



# HEALTHCARE RISK MANAGEMENT™

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## Diagnostic Errors Tied to Specific Diseases, Showing Focus for Risk Managers

Despite several years of attention from the medical community, diagnostic errors remain one of the largest threats to patient safety. Three disease categories account for nearly three-quarters of all serious harm from diagnostic errors, according to recent research.

Those categories are vascular events, infections, and cancers. The research was led by **David Newman-Toker**, MD, PhD, director of the Johns Hopkins Armstrong Institute Center for Diagnostic Excellence, who says risk managers and clinicians can use that information to more sharply focus their efforts to reduce diagnostic errors.

The research was based on an analysis of a malpractice insurance claims from CRICO's Comparative

Benchmarking System, representing 30% of all malpractice claims in the United States. Previous closed claim studies have indicated that diagnostic-related events are the single largest root cause of medical professional liability claims. An analysis from Coverys, a medical malpractice insurer based in Boston, revealed that diagnostic errors account for 33% of medical professional liability claims and 47% of indemnity payments.

In the Coverys research, most diagnostic errors occurred in outpatient settings, with 24% of

**FOR DIAGNOSTIC  
ERRORS LEADING  
TO DEATH  
OR SERIOUS,  
PERMANENT  
DISABILITY,  
MISDIAGNOSED  
CANCERS  
ACCOUNTED FOR  
37.8%, VASCULAR  
EVENTS FOR 22.8%,  
AND INFECTIONS  
FOR 13.5%.**

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**EDITORIAL QUESTIONS**  
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diagnostic-related claims taking place in the ED and urgent care facilities. Another 35% of diagnostic errors occurred in non-ED outpatient settings, such as physicians' offices or clinics. *(The full report is available online at: <https://bit.ly/2q1mVtz>. For more on the report, see the story in the May 2018 issue of Healthcare Risk Management, available at: <https://bit.ly/2MVWeYE>.)*

## List of Conditions

In the research led by Newman-Toker, diagnostic errors were the “most common, most catastrophic, and most costly of medical mistakes.” For diagnostic errors leading to death or serious, permanent disability, misdiagnosed cancers accounted for 37.8%, vascular events for 22.8%, and infections for 13.5%.

The research also identified 15 specific conditions related to those three disease categories that together account for nearly half of all serious, diagnostic-related harm: stroke; sepsis; lung cancer; heart attack; venous thromboembolism; aortic aneurysm and dissection; arterial thromboembolism; meningitis and encephalitis; spinal infection; pneumonia; endocarditis; and breast, colorectal, prostate, and skin cancers. *(The study is available online at: <https://bit.ly/2NNSj1Z>.)*

There was some difference across patient demographics. In children and young adults, the most serious harms were from missed infections (27.6%) rather than vascular events (7.1%) or cancers (9.1%). Older adults had the opposite experience. Half of the high-severity harm cases related to diagnostic errors resulted in death and the other half caused permanent disability.

## Risk Managers Are Aware

Researchers in diagnostic errors think of risk managers as already part of the solution, Newman-Toker says. Among healthcare professionals, risk managers are among the most in tune with this risk, he says, but this latest research can help them direct their prevention efforts more strategically.

“Risk managers know that diagnostic errors are a serious threat to patient safety, but what they may not know is how many of these errors are tied to the big three: vascular events, infections, and cancers,” Newman-Toker says. “The top five diseases in each of those three big buckets account for nearly 50% of claims related to diagnostic errors. That is more important in some sense than the three big

## EXECUTIVE SUMMARY

Diagnostic errors continue at a significant rate despite recent efforts to reduce them. New research identifies the three most common diagnostic errors and 15 specific conditions.

- The research should help risk managers focus their patient safety efforts.
- The most common claims do not necessarily represent the most common errors.
- Any solution must involve improving clinical decision-making at the bedside.

buckets accounting for three-fourths of the claims, because diagnostic errors are one of those huge problems that can seem infinite.”

Knowing that those 15 diseases figure predominantly in diagnostic errors gives risk managers a roadmap for directing their efforts and resources, Newman-Toker says. He points out that the research focused on serious harm from diagnostic errors, rather than including all diagnostic errors that may be unfortunate but do not result in death, permanent disability, or serious harm.

With limited resources, patients have indicated that they are willing to ask the medical community to focus on diagnostic errors that are devastating, such as the loss or permanent disability of a loved one, rather than things that might cause suffering but are not as catastrophic, he says.

“For risk managers, that means that if you are going to invest in fixing these problems, you should invest in those 15 diseases. They are your top claim sources and they are likely to be your top public health problems,” Newman-Toker says. “Whatever quality improvement programs you support, whatever payment programs and incentives you suggest or research projects you fund, your focus should be on those 15 diseases.”

## Research Looks at Serious Cases

The research emphasizes that diagnostic errors are among the most common and costliest threats to patient safety, says **Paul Epner**, MBA, CEO of the Society to Improve Diagnosis in Medicine.

“There are people who say

diagnostic errors are a problem, but people do get better. even if their condition lasts a week longer until they got the right treatment, whereas this research looks at the very serious conditions,” Epner says.

Sometimes, diagnostic errors can escape the risk manager’s oversight when they are traced to a cognitive error, a clinician’s failure to recognize symptoms, and make the right judgment call, Epner says. Those cases often are diverted to the hospital’s peer review process, which may not directly involve the risk manager.

Some hospitals separate their peer review process and the root cause analyses in such a way that the true effect of diagnostic errors can be lost on the risk manager, Epner says. A key first step is to make sure you are tracking diagnostic errors properly.

“Many health systems don’t even have a category for diagnostic error. Things get tracked in other categories and you can find them if you dig deep enough and know where to look,” he says. “For a risk manager, if you look in your system and you don’t have a category for diagnostic error, then you’re not able to appropriately allocate resources to address the problem.”

## Bias in Closed Claims

Newman-Toker notes that closed claims are a biased subset of all medical errors and harm events. They are not necessarily representative of all such events because only a small fraction lead to multiple claims. Several factors influence that fraction.

However, Newman-Toker says, his research compared the three disease categories accounting for nearly three-quarters of all serious harm from diagnostic errors in malpractice

claims to their prevalence in clinical case series, reports of certain types of medical conditions that are noteworthy but not necessarily related to a malpractice claim.

“It shows the exact same total — three-fourths of all the serious harms in clinical practice are from the big three,” he says. “But it shows a very different weighting schema, with cancer cases much less prominent in clinical series than they are in claims. Vascular events and infections dominate with a greater percentage than cancer cases in clinical case series.”

That means cancer cases are overrepresented in claims, and the other two are underrepresented, he explains.

“That make some sense, because there is a paper trail with cancer cases and they unfold over time, with lots of opportunity to diagnose it. With a lot of vascular events, it’s a one-time thing with one shot at diagnosing it, and then it becomes a he-said/she-said about whether you should have diagnosed it,” Newman-Toker says. “Those suits are harder to bring, so we think a disproportionate number of them do not make it all through the system to become a claim. The lawyers are focusing on the cancer claims they think they can win.”

That issue is important to risk managers, Newman-Toker says, because they have to choose whether their patient safety efforts regarding diagnostic errors should focus on the category most likely to result in liability — cancer — or the issue that probably is a more common threat to patients — vascular and infection issues.

“You wouldn’t want to abandon any focus on cancer, but you might want to rebalance your portfolio in light of this information,” he says.

The causes of diagnostic error

also should be a concern for risk managers, he says. The reasons these errors occur should drive any campaign to reduce them, but Newman-Toker says the medical community often takes a different approach.

“The politically correct thing to do in the diagnostic error world and the risk management world around this issue is to focus on solutions that feel like Mom and apple pie. You get things like better teamwork and more effective communication with patients,” he says. “But when we looked at the actual causes, far and away and in all three big buckets, the leader was clinical judgment. That’s the elephant in the room.”

That means one cannot solve the problem without improving clinical reasoning at the bedside, Newman-Toker says. “You’re spitting into the wind if you’re just trying to just fix communication gaps and teamwork problems. It’s true in other areas that if you fix those things you can solve the problem, like handwashing

and sterile precautions for catheter insertions,” he says. “It works because everybody knew how to wash their hands; they just weren’t doing it. If they have the technical ability to do a thing but lack the motivation to do it, then fixing teamwork and culture will fix the problem.”

## Join National Effort

But the root of diagnostic errors is different, he says. The technical ability to make the correct diagnosis, particularly in cases that are not obvious, is necessary to avoid these errors. That cannot be addressed with teamwork and communication, he says.

“The message for risk managers is you must address clinical reasoning at the bedside as part of your solution strategy. You don’t need to forgo teamwork and culture, but in this case you’re not going to solve the real problem that way,” Newman-Toker says.

Newman-Toker also says it is important for risk managers to be a part of the community addressing this issue, not just locally but on a national level by working groups such as the Society to Improve Diagnosis in Medicine.

“We want risk managers who are committed to this cause. This is a critical juncture where we need everyone to speak with one voice about how important this is,” he says. “Risk managers have been out there in the wilderness, the lone voice crying out. They need to join chorus with the newly woke members of the team.” ■

## SOURCES

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- David Newman-Toker, MD, PhD, Director, Johns Hopkins Armstrong Institute Center for Diagnostic Excellence, Baltimore. Phone: (443) 287-9593.

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# Patients Leaving AMA Require Good Communication to Avoid Liability

**P**atients who leave against medical advice (AMA) can be frustrating to clinicians who want to provide the best care and to risk managers who worry that the patient will blame the hospital if the decision leads to a bad outcome. The best way to avoid potential liability is by ensuring that clinicians understand the need to communicate effectively and document thoroughly.

Involving the patient’s family members may not always be a good idea, and the risk manager should be careful about intervening.

AMA patients account for

0.8-2.2% of discharges at acute care hospitals in the United States, according to information from the Agency for Healthcare Research and Quality. Patients who leave AMA are twice as likely to die within 30 days, according to research from Montefiore Medical Center in New York City. The researchers found that 1.3% of AMA patients died within one month, almost twice the rate of planned discharge patients. (*The study is available online at: <https://bit.ly/2YSjtFs>.*)

A report from the California Office of Statewide Health Planning

and Development showed that in 2017, an estimated 352,000 California ED patients left AMA, an increase of 57% from 2012. Long wait times and other forms of patient dissatisfaction often are to blame for patients leaving AMA. In California, ED wait times are higher than the national average, but in 2017, Maryland, New York, New Jersey, and Delaware had longer wait times, the office reported. (*More information can be found at: <http://bit.ly/325i0hy>.*)

Risk managers look at AMA patients as potential liabilities because they or their families may sue if the

patient suffers from not accepting the offered care. The hospital may have a strong defense if the physicians and staff addressed the AMA patient appropriately. Even then, the hospital can face the costs of defending itself in court, plus the potential damage to reputation if the plaintiffs take their case to sympathetic media outlets.

The hospital's defense will depend on whether clinicians and administrators communicated effectively with the patient, respected his or her wishes, and documented the exchange thoroughly, says **Sharona Hoffman**, JD, LL.M., SJD, professor of law and bioethics, the Edgar A. Hahn Professor of Jurisprudence, and co-director of the Law-Medicine Center at Case Western Reserve University in Cleveland.

Hoffman also serves on the ethics committee of a hospital that addresses AMA patients, finding that their reasons for leaving include financial concerns, distrust of the medical community, disinterest after pain is relieved, and worries about police discovering a warrant for their arrest, among many other reasons.

The first thing for medical professionals to remember is that patients do have the right to leave, even if it clearly is not in their best interest, Hoffman says. Clinicians may try to persuade patients to stay and accept treatment, but ultimately they must respect the patient's

decision unless the patient is deemed legally incompetent, she says.

"People have an absolute right to refuse care and leave the hospital. There shouldn't be liability from that action alone," she says. "There may be costs because the patient will come back sicker, but the patient's decision to leave against medical advice does not have to create liability as long as the hospital responds appropriately."

The question of how much to try to change the patient's mind can be difficult, Hoffman says. Clinicians should not just casually accept a patient's refusal of care, especially when the consequences could be serious or life-threatening, but neither should they insist that the patient stay or browbeat him or her for making a bad choice.

Trying to understand the reason a patient wants to leave often is at the core of these interactions, she says.

"We also advise that you bring in social workers or the ethics committee, because it could just be a trust issue or the person may be cognitively impaired," Hoffman says. "There may be a language barrier, or the person doesn't understand the technical terms the doctors are using. If you bring in someone who can speak in more accessible language, maybe have more time and patience — that can be helpful." A clergy member also may be brought in to help discuss the patient's concerns, she says.

Risk managers should remind clinicians that the patient's decision may be entirely reasonable from the patient's perspective, even if it is not apparent to those who want to provide care. For example, a kidney disease patient may have seen a relative suffer the ill effects of dialysis and chooses to forgo that treatment. It can be difficult for clinicians to accept that choice when the standards of care clearly indicate dialysis, but they are not the ones who must accept the potential consequences, Hoffman says.

Interaction with a patient who wants to leave AMA must be thoroughly documented, Hoffman says, with detailed accounts of what was said to the patient and the patient's response. A cursory "advised the patient to stay but he refused" is insufficient. Liability can arise when the documentation does not show that hospital staff made a reasonable effort to explain the need for care and accommodate the patient's concerns, Hoffman says.

"Ultimately, if the patient says 'I can't afford this anymore' or 'I have kids to take care of,' or whatever the reason is, the hospital should be protected as long as the record illustrates that exchange," she says.

Another difficult issue is just how much to push the patient to change his or her mind, and how long clinicians should spend on the effort. There is no bright line that defines too little or too much, but Hoffman says there should be a reasonable effort to convey the care team's advice and to understand the patient's objections.

However, it is clear that directing a single doctor to engage the patient in one conversation is not enough, she says.

"If they appear to be mentally competent, and you have brought in

## EXECUTIVE SUMMARY

The number of patients leaving against medical advice may be increasing due to financial factors and long wait times. Hospitals can face liability if these patients are not handled appropriately.

- Remember that patients are allowed to decline necessary care.
- Communicate thoroughly about recommended care.
- Use caution when involving family members.

others, like clergy members or social services, to talk to them but they still refuse care, then there is a point at which you have to be satisfied that you have done all you can," she says. "You do want to have more than one conversation and feel confident that they are mentally competent."

Often, there is a gray area in which you are not sure if the patient is mentally impaired. In those cases, you may have to talk to family members to get a better assessment of the patient's ability to make decisions, she says. They can sometimes be difficult to track down. Involving family members may introduce new complications to the situation, she says.

Particularly when the patient appears competent to make care decisions, it can be a mistake to involve family members, Hoffman says.

"Involving family members can actually complicate things," she

explains. "You might have a Jehovah's Witness who absolutely refuses blood transfusions, but the family members don't agree with the religion. That can lead to a big hullabaloo that complicates everything. Even if the family members are on your side, so to speak, the competent patient has a right to refuse care."

Similarly, it might not always be a good idea for the risk manager to get involved, Hoffman says. The risk manager should be involved if, for example, family members are disagreeing with the patient's decision and threatening to sue the hospital if the patient is allowed to leave. But in other situations in which the patient is simply not agreeing to the recommended course of care, it might be best for the risk manager to stay out of it, she says.

The risk manager may, consciously or unconsciously, urge the patient to

do what minimizes the potential liability for the hospital, she says. That is not necessarily in the best interest of the patient.

"We often find that involvement by the risk manager complicates matters," Hoffman says. "If they do get involved, they should remember that there are legitimate reasons for patients to decline care and leave AMA. The risk of liability should not always be the first and foremost concern when it comes to respecting a patient's decision." ■

#### SOURCE

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## Legislation Aimed at Surprise Billing Could Bring Liabilities

States and Congress are working to address the "surprise billing" that can hit consumers after a hospital stay or other care in which they learn that they owe thousands of dollars for services they thought were covered by insurance. The legislation is popular among consumers but could create significant potential liabilities for hospitals and health systems.

Reducing the risk of those penalties and other consequences will require the risk manager to work with multiple departments within the organization to prevent surprise bills from going out to patients, says **Amy Andersen**, healthcare industry lead with North Highland Worldwide Consulting in San Francisco.

Multiple states have enacted

legislation to restrict or prohibit surprise billing, with various penalties. The National Academy for State Health Policy says the state legislation usually employs one or more these policies: prohibiting balance billing in certain circumstances such as when a consumer had no other provider choice; holding consumers harmless when insurance carriers and providers dispute a balance bill; setting reimbursement standards for providers in the case of balance bills; requiring providers and carriers to provide accurate and updated information about the provision of in- and out-of-network services; and establishing a balance billing dispute resolution process, facilitated by the state or an independent entity. (*More*

*information on the state legislation is available online at: <https://bit.ly/2ZQqPdK>.)*

### Federal Law Likely

One bill moving through the Senate is the Lower Health Care Costs Act, which would impose penalties on hospitals and health systems that send surprise bills. It also would cause physician and hospital payment rates to fall as much as 20% on average nationally, according to a study by the Congressional Budget Office.

Known within the healthcare community as balance billing, these bills usually involve ED visits, out-

of-network physicians at in-network facilities, and ambulance services, Andersen says.

“This is not a new problem. There’s been a lot of finger-pointing when the issue is raised because providers depend on the revenue. Payers say they are justified because their policies clearly say that services above a certain threshold are the responsibility of the patient,” Andersen explains. “States have enacted their own laws, and now there is bipartisan consensus that this is something that should be addressed.”

Failing to comply with state and federal legislation on surprise billing could result in large fines, but Andersen notes that a potentially worse consequence is the scrutiny that could come with any investigation.

“Surprise billing is a strong consumer issue. If you are not complying, that could be damaging to your brand in the community,” Andersen says. “Even worse is having the regulator come in to audit your compliance. Once the regulator comes in to do a review, they can look at anything. Once a regulator starts sniffing around at your systems and processes, then you can get into corrective action plan hell.”

The initial compliance failure on billing could lead to a series of corrective action plans that last months or years, requiring many more additional steps and allowing the regulator to come in regularly for reassessments.

Risk managers should start formulating plans for complying with surprise billing legislation, Andersen advises. Each organization must determine what state legislation may apply, and soon will have to assess the effect of federal laws.

A likely first step is to start providing out-of-contract estimates and statements to patients before provision of medical services, she says. That could require a significant system and process update.

“This could be super complex to determine that individual’s contract, under what insurer or payer are they seeking care, and based on that specific coverage what are the levels of care that will be provided by the payer, and the difference between that and what the provider expects to be paid,” Andersen says. “The difference is the cost estimate that must be provided to the patient prior to receiving care. I can’t stress this enough to say that it is not enough to provide the information. Because this is regulatory, there must be documentation that it occurred in a timely fashion.”

Andersen notes that compliance will be especially important with Medicare enrollees because there is a higher bar for what must be communicated to them and through what processes.

“It sounds like a super simple thing to say ‘People should know what they might have to pay, so let’s get that information to them so they can make an informed decision,’”

Andersen says. “But when you look at what they’re potentially liable for, how to communicate that to them, how to document that you communicated it, it’s not such a simple thing to accomplish.”

## Involve Multiple Departments

Risk managers should note that complying with surprise billing legislation will not be a matter of reminding one department of the potential liabilities and letting them take the necessary steps, Andersen says. Compliance will require the cooperation of multiple silos within the organization, she says.

Most organizations will need to involve all the departments involved with claims, eligibility, communications, grievance, arbitration, and billing, she says.

Andersen notes that healthcare organizations are lobbying to minimize the scope and financial effect of surprise billing legislation. However, legislation protecting consumers enjoys bipartisan support and is gaining momentum.

“I don’t think the train is going to stop. We will see more of surprise billing legislation. The only question is exactly what it will include, what the penalties will be,” she says. “I think risk managers are critical elements in responding to this legislation and this is something that should be on the radar of the CEO, CFO, and chief counsel. This requires an organizational commitment.” ■

## SOURCE

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## EXECUTIVE SUMMARY

Legislation aimed at curbing “surprise billing” for healthcare costs could bring significant liabilities for hospitals and health systems. Risk reduction will require a multipronged effort within the organization.

- Several states have passed legislation.
- A federal law is likely, with bipartisan support.
- Noncompliance could invite scrutiny that leads to corrective action plans.

# 'Second Victim' May Not Be the Best Approach to Adverse Events

In the effort to more effectively and humanely address adverse events in healthcare, one common method has been to consider the clinicians involved the “second victims.” But is it time to stop that practice?

This terminology has been used to highlight the effects on clinicians who are part of a patient’s adverse outcome, signifying that in addition to the patient being a victim, the doctor or nurse also can be traumatized. While well meaning, the “second victim” terminology may produce detrimental effects, says **Melissa Clarkson**, PhD, MDes, MA, assistant professor in the Division of Biomedical Informatics at the University of Kentucky in Lexington.

The intention behind the phrase is legitimate, Clarkson says. She does not doubt that clinicians can suffer greatly after a harm event, and she strongly believes that they deserve recognition and assistance. But the terminology is wrong, she says.

“It became apparent to me over the years that patient advocates are uncomfortable with this term. But at the same time, I was seeing it used more and more and more,”

Clarkson says. “Healthcare providers would come out of training sessions about harm events and suddenly they’re using this term all the time.”

Clarkson recalls once questioning the use of the term with a nurse, who countered that it was appropriate and expressed strong beliefs about how nurses were the second victims in tragic circumstances.

“There’s something about that term that puts people in a mindset that leads down a path that is not consistent with patient safety,” she says. “I’ve had experiences where doctors or nurses were passionately defending how they are victims, to the point where I said ‘You have taken this to a level that is not appropriate.’”

Those experiences, combined with concerns from patient advocates, led Clarkson to write an editorial for a medical journal questioning the use of “second victim.” The article prompted some strong feedback from readers who thought she was minimizing the potential effect of tragedies on doctors and nurses. (*An abstract of the editorial is available online at: <https://bit.ly/2TM1ttB>.*)

Clarkson says the issue is more nuanced than some people think, and that the term comes with more effects than the desired outcome of recognizing healthcare workers’ trauma.

“We’re not saying that healthcare providers should just suck it up and not get help. We’re saying that viewing this through the lens of being a victim may unconsciously remove from the healthcare professional the responsibility for safety,” Clarkson says. “We think of victims of sex trafficking and domestic violence, and with those victims it is not on them to shape the situation they’re in. But with healthcare providers, that term ‘victim’ is just not appropriate.”

The terminology has even expanded to call healthcare organizations the third victim, which Clarkson says is a bad trend. “It’s out of control. People need to take a step back and remember that there is a responsibility in healthcare for patient safety, at the organizational level and the individual level,” she says. “When you bring the concept of victim into that, it messes up that line of responsibility.”

But people who use the term “second victim” are not forgoing all efforts at patient safety. If the term helps some doctors and nurses feel better, then what is the harm? Clarkson says the problem is all in the mindset that it encourages.

“A victim is passive, and we don’t have an expectation that victims address the situation they are in. It’s not their responsibility. We expect society as a whole or someone else to fix the situation that makes them a victim,” she says. “That mentality

## EXECUTIVE SUMMARY

The practice of calling clinicians the “second victims” in adverse events may be misguided. It could send the wrong message to both clinicians and patients.

- The term is meant to recognize the emotional impact of adverse events on doctors and nurses.
- It may run counter to patient safety culture.
- “Second victim” may cause some healthcare providers to avoid needed assistance.

goes against the culture of patient safety, which encourages people to be proactive and step up.”

Clarkson also says physicians, more so than other clinicians, tend to bristle at the “victim” label. If a care-for-the-caregiver program is promoted as being for second victims, physicians — and any other healthcare professionals who shy away from the term — may be reluctant to attend and get the help they need, she says.

It is not common to call the patient who was harmed the “first victim,” Clarkson notes. That is because the word connotes helplessness and being the subject of someone else’s

harmful actions; yet it is acceptable to use the same terminology with healthcare providers, she says.

“We don’t do programs for patients telling them they might be a victim of an error while they’re here in the hospital, and we don’t talk about injured patients as the victims of whatever happened,” Clarkson says. “But we’re educating care providers to see themselves as victims. There’s an incredible disconnect there.”

As an alternative, Clarkson favors plain terminology such as “physician involved in a harm event” or “nurse involved with an error.” Others have suggested the term “traumatized

caregiver,” which she says may sound extreme but still is better than “second victim.”

“There are different options and they all can work as long as you’re not using the victim terminology,” Clarkson says. “It’s not appropriate to teach people to see themselves as victims when they actually are responsible for ensuring patient safety.” ■

#### SOURCE

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## DOJ Specifies What Can Earn Credit in False Claims Investigations

The Department of Justice (DOJ) has released formal guidelines on how it will award credit to entities for cooperating with False Claims Act (FCA) investigations, giving healthcare organizations under scrutiny a way to reduce the potential effect.

The guidelines formalize discretionary practices already in use by investigators, outlining these three ways in which entities can earn cooperation credit in FCA investigations:

- Voluntarily self-disclose misconduct giving rise to FCA violations;
- Cooperate with existing government investigation;
- Implementing meaningful remedial actions.

The guidelines state that entities will qualify for credit by voluntarily disclosing additional misconduct even after an FCA investigation is initiated. *(The guidelines are available online at: <https://bit.ly/2Vvk12Jd>.)*

A key message in the guidelines is that the government expects entities under investigation to actively aid investigators if they want credit for cooperation, says former assistant U.S. attorney **Jason Mehta**, JD, now an attorney with Bradley in Tampa, FL.

“Simply responding to subpoenas and producing records in response to requests is not considered cooperation,” Mehta says. “They’re looking for affirmative self-disclosure. If you see something problematic, you disclose it to the government, identify individuals involved with it, and institute remedial actions.”

However, there are risks involved in affirmatively disclosing malfeasance, Mehta says.

“Healthcare practitioners should understand the government’s framework for awarding credit but avail themselves of the advice of legal counsel before taking any of these affirmative steps,” Mehta says.

DOJ explains in the guidelines that cooperation can take many forms. It provides a list of examples that could earn credit, including the following:

- Identifying the involved or responsible individuals;
- Disclosing relevant facts and evidence;
- Preserving, collecting, and disclosing relevant documents and information relating to their provenance beyond existing business practices or legal requirements;
- Identifying people who may be aware of the misconduct, including an entity’s operations, policies, and procedures;
- Making employees available for meetings, interviews, examinations, or depositions.

#### SOURCE

- **Jason Mehta**, JD, Bradley, Tampa, FL. Phone: (813) 559-5532. Email: [jmehta@bradley.com](mailto:jmehta@bradley.com).

# False Claims Act Ruling Is a Win for Healthcare Providers

Risk managers received good news from a recent ruling in a False Claims Act (FCA) case that means that relators alleging medically unnecessary treatment must provide specific evidence to prove their case.

The ruling came in an Illinois federal court that entered summary judgment in favor of skilled nursing facilities and a therapy provider in a Medicare fraud case. The relators alleged that the defendants furnished medically unnecessary therapy. (*The case is available online at: <https://bit.ly/31sqnmn>.*)

The court determined that in such cases there must be a clear showing of why a particular episode of therapy was improper for a certain patient, explains **Daniel T. Hartnett**, JD, an attorney with Clark Hill in Chicago and one of the lead attorneys for the defendants. The court also said that the relators must link that improper treatment to a particular claim tendered to Medicare.

The relator was a former corporate nurse based at a skilled nursing facility in Long Grove, IL. He alleged in a 2010 lawsuit that the facility and two other skilled nursing facilities and a therapy provider committed fraud by providing therapy that was medically

unnecessary. They maximized the number of days billed to Medicare at the highest possible reimbursement level, the nurse claimed.

An expert for the relator estimated damages to the government at more than \$120 million, but the judge granted the facilities' motions for judgment on all claims because the relator did not provide evidence showing the medically unnecessary care was provided to a particular patient.

"The lesson for healthcare organizations is that charting hygiene has to be at top of mind at all times. Bookkeeping discipline also has to be a top priority," Hartnett says. "Those are hardly startling revelations, but they are so critical because in these cases some insider with knowledge of how the organization does business is painting something as improper. You don't have someone who is not knowledgeable, and they can make allegations that can be quite hurtful."

## Keep an Eye on Little Data

The case also illustrates that even in the era of big data, sometimes the little data matter the most, Hartnett says. The relator made serious allegations, and the statistical expert

estimated a substantial defrauding of the government, but Hartnett and his co-counsel insisted that the relator prove the most basic facts of the case.

The relator claimed that the nursing facility provided therapy to the patients that was not medically necessary. He did not claim that the facility just billed for the therapy without providing it, notes **Mason N. Floyd**, JD, also an attorney with Clark Hill in Chicago.

"The relator in this case tried to look at the data as a whole, doing a statistical analysis of all the days and minutes of therapy that we billed Medicare for. In the end, that proved insufficient because he could not point to a single instance of therapy that was not medically necessary or a single bill to Medicare that was false," Floyd says. "Instead, he wanted to do a 30,000-foot level analysis and tell the court these data were so out of line that it exemplifies a pattern of fraud. The court said 'no, you still have to get down to the little data — the claims, the charts.' That should be very reassuring to healthcare facilities."

Hartnett notes that the case could have turned out very differently for the skilled nursing facilities if the judge had not insisted on specific findings of medically unnecessary care tied to specific patients and bills.

"The exposure in these False Claims Act cases is so immense that these cases tend to become something of a blood sport," he says. "Once past the motion to dismiss, there is no easy exit point without paying immense amounts of money."

Good risk management is the key

### EXECUTIVE SUMMARY

A recent ruling in a False Claims Act Case affirms that relators must be specific with claims. Summary judgment was issued because the relator did not tie allegations to particular patients and bills.

- The case shows the need for good chart hygiene.
- Sometimes "little data" are as important as "big data."
- Bookkeeping discipline is critical in billing cases.

to defending these cases, Hartnett says.

“I know it’s expensive and it requires lots of repetition when you’re educating your frontline staff, but if you are ever called to answer for the care you billed Medicare for,

you’ll be glad you took the necessary steps to document the medical necessity of care,” Hartnett says. “This judgment should reinforce the sound risk management processes that facilities should already have in place.” ■

## SOURCES

- **Mason N. Floyd, JD**, Clark Hill, Chicago. Phone: (312) 360-5032. Email: mfloyd@clarkhill.com.
- **Daniel T. Hartnett, JD**, Clark Hill, Chicago. Phone: (312) 360-5020. Email: dhartnett@clarkhill.com.

# Opioid Order Should Ease Physician Discretion

**A**n order from the judge overseeing the National Prescription Opiate Litigation should make it easier for healthcare providers to comply with best practices designed to reduce opioid abuse.

U.S. District Judge Dan Polster entered an order confirming that the three largest pharmacy benefit managers (PBMs) in the country either have or will implement changes designed to curb the overuse of opioids. They will comply with the CDC’s Guidelines for Prescribing Opioids for Chronic Pain.

The order was in response to a motion from Webb County, TX, filed in September 2018, addressing the fact that PBM standard national offerings were not consistent with the CDC Guidelines, even though PBMs had endorsed the guidelines as the standards of care. (*The court order is available online at: <https://bit.ly/33jSCW8>.*)

Webb County co-counsel **Kevin Sharp, JD**, managing partner of Sanford Heisler Sharp in Nashville,

TN, and a former judge on the U.S. District Court for the Middle District of Tennessee, says, “The catalyst for filing this motion was that the CDC had come out with these guidelines years ago and the PBMs weren’t following them, even though they are in a very good position to influence opioid use and curb misuse. Judge Polster’s goal is to solve this problem to the extent that the judicial process can solve it, and recognized that PBMs are part of the triumvirate controlling opioids.”

The order outlined steps taken by the PBMs Caremark, Express Scripts, and OptumRx to promote restrictions on the strength and supply of opioid drugs prescribed to patients, the availability of medication-assisted treatment, and heightened restrictions on opioid prescriptions for minors.

Prior to PBM compliance with the guidelines, physicians sometimes found it difficult to prescribe alternatives to opioids or take other measures to reduce abuse because the

PBM practices got in the way, Sharp says.

Providers have been encouraged to think before prescribing opioids, as the CDC guidelines do not mandate anything and leave individual healthcare decisions to the physician.

“This order reaffirms the CDC guidelines. PBMs had such ability to control the thought process of providers with how things get paid, if things are on a formulary, where they are on the tiers in a formulary,” Sharp says. “By having them acknowledge the CDC guidelines, it gives providers more options about prescription options that will be paid for and lets them comply with the best practices without PBMs getting in the way. There should be relief that there are options now that they can get paid for.” ■

## SOURCE

- **Kevin Sharp, JD**, Managing Partner, Sanford Heisler Sharp, Nashville, TN. Phone: (615) 434-7001. Email: ksharp@sanfordheisler.com.



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## CE QUESTIONS

- 1. In what category are the most common diagnostic errors leading to death or serious, permanent disability?**
  - a. Misdiagnosed cancers
  - b. Orthopedic conditions
  - c. Genetic conditions
  - d. Birth defects
- 2. According to research from Montefiore Medical Center in New York City, how much more likely are patients who leave against medical advice to die within 30 days compared to other discharged patients?**
  - a. Twice as likely
  - b. Half as likely
  - c. One-third as likely
  - d. Three times as likely
- 3. What does Sharona Hoffman, JD, LLM, SJD, advise about including family members in the discussion with patients who want to leave without treatment?**
  - a. It is always a good idea.
  - b. It is never a good idea.
  - c. It is prohibited by privacy laws.
  - d. It may complicate the situation if they disagree with the patient's choice.
- 4. What is one possible consequence of not complying with "surprise billing" legislation, according to Amy Andersen, healthcare industry lead with North Highland Worldwide Consulting?**
  - a. Increased scrutiny from regulators, which may lead to corrective action plans
  - b. Returning overpayments to payers
  - c. Lawsuits from patients and families
  - d. Withholding Medicare payments



# LEGAL REVIEW & COMMENTARY

EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

## Gastroenterologist's Negligent Procedure Results in Patient's Death, \$4.8 Million Verdict

By **Damian D. Capozzola, Esq.**  
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*President and Founder, Healthcare Risk Services*  
*Former Director of Risk Management Services*  
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Los Angeles

**N**ews: A patient underwent gallbladder removal surgery. When she experienced gastric pain after the procedure, she visited a different physician who performed an endoscopic retrograde cholangiopancreatography to remove what the physician thought was a stone in the patient's bile duct. Following the second procedure, the patient developed acute pancreatitis and suffered sepsis due to severe necrosis, which resulted in the patient's death.

The patient's husband sued, and a jury awarded \$4.8 million to the patient's family and estate. The physician appealed, claiming that the weight of the evidence did not support the verdict. An appellate panel upheld the verdict, finding that there was no dispute the patient developed pancreatitis because of the physician's procedure.

**Background:** In 2012, a patient suffering from intense abdominal pain caused by gallstones underwent gallbladder removal surgery. After the surgery, the patient experienced gastric pain and sought a consultation with a different physician than the one who performed the gallbladder removal. The second physician performed an endoscopic retrograde cholangiopancreatography (ERCP). It is

performed to diagnose and treat conditions of the pancreas or bile ducts, and is commonly employed when a patient reports abdominal pain, jaundice, or when an ultrasound or CT reveal stones or a mass in the affected organs. Complications from gallbladder surgeries often require an ERCP to evaluate and treat.

In this case, the physician performed the ERCP to remove what the physician believed was a stone in the patient's common bile duct. Following the ERCP, the patient developed acute pancreatitis and was transferred to a local hospital for treatment. Unfortunately, the patient's condition deteriorated quickly and significantly. Despite multiple procedures and surgeries, the remedial efforts were unsuccessful. The patient died five months after the initial gallbladder removal, and three months after the ERCP. An autopsy determined that the patient's cause of death was sepsis due to severe necrotizing pancreatitis.

The patient's husband filed a medical malpractice action against the physician who performed the ERCP and the physician's employer, alleging the physician performed the procedure negligently and perforated the patient's pancreatic duct when attempting to access the common bile duct. The plaintiff presented expert testimony from a gastroenterologist who reviewed the images taken during the ERCP and testified that the physician had punctured the patient's pancreas. The plaintiff's expert also opined that the physician was negligent for failing to place a pancreatic stent at the time of the procedure and did not adequately hydrate the patient after diagnosing the pancreatitis. According to the expert, the patient would have survived if proper procedures were followed, even with the

FOLLOWING THE SECOND PROCEDURE, THE PATIENT DEVELOPED ACUTE PANCREATITIS AND SUFFERED SEPSIS DUE TO SEVERE NECROSIS, WHICH RESULTED IN THE PATIENT'S DEATH.

pancreatitis diagnosis. The defendants denied liability.

A jury found that the physician's treatment fell below the standard of care and awarded \$2.52 million to the patient's family for her pain, suffering, and loss of society, and \$2.26 million to the patient's estate for her pain and suffering, emotional distress, and medical expenses. The defendants appealed, arguing the jury's verdict was against the weight of the evidence. However, an appellate court panel upheld the full award and ruled that there was no dispute the patient developed pancreatitis because of the ERCP. The court noted that the plaintiff's expert physician's testimony supported the verdict.

**What this means to you:** In this case, one of the most critical lessons is the importance of experts in medical malpractice cases. Since medical malpractice cases almost always involve issues beyond the knowledge of laypersons, experts play a vital role in the litigation process and in convincing a jury that a physician or care provider satisfied, or failed to satisfy, the applicable standard of care. An effective expert can explain persuasively the applicable standards in a manner jurors can understand easily, and how the care provider's actions met the standard. Picking the right expert to assist in the defense of a medical malpractice action is equally crucial. Physicians and care providers should work closely to evaluate prospective experts. Similarly, once the expert is selected and retained, physicians and providers, along with their counsel, can evaluate the patient's claims and discuss the applicable standards of care that the plaintiff claims were not satisfied.

Here, the plaintiff's expert opined that the defendant physician's actions fell below the standard of care not only because of the perforation dur-

ing the procedure, but also because he failed to hydrate the patient and place a stent at the time of the procedure. Perforations during surgical procedures may or may not be an inherent risk of a procedure, depending on the specific procedure involved. Pancreatitis and perforations are known risks for patients undergoing an ERCP. Physicians and care providers must inform patients about such risks — as well as prepare for the possibility of these developments. This is one of the reasons why the physician in this case committed malpractice, according to the plaintiff's expert: The defendant could have saved the patient's life had a pancreatic stent and adequate hydration been provided.

Clinical expertise is important for physicians to avoid the need for experts during a trial. Physicians and surgeons must continue to upgrade their skills and keep abreast of the latest updates based in current research and trends in care as published in professional journals. Medical staffs must follow peer reviewed standards to assure their members maintain the established standards of care and incorporate new changes in a timely manner. Regardless of how common or routine a procedure may be to the physician, the variables with which each patient can present must be taken into consideration, especially if previous interventions performed by a different provider did not go well. If proctoring is recommended, it must be provided and monitored. In instances where experts are not available for proctoring, consultation, or peer review, outside resources must be provided, either on site or remotely. Each physician's reputation and the reputation of the organizations they work for and/or in is based on the performance of each individual. Barriers to open

communication, a reluctance to seek out consultation, and the drive to practice with the assumption that the practitioner can be independent of the aforementioned puts them in jeopardy at the very least and at the worst puts their patients at extreme risk.

While appeals always are a possibility, the process is costly, time-consuming, and often unsuccessful. Appellate courts employ deferential standards, especially for factual issues, as trial courts and juries are better suited to evaluate witness testimony and credibility. Here, the appellate court found that the evidence was not "overwhelmingly" in the defendants' favor such that "no contrary verdict" could stand.

Appellate courts work from written records and transcripts of the proceedings, which do not facilitate evaluation of credibility. Thus, if a jury determines that a witness's version of events is suspect, an appellate court is unlikely to change that or the results of such a determination. Physicians and care providers should consider these facts when evaluating whether to pursue an appeal. In the face of an adverse verdict, it may be more prudent to forgo an appeal; such an option can be leveraged further by agreeing with the plaintiff to forgo the appeal in exchange for the plaintiff agreeing to waive certain legal costs such as court filing fees, which the prevailing party often can recover. If the appeal is pursued and unsuccessful, the prevailing plaintiff inevitably will seek those in addition to the appellate costs, adding even more expense to the adverse verdict. ■

## REFERENCE

Decided on July 5, 2019, in the Appellate Court of Illinois, Fourth District, Case Number 4-18-0547.

# Misreading of Test Results Causes More Harm, Results in \$3.5 Million Verdict

**N**ews: A patient was referred to a hospital's heart and vascular institute by his family physician due to a family history of coronary artery disease. The patient underwent testing, including a heart monitoring test known as a stress ECG, to evaluate his condition. The ECG result was abnormal, but the cardiologist and hospital failed to properly read the tests and inform the patient or his primary care physician of the abnormalities. Two years later, the patient was diagnosed with nonischemic cardiomyopathy.

The patient sued the hospital and cardiologist, alleging that the failure to report the abnormal test results prevented timely treatment of the patient's heart disease, increasing his risk of harm and worsening his medical condition. The defendants denied liability. A jury found in favor of the plaintiff and awarded \$3.5 million. The hospital appealed, but an appellate court affirmed the verdict.

**Background:** In 2014, a 47-year-old patient, who had a family history of coronary artery disease, was referred to a hospital's heart and vascular institute. The patient underwent a stress ECG and the results were abnormal. However, the cardiologist did not accurately read the test results, and instead reported to the patient's primary care physician that the overall impression of the ECG was normal except for poor patient physical conditioning.

Approximately two years later, the patient presented to the same hospital's ED with shortness of breath, leg swelling, and a persistent cough. Another ECG revealed profound abnormalities, including worsened left ventricular dysfunction

with ejection fraction of 10-15%. The patient was diagnosed with nonischemic cardiomyopathy and underwent cardiac catheterization. He was placed on a wearable defibrillator "life vest."

The patient filed a medical malpractice suit against both the hospital and cardiologist, alleging that the misreading of the initial ECG and the failure to report the abnormal test results prevented the patient's timely treatment of the medical condition, and that it increased his risk of harm. The patient settled his claims with the cardiologist prior to trial, but the litigation against the hospital proceeded to a jury trial. During trial, the hospital's director of cardiology services testified that the hospital's internal policy calls for an ECG report to be signed by a physician or recorded within 72 hours of a test; if not, it would be flagged for a sonographer to request a cardiologist to interpret the study to send it out. The director testified that it was the hospital's responsibility to send the patient's complete ECG report to the patient's primary care physician.

An expert witness in internal medicine and cardiology testified for the patient. The expert opined that a "normal" ejection fraction is 60-65% and that the lack of follow-up care for the patient could have allowed his condition to worsen. The patient's 10-15% ejection fraction at the time of the second ECG revealed that the heart is barely moving, according to the expert, and the cardiologist's failure to evaluate the ejection fraction, failure to communicate the ECG report, and failure to sign the ECG report all fell below the standard of care. The hospital argued that the

patient failed to present sufficient expert testimony that it deviated from the standard of care, or that any deviation caused the patient's injury.

A jury found that the hospital and cardiologist's conduct fell below the applicable standard of care, and that their negligence caused the patient's harm. The jury attributed 80% of the fault to the cardiologist and 20% to the hospital, and awarded the patient a total of \$3.5 million. The hospital appealed, arguing the patient did not submit sufficient evidence to support the verdict. An appellate panel rejected the appeal and affirmed the verdict.

**What this means to you:** This case illustrates the importance of expert witnesses. Another lesson from this case is the varying standards that courts and juries apply when evaluating the sufficiency of such evidence. This case focused on an alleged "increased risk of harm," which is less common than a typical medical malpractice action involving a patient directly suffering harm. The patient here presented expert witness testimony concerning ejection fractions and the course of treatment that the expert contended satisfied the standard of care in such circumstances. The defendant hospital argued that this evidence was insufficient as a matter of law to support the jury's significant verdict.

According to the appellate court, this state's law provided for a "relaxed standard" for medical malpractice cases that allege an increased risk of harm. It found that the patient's testimony, including the expert testimony, was sufficient to satisfy that relaxed standard. The appellate panel determined that the jury was properly

instructed to resolve the question about whether the hospital's acts or failures to act were a substantial factor in causing the patient's harm by a preponderance of the evidence standard. These legal standards are important and may factor into a care provider's evaluation of a medical malpractice action; a patient who is required only to prove a "relaxed" standard will have an easier time convincing a jury about complicated issues or contentions, especially those raised by conflicting expert testimony. It is important to consult with legal counsel when evaluating a medical malpractice action to understand the applicable standards and to weigh the risks of confronting such standards at a jury trial.

On a related point, physicians and care providers can avoid the prospect of a multimillion-dollar adverse verdict by engaging in methods of alternative dispute resolution with the goal of settling the case prior to trial. Here, the defendant cardiologist settled before trial. Although the settlement amount was not disclosed, it is extremely likely that the amount was less than the amount awarded by the jury. At trial, the jury attributed 80% of the fault to the cardiologist and 20% to the hospital. Many states use a method of joint and several liability where if two parties are found liable, the injured party may recover the entire amount from either party, and the two liable parties may seek contribution based on the percentage of fault between each other. Thus,

in this case, the patient could have recovered all \$3.5 million from the cardiologist, and the cardiologist then would have been able to seek contribution of \$700,000 from the hospital — leaving the cardiologist responsible for \$2.8 million.

Alternative dispute resolution, such as mediation or arbitration, offer options to facilitate settlement and reduce any final adverse award.

Along with these important legal principles, a lesson from this case is the importance of reporting and documentation. In this case, liability arose in part because the cardiologist failed to communicate the full ECG report and failed to sign it. Thus, beyond the misreading of the report, the lack of communication constituted actions below the standard of care. Physicians and care providers must ensure that diagnostic results are forwarded to the appropriate recipients, including recipients outside the hospital or medical group where the test was performed, if necessary. The defendant hospital employed an internal policy about reporting test results to patient's family physicians; unfortunately, the policy in this case was not followed. While a failure to follow such an internal policy does not automatically constitute negligence, it does support a patient's contention that such actions were negligent. Ultimately, the determination is whether the care provider failed to satisfy the standard

of care applicable to a physician in the same or similar circumstances.

Finally, it is not rare for a test result to be misinterpreted. The sonographer prepares the findings for a cardiologist's interpretation. Part of this preparation includes assurance that the report belongs to the correct patient and that all pertinent data have been obtained. If policy requires the sonographer to flag an unsigned study for interpretation and signature within 72 hours, then the organization must have procedures in place to assure that this happens 100% of the time. The physician ordering the study is responsible for ensuring the study is performed and that results are received. If results are not signed, they are not valid and should not be used as a diagnostic tool. Additionally, if the test results do not match the patient's clinical picture, the ordering physician should request a second opinion or a repeat study. In this case, with a strong family history of cardiovascular disease, there may have been a reason to doubt a completely normal study. Finally, the cardiologist should be monitored for similar events. If trends are noted, then a collegial intervention from peers and/or departments chairs may be warranted. ■

## REFERENCE

Decided July 19, 2019, in the Superior Court of Pennsylvania, Case Number 1682 MDA 2018.

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# HIPAA REGULATORY ALERT

CUTTING-EDGE INFORMATION ON PRIVACY REGULATIONS

## Vendors Continue to Be Weak Point in HIPAA Security

Vendors always have been one of the most worrisome parts of HIPAA security because hospitals and health systems must rely on them for the appropriate technological and physical security for protected data — without the ability to dictate exactly how.

Research shows that those fears are well founded, with many health organizations experiencing an increase in investigations and fines from HHS that are related to poor vendor HIPAA security. A study from the Ponemon Institute, a research organization in Traverse City, MI, that addresses data protection and information security practices, found that health systems are increasingly worried about their reliance on third-party medical devices and how they could compromise protected health information (PHI).

Seventy-two percent of respondents said they believe the increasing reliance on third-party medical devices connected to the internet is risky; 68% expressed similar concerns about connecting medical devices to the cloud.

Risk management processes are not keeping pace with cyber threats and vulnerabilities, according to two-thirds of those surveyed. Sixty-three percent also said their security efforts cannot keep pace with the growing use of digital applications and devices. (*The report is available online at: <https://bit.ly/2SCDSg4>.*)

One of the more interesting findings was that 56% of respondents had experienced a third-party data breach in the past two years, says **Ed Gaudet**, CEO of Censinet, a company based in Boston that provides risk management software for healthcare organizations. Earlier research had suggested lower rates of third-party vendor breaches. “It’s kind of amazing that there is all of this money going into healthcare data security; yet, the data breaches are still

trending upward. If you just look at this year alone, in the first half of the year we’ve already had breaches affecting more records than in all of last year,” Gaudet says. “We think the attack surface, the cumulative measure of the points where someone can try to gain access, is actually getting bigger, not smaller.”

In years past, the attack surface was on software and hardware that you controlled in your data center, Gaudet explains. That has changed dramatically in recent years, he says.

“Now, it’s the Wild West. So much of your business processes are being outsourced and your data is hosted in the cloud. It is a completely different attack surface from just five years ago,” Gaudet says. “We think the problem is going to get bigger. The risk analysts are woefully unprepared for this because a lot of their risk processes are manual or ad hoc, taking a lot of time.”

### Assessments Seen as Costly

At the same time, healthcare organizations are feeling the need to draw skilled digital security professionals to other pressing needs rather than have them spend so much time on verifying vendor security, Gaudet says.

A troubling finding in the Ponemon report was that 76% of healthcare organizations see their vendor risk assessments as costly, inefficient, and having no effect on reducing exposure to a breach, says **Larry Ponemon**, PhD, chairman and founder of the Ponemon Institute. He also was concerned to see that a majority of respondents thought senior executives in their organizations were allowed to skip the vendor risk

assessment when they wanted to secure a lucrative business deal.

Ponemon also notes that 54% of respondents said they were at risk of a data breach because they could not complete a risk assessment of all vendors.

That shortcoming may be even worse than it appears because those in charge of HIPAA security may not even know all the vendors who potentially can access PHI.

“Healthcare is so complex that there can be an enormous number of vendors and third parties involved. In some cases, their access to secure data is not so obvious. If you don’t know they even have that access, you don’t put them in the process for risk assessment,” Ponemon says. “Organizations are not doing all they can do create a safe and secure environment for protected data. A portion of that is due to the organizational culture that does not make this a priority.”

There also is a significant budget gap to address, Gaudet says. The survey respondents said they need 2.5 times their current budget to

adequately address the data security threats from third-party vendors.

## Little Confidence in Effectiveness

Gaudet also calls attention to how many study participants assessed the effectiveness of their vendor security procedures. There was a big disconnect between how important they consider those procedures and how effective they think they actually are.

“We asked about the importance of data breach response procedures, and everyone said they were very important, but they didn’t consider their own response procedures very effective,” Gaudet explains. “The same result came from things like prior authorization of vendor risk, with a great majority saying it was very important, but only 36% of them saying they are doing it effectively.”

Ponemon suggests that risk managers and other healthcare leaders use the data to push for more

resources and a better buy-in from upper management when discussing the need for data security.

Gaudet agrees, saying the data give risk analysts and IT professionals the information they need to make the business case for a more robust vendor risk assessment program, which may include upgrades in staffing and technology.

Cloud apps and connected devices have increased the risk of data breaches sharply, leaving some IT professionals and HIPAA compliance leaders feeling unable to keep up, Gaudet says.

“Cloud apps have been expected, but the connected devices have surged quickly with more and more consumer-connected devices and the internet of things. When you combine that with the increased attacks and vulnerability, you have a perfect storm of factors coming together for professionals responsible for protecting organizations from a data breach,” Gaudet says. “That is what is driving a lot of the pressure and anxiety in healthcare organizations.” ■

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# Checklist Items for Selecting a Compliant Vendor

There is no quick and easy way to select a vendor to trust with HIPAA-sensitive data. It requires some legwork to determine what kind of security they have in place and possibly identify any shortcomings.

Organizations using hybrid systems (where some data are hosted in the cloud and some within the organization on a server) open more avenues for data breaches due to the complexities of the system’s landscape, says **Sunil Konda**, vice president of product at SYNERGEN Health, a company in Dallas that provides software and

consulting services for healthcare organizations. So far in 2019, 79 healthcare privacy incidents have been reported, including at companies such as OXO, BlackRock, Ascension, Rubrik, Advent Health, UConn Health, EmCare, and Quest Diagnostics, Konda notes.

“Pre-emptive and proactive cybersecurity crisis plans are important. As the use of digital healthcare services such as telemedicine, electronic health records, and wearables become the new normal in the industry, there has been an increase of cybersecurity threats due to the growing number of points of entry for hackers looking

to capitalize on highly sensitive and valuable information,” Konda says. “The question isn’t if but when there will be a breach, as there is a high chance that every organization across industries and sectors will encounter some level of cyberattack at some point.”

To reduce the chances of a security breach, Konda says there are eight essential items that healthcare entities should look for when selecting a vendor to meet the challenges of keeping patient information safe:

- **Information Security, Quality, and Compliance Framework.** A cybersecurity compliance framework

provides steps and recommendations on implementing and managing various aspects of the vendor relationship. Putting committees in place with coordinators ready to address compliance, information security, and quality and knowledge management creates a strong approach that spans the width of the organization to show how trustworthy the vendor is, Konda says.

- **Policies and Attestations.**

When entering into an agreement, the policies and attestation standards should be clearly developed and presented. Key areas include HIPAA compliance audits, quality policy, and information security policy.

- **Administrative Safeguards.** Administrative policies and procedures should be in place to address security with agreements, business associates, and supplier management. Periodic audits of processes, documentation, and compliance protocol along with annual assets, risk assessments, and technical compliance reviews will further strengthen a vendor's security measures, Konda says.

- **Physical Security.** Ensuring the server room is monitored and

nonessential areas are restricted to unauthorized employees or guest access will assist with physical barriers. Additional physical security measures include 24/7 closed-circuit television monitoring and biometric access control.

- **Technical Infrastructure Security (Cybersecurity).** The investment of a cyber infrastructure with multiple levels of security will assist vendors in preventing external and internal threats. Using encryption, secure backups, and additional network security, hackers' attempts to gain access can be prevented.

In addition, vendors need to show proof that a third-party organization is contracted to conduct penetration tests on the network on an annual basis to identify any vulnerabilities, Konda says. Proper action then can be taken to correct any detected risks.

- **Human Resource Security.** Steps vendors can take to mitigate internal personnel security risks include a robust screening and background check prior to the applicant's employment, continuously updating access control during employment, changing of roles within the company,

and proper termination procedures to safeguard access throughout an employee's tenure with a company, Konda says. Scheduling monthly and quarterly reviews and compliance refreshers can assist with creating a company culture rooted in security and compliance.

- **Incidence Response.** The vendor should have a comprehensive incident response framework in place in case of a breach. Konda says this framework should be made up of essential personnel including but not limited to an interactive response technology team lead, an IT expert, legal representative, and management. It also should include steps to review and assess the incident and impact of the breach on the business, the response, implementing temporary and permanent fixes, and reporting to law enforcement officials.

- **Applicable regulations.** Ensure vendors are up to date with major U.S. laws and regulations. This includes the Health Information Technology for Economic and Clinical Health Act Omnibus Rule, HIPAA, and the Fair Debt Collection Practices Act. ■

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## Social Engineering Scams, Attacks Can Threaten HIPAA Security

Despite years of educating healthcare staff about the need for data security and the myriad ways people can worm their way into an otherwise secure system, employees still can fall prey to social engineering scams and allow HIPAA data breaches.

Social engineering refers to the ways hackers and other criminals prey on people's natural tendencies and weaknesses to create a way into a data system. It remains a huge problem, says **Dan Hanson**, an insurance

and risk management professional with Marsh & McLennan Agency in Minneapolis.

"The problems caused by social engineering have been with us for a long time now. Bad actors use a variety of schemes to hack into business databases, pose as qualified vendors — often referred to as reverse social engineering — or even gain access to physical spaces," Hanson says. "There are literally thousands of variations. The only limit to the number of ways hackers

can socially engineer users is the criminal's imagination."

Social engineering plays a role in most HIPAA breaches. Clinical Pathology Laboratories in Texas recently reported that PHI of approximately 2.2 million patients had been compromised in the data breach at American Medical Collection Agency (AMCA), which provides debt collection services to healthcare organizations. (*Read more at: <http://bit.ly/2YvtCrg>*) AMCA reported that a cyberattack on its

payment website allowed hackers to obtain PHI for eight months. AMCA filed for bankruptcy after the attack. (*Read more about the filing at: <https://bloom.bg/2GB8ARS>.*)

A healthcare organization can even experience multiple forms of exploits in a single attack, Hanson says. These are some of the most popular forms of social engineering:

- **Phishing.** The most common scheme, often using fear and threats to create a sense of urgency, all in an attempt to wrangle usable information.

- **Pretexting.** Usually a fabricated scenario designed to fool an employee to extract information.

- **Baiting.** Similar to phishing but often promises a reward to entice victims, such as free music or movie downloads, to steal login credentials.

- **Quid Pro Quo.** These attacks promise a benefit in exchange for information, usually some kind of a service (e.g., an offer of IT that promises a software update but is instead a way to install malware).

- **Tailgating.** This involves someone without proper authentication literally following an employee into a restricted area.

- **Identity Theft.** The hacker steals an employee's identity he or she can use online or even create fake ID badges to gain access to the office.

Many companies know about these schemes and they have often made attempts at guarding against them. But the unfortunate truth is the criminals have become smarter, and they are constantly changing and updating their schemes, Hanson says.

"Just because many social engineering scams, like the Nigerian prince, seem so obviously fake and illicit, you can't assume that all schemes will be equally obvious

to your employees," Hanson says. "Hackers are uniquely adept at spotting the flaws in their attacks and revising them. A lot of these people are incredibly smart and very good at what they do."

One of the latest innovations is invoice manipulation. This form of attack is not necessarily new but it has received more notoriety lately because it has become a bigger problem than ever before, Hanson says. Criminals posing as suppliers, vendors, or even customers attempt to defraud a company using fake, duplicate, or inflated invoices. It is important for companies to be vigilant about checking every invoice, Hanson offers.

Invoice manipulation has become a go-to attack choice for bad actors hacking email accounts, intranet, or databases. Hanson describes one way it can work: An employee's email is hacked, or their credentials are stolen. Now, the hacker has access and can monitor emails to determine who sends or requests an invoice. The hacker knows the company's vendors and sends an invoice that appears to be legitimate, but the routing, account, or vendor ID numbers have been altered.

"Guard against invoice manipulation by empowering employees to double check any time anything changes — numbers, banks, addresses," Hanson says. "Have them call the vendor directly to ask whether or not the information is legitimate. Don't send emails. If the hacker is already in your system, it's easy to fake the response."

If the hacker has no luck gaining access digitally, he or she can coerce or even hire a disgruntled employee. This is potentially the most powerful attack because the employee has physical access to the organization

and generally can move anywhere without any restriction as well as access company data, Hanson says.

"A lot of companies are still getting caught flat-footed. It's not hyperbole to state that all organizations are, at one time or another, getting hit by social engineering attacks," he says. "All it takes is one employee to not be thinking clearly. That's when bad decisions are made. That's why continuous training is necessary."

Hackers who engage in social engineering attacks prey off human psychology and curiosity to compromise their targets' information, Hanson notes. Guarding against most of these does not require much more than paying attention to the details. But it is important to keep reminding employees how they can avoid social engineering schemes. Hanson suggests frequent reminders on these safeguards:

- Do not open emails from untrusted sources;
- If offers seem too good to be true, they probably are;
- Lock laptops;
- Read and know the company privacy policy;
- Do not react too quickly — hackers want someone to act first and think later;
- Be suspicious of unsolicited messages;
- Beware every download;
- Foreign offers are fake — end of story;
- Delete any request for financial information or passwords;
- Reject requests for help or offers of help;
- Set spam filters to high;
- Do not be afraid to ask questions or delay decisions until thoroughly checking out the situation. ■