s was admitted to a hospital to give birth to her daughter. During labor, her physician used forceps to attempt to forcibly remove the baby. After three unsuccessful attempts to deliver the baby via forceps, a cesarean section was performed. Because of the force used by the physician during the failed attempts, the baby suffered from hypoxic ischemic encephalopathy caused by skull trauma and was born limp, lifeless, and unresponsive. She was subsequently taken off life support on Jan. 1, 2014.

The patient sued the hospital and physician, alleging their negligence caused the baby's wrongful death. The jury found the physician 95% liable for the death and ordered him to pay $9.7 million. The remainder of the $10.2 million damage award was ordered to be paid by the hospital. Statutory caps on damages will reduce the physician's liability to $1.8 million.

Background: On Dec. 27, 2013, at 7:45 a.m., the pregnant patient was put on oxytocin. The medication was discontinued twice after it was determined the baby was not tolerating it. Just after 8:00 p.m., the oxytocin was resumed and increased five times until 12:19 a.m.

By 9:00 p.m., the fetal heart monitor indicated that the baby was distressed. The physician allegedly discounted the distressed monitoring strips, against the protests of the head delivery nurse. The head delivery nurse informed her supervisor of the situation and they confronted the physician, telling him that the distressed monitoring strips were a serious concern requiring the cessation of oxytocin. The physician allegedly disagreed, and instead ordered a different nurse to increase the oxytocin.

At 11:30 p.m., the fetal monitoring strip indicated that the baby was severely distressed, and the physician determined the baby should be delivered. An expedited delivery was performed at midnight, and in the next 17 minutes the physician unsuccessfully used forceps three times to attempt to forcibly extract the baby. On the second attempt, cracking or crushing noises were allegedly heard. After the three attempts to deliver the baby failed, a cesarean section was ordered, and the baby was born limp and lifeless shortly thereafter. She was taken off life support on Jan. 1, 2014. The baby's father committed suicide in 2015. The patient sued the physician and the hospital, alleging they were negligent in the delivery of her daughter, causing her wrongful death.

At trial, the mother's OB/GYN expert testified that the nurse should have proceeded up the chain of command until the physician ceased the administration of oxytocin. According to the expert, the physician was so reckless in using the forceps that he caused a linear left parietal fracture and depressed right parietal fracture on the baby's skull (one of the fractures depressed into the baby's

brain) as well as a cervical vertebra dislocation/subluxation, which damaged the vertebral arteries. The expert cited the autopsy, which stated that the baby's hypoxic ischemic encephalopathy was caused by skull trauma, and cited literature that prohibits physicians from using their leg muscles when applying the forceps, and that gentle application was critical. The grandmother of the decedent testified that in one of his forceps attempts, the physician put his leg on the bed to gain leverage for pulling.

A video was played at trial of the baby's deceased father, in which he described the painful experience of taking his daughter off life support. He also stated he spoke with the physician after the baby's death and was told that the physician "was very sorry for what happened and everything was going to be OK."

The defense denied any negligence in the delivery of the baby. The physician's expert attributed the traumatic skull injuries to the mother's expulsive efforts over an extensive 29-hour labor, and thus the expert found no negligence despite the rarity of such injuries.

After the three-week trial, the jury returned a $10.2 million verdict in favor of the plaintiff. One of the 10 jurors in favor of the plaintiff was a pregnant mother. That juror stated that the jury attempted to keep emotions out of their decision and focus solely on the accountability of the physician and hospital.

The defense moved for a judgment notwithstanding the verdict, and will appeal the decision of the trial court.

What this means to you: This case demonstrates the need for hospitals to provide an environment for nurses to safely report actions by physicians that fall outside the standard of care. While it may have been the case that this hospital had the internal framework to permit such reporting, it is clear by the nurses' behavior that reporting was not encouraged to the extent necessary to prevent this catastrophe. At trial, the nurses involved in the delivery testified that they asked the doctor multiple times to stop using forceps and move to a cesarean section, to no avail.

Prudent physicians, especially obstetricians, learn very quickly, usually during their residency training, to heed the advice, warnings, and recommendations of experienced senior nurses. Obstetrics is the area of medicine that incurs the greatest risk and highest costs in litigated claims. Many excellent obstetricians leave the profession because of the many hours spent defending their actions. Nursing leadership should have contacted either the physician who directs the OB department or the chief of staff who oversees all physicians. Anyone on staff has the ability to intervene when faced with obvious clinical negligence, and to not do so causes a shared liability.

The Mayo Clinic advised medical personnel to "keep in mind that whenever a forceps delivery is recommended, a c-section is typically also an option." Forceps should be viewed as a last resort and never used multiple times or with physical force. The mother in this case did not want a cesarean section because she feared the scars that accompany the procedure. However, delivery by forceps is a risky procedure; for example, forceps can cause incontinence and internal damage to mothers and skull or facial injuries to babies. Physicians ought to remind patients of these dangers prior to using forceps in lieu of routine procedures, and hospitals should encourage utilizing standard procedures.

It was reported that the physician in this case remains licensed. While the patient is lobbying to have his license revoked, hospitals should avoid employing a physician who strays so far from the ordinary standard of care. This physician's insistence on continued use of oxytocin and multiple forceps attempts showed poor judgment, and the jury punished the physician for it. Background checks must be used to ensure physicians with poor judgment are not rehired, risking injury to future patients and exposing hospitals to unnecessary risks.

Finally, this case illustrates the value of settling cases that involve clear negligence. There was no doubt the physician acted outside the ordinary standard of care; using forceps with enough force to require using one's leg is unquestionably outside the standard of care, especially given the circumstances. This mother may very well have wanted her day in court because she was so outraged by the physician's behavior and decisions, but this case surely generated bad publicity for the hospital. It is a hard argument to make in front of a jury that a doctor is not responsible for the death of a baby in these circumstances. While it is true that the federal and state court rules of evidence typically provide safeguards against the introduction of evidence that could lead a jury to make decisions based on emotion rather than reason, the very nature of this case would make many juries base their decisions on emotion rather than reason. In emotionally charged cases, it may be a wise strategy for medical professionals and hospitals to cut their losses and settle prior to trial. ■

REFERENCE

Jefferson County District Court, 60th Case No. B0195944.