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INSIDE

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Know How False Claims Act Works to Prevent Violations

Understanding the ins and outs of the False Claims Act (FCA) can prevent violations and improve the outcome if the government or a whistleblower does allege fraud and abuse. FCA investigations are almost impossible to avoid for large companies, so risk managers must thoroughly understand the law.

The issue is more important because the government is starting to look closely at the novel ways in which entities are delivering care post-pandemic, says **Jaime L.M. Jones**, JD, partner with Sidley Austin in Chicago.

"We will see enforcement against hospitals and health systems for providing telehealth services in ways that are inconsistent with the federal program. To date, all the enforcement around the delivery of telehealth has really been about Anti-Kickback Statute issues," Jones explains. "There have been problems with financial arrangements between providers and other referral sources, but I think what you're going to start to see is enforcement based on the way that telehealth services themselves were delivered."

THE ISSUE IS MORE IMPORTANT BECAUSE THE GOVERNMENT IS STARTING TO LOOK CLOSELY AT THE NOVEL WAYS IN WHICH ENTITIES ARE DELIVERING CARE POST-PANDEMIC.

The government will look for care that was delivered inconsistently with the waivers that were put in place to facilitate telehealth since the pandemic began. They will focus on whether the services were necessary, Jones says. A related issue is remote patient monitoring, the use of which is expanding for cardiac monitoring and other kinds of patient monitoring.

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"We see the government starting to bring cases saying those services were not medically necessary and/or they were not being provided in full compliance with Medicare billing rules regarding how you provide and get paid for remote patient monitoring," Jones says.

Healthcare organizations should create tight policies and procedures regarding how they engage with anybody in a position to refer patients for services, Jones recommends. Training is important. While there are regulatory and statutory safe harbors to kickback and self-referral laws, they often are misunderstood. People can become too comfortable with assuming a certain type of referral is safe.

"Safe harbors are super technical, and you have to comply with every single element, or you don't get the protection. I would say, in almost every instance, where a healthcare entity is in the crosshairs with DOJ [Department of Justice] over one of these sorts of arrangements, they tried to comply with the safe harbor, or they thought they were complying with the safe harbor, but they didn't nail it," Jones says. "If you don't nail it, then it is very hard to talk DOJ down."

For the past 20 years, whistleblowers drove 99.9% of the FCA enforcement. That is changing now that DOJ has access to more healthcare data, Jones says. DOJ is performing more of its own analytics research now instead of waiting for violation reports.

"I have had numerous enforcement matters that I'm handling and have handled over the last few years where DOJ has acknowledged to me that there is no whistleblower. 'We found them on our own. We looked at the data and we found it and we now have a bunch of questions for your clients,'" Jones reports. "Knowing that you have the government looking at your data on the other end, you need to be making sure you're looking at your own data."

Medical Record Must Support Claim

It is important to ensure a valid medical record supports the claim, says **Bob Wade**, JD, partner with Nelson Mullins in Nashville, TN. If a claim is submitted before the medical record is completed, then it must be reviewed to ensure the claim can be validated.

Medical necessity is another concern. "You may have doctors who, especially because of the electronic medical records, are copy-pasting and bringing documentation forward in order to populate the medical record. But somebody needs to go through and validate that what is being input into the electronic medical record was actually happening on that day," Wade cautions. "I'm seeing a lot of

EXECUTIVE SUMMARY

The False Claims Act (FCA) poses significant risks to healthcare organizations. Claims can arise from many different sources.

- Violations do not have to be intentional to violate the FCA.
- The response to the government must be professional and diligent.
- Settlements can be presented to the public in a positive way.

issues out there on that very point — the copying and pasting."

Fraud and abuse issues under the Anti-Kickback Statute and Stark Law also can create false claims, Wade says. Once a Stark Law violation is discovered, it becomes a false claim if the organization continues to bill or does not self-report.

Fair market value for physician compensation is a big issue under the Stark Law and the Anti-Kickback Statute. "If you have an inappropriate financial arrangement with a referral source, whether it's the physician or otherwise, and you have knowledge of that, then that can create a false claim if you're continuing to bill for the service without correcting the issue," Wade says.

Look Beyond First Overpayment

Healthcare organizations can wander into FCA territory by not sufficiently following up when an overpayment is discovered, says **Jordan Kearney**, JD, partner with Hooper, Lundy & Bookman in San Francisco.

"A common pitfall that people encounter is they know that if they identify an overpayment, they need to report and return the overpayment. What they don't know is that if this overpayment gives them some information suggesting that the problem is systemic or impacts more claims, they have an obligation to go find the other overpayments," Kearney says.

For example, a hospital may audit records on a high-risk procedure and find a 40% error rate on billing, Kearney explains. With the best intentions, they self-report and return the overpayment on the claims in the audit sample. But the look-back period for Medicare fee for services is six years.

"Now they've reported and returned a handful of claims from the sample, but they didn't go look for all the other claims that would be impacted by the same issue," Kearney says. "It's well-meaning but opens the door to a false claims investigation."

Work with Human Resources

Often, FCA cases are filed by current or former employees. Many companies have limited resources to review all compliance concerns raised by their employees that implicate claims submitted to government payers, says **Selina P. Coleman**, JD, partner with Reed Smith in Washington, DC.

"Not having or committing the time and resources to address these compliance concerns, or not taking seriously those who raise those concerns, may lead to a current or former employee electing to bring a claim under the FCA," Coleman notes. "Whether a company has taken these concerns seriously and as needed, taken corrective action may also affect the government's intervention decision."

Almost any time companies submit claims to the government, it runs the risk of billing practice scrutiny under the FCA, which carries the risk of treble damages and per-claim penalties, Coleman says. Even if a company thinks it is billing claims correctly and consistently with the law, it may still face challenges when a whistleblower or a regulator disagrees, particularly where billing requirements are ambiguous.

Beyond providing information or training on the federal FCA and state false claims acts, companies can monitor government initiatives such as those described in the Office of Inspector General's annual work plan and claims pursued in FCA cases within their industry to identify and prioritize risks for potential review, Coleman suggests.

Because employees are a common source of FCA reports, risk management must work closely with human resources, says **Mark J. Silberman**, JD, chair of the white collar, government investigations, and regulatory compliance practice group with Benesch in Chicago.

"I would love to see every exiting employee be asked the question of whether or not they know or are aware of anything that needs to be improved or needs to be done that wasn't being done. Then, obviously, something needs to be done with that information," Silberman says.

When defending against FCA allegations from a former employee, it will be helpful to collect evidence the organization inquired about any potential problems, and none were reported.

"Three months later, he puts forth an allegation of rampant fraud that is designed in part to enrich him. Your exit interview undermines the credibility of that in the eyes of anyone and everyone who is looking at it," Silberman explains. "The purpose and the goal of the hospital system is to avoid the problem, so if you ask and this person does raise issues, you have to evaluate them. They're not all going to be legitimate, but if someone raises an issue, you need to have that environment where it is assessed, and if necessary, you take the next steps."

Employee Concerns

Allegations a healthcare entity submitted false claims can come in

the form of an employee concern, a Civil Investigative Demand through which the government may be reviewing a qui tam under seal, or through the unsealing of a qui tam lawsuit, Coleman notes. In any case, the company must take the issue seriously and determine if any corrective action is needed, such as changing billing practices or refunding overpayments.

"If defending against a qui tam action, we explore a number of legal defenses, such as bars to a whistleblower bringing the claim, as well as pleading deficiencies, such as the allegations failing to satisfy the requisite elements under the FCA," Coleman says. "If a case proceeds, we typically seek discovery from the government to explore whether the whistleblower cannot satisfy the requirement of proving that the alleged misconduct was material to the government's payment decision."

Although settlement tactics will depend on the facts of the case, the weaknesses of the alleged claims, and the strengths of the company's defenses, defendants need to be prepared to challenge the alleged damages, Coleman says. This may include a credible alternative methodology that reveals the overstatement of alleged damages.

"Any settlement strategy should also leverage any data and documents that support the company's compliant practices, show the company did not have the requisite intent to submit false claims, or show that the company's practices were not material to the government's payment decision," Coleman says.

Some companies might not know they can take discovery from the government to determine whether the government knew of the alleged misconduct, and whether the government continued to pay the claims with full knowledge of this conduct.

"Although companies typically know they will be scrutinized for their action or inaction, they may not know they can turn the tables when confronting these claims and seek to defeat the claims — or achieve a more favorable settlement — by showing alleged misconduct was not material to the government's payment decision," Coleman says.

Three Categories of Risk

In healthcare settings, leadership can analyze or search for FCA risk in one of three categories: how patients got there, how patients are cared for, and how services are billed, says **Alissa D. Fleming**, JD, shareholder with Baker Donelson in Charleston, SC. For instance, common pitfalls may include inappropriate financial relationships resulting in referrals (category 1); inappropriate financial incentives or relationships with outside vendors or entities resulting in unnecessary procedures or testing (category 2); or improper coding or "upcoding" that increases revenue (category 3).

In many cases, conduct might have started as an innocent mistake or inadvertent, but when the company discovers it, the failure to appropriately respond can turn it into a false claim.

"Innocent mistakes not correctly addressed or overlooked can turn into false claims. However, being investigated for false claims is almost part of being in the healthcare industry," Fleming says. "Misperception by employees, complicated federal regulations, and the interplay of business and clinical judgment are all otherwise innocent activity that will have to be explained and discussed in response to an investigation. At the end of the day, a health system may be able to explain all of its actions as lawful, but still have to go through the expense and effort of responding."

It is critical to remember the FCA does not require intent to violate the act, Fleming cautions. Acting recklessly on the accuracy of what an employee enters in a record or approves for billing can be the basis for a claim.

"Check, recheck, and double check the accuracy of claims," Fleming stresses. "Also, never enter into any financial or beneficial relationship with any other party as a hospital without getting a legal review by someone knowledgeable of relevant regulations — the Anti-Kickback Statute and Stark."

Respond Carefully

The response to an FCA claim must be professional and diligent, says **Thomas H. Barnard**, JD, shareholder with Baker Donelson in Washington, DC. The company should maintain open lines of communication with the government.

"As a healthcare entity, the last thing you want is to be perceived as being nonresponsive, hiding something, or having a lack of concern for patient safety," Barnard says. "Get assistance from a lawyer who has experience with the False Claims Act. Don't simply rely on your go-to outside counsel for other litigation, as the issues are very different."

Also, never try to hide mistakes. Resolve the mistakes, then explain how they were discovered and solved, Barnard says. Always take the inquiry seriously. Remember you are dealing with the government, not just a commercial dispute.

Another common error is acting overly defensive about every issue. "In a large organization, mistakes are bound to happen. Remember, let the facts speak for themselves, and do good legal research to show how the conduct was lawful or explainable without a bad motive," Barnard explains. "It is a mistake to not be prepared to address issues and learn from them. Being ready to 'do things better' is always a winning attitude."

If the organization is settling, it should be treated as a positive sign of leadership taking accountability and doing the right thing.

"You want to be able to show it's not just paying money, but also taking steps to make sure something does not happen again through reviewing policies, improving education and training, and best practices," Barnard says. "Be prepared for the press release from the government and how to manage the reputational impact of the public nature of the settlement. Remember that the most important fact for the future is not what happened, but how you responded." ■

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Supreme Court Ruling Helps with Meritless False Claims Act Lawsuits

The U.S. Supreme Court issued an important ruling that will help healthcare organizations and practitioners gain relief from meritless whistleblower lawsuits under the False Claims Act (FCA).[1]

Under the FCA, a whistleblower may file suit on behalf of the United States against a healthcare organization that commits fraud in Medicare or Medicaid. The Department of Justice (DOJ) decides whether to intervene (i.e., to join the lawsuit). In the case of *United States ex rel. Polansky v. Executive Health Resources, Inc.*, the Supreme Court determined the DOJ can move to dismiss a whistleblower action at any time, including after DOJ decides not to intervene.

Previously, the various circuit courts took different approaches to how the court should respond to a request from DOJ to dismiss the whistleblower case, says **Jose Vela, Jr.**, JD, senior counsel with Clark Hill in Chicago. Vela served as an Assistant U.S. Attorney for more than 20 years.

Whistleblowers Still Proceed

Generally, DOJ would allow whistleblowers to proceed with the case after DOJ declined to intervene because it did not see enough merit in the claim of fraud, Vela notes. In his experience, if Vela declined to intervene, most whistleblowers would decide to dismiss the case.

"But there are those who wanted to proceed for a variety of reasons. The office would allow them to proceed with the case," Vela says. "I would say the majority of the time, those cases get dismissed anyway. They didn't get very far."

Fighting those whistleblower cases still cost the healthcare defendant substantial money, time, and effort, Vela notes.

In cases in which DOJ recommended dismissal, plaintiffs would sometimes disagree and argue the DOJ had no right to do so. The Supreme Court determined that nothing in the FCA barred the DOJ from moving to dismiss after it decides not to intervene.

"Now, if the healthcare organization learns that there is a whistleblower case, and if in the end the government finds that there's no evidence of fraud and they're going to decline intervention in the case, they should make it part of their pitch to the government to ask

them to dismiss the case," Vela says. "Organizations are in a much better position to ask the government to go ahead and dismiss these cases and not allow the whistleblowers to proceed with a case that, quite frankly, could last years. If there are interlocutory appeals, it could go back and forth from the district court to the court of appeals, and that can take so much time, money, and damage to your reputation." ■

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National Patient Safety Board Could Be Implemented

A bill in Congress could create a patient safety board modeled after the successful safety efforts in transportation. The bill would create a National Patient Safety Board (NPSB) that would do for the healthcare industry what the National Transportation Safety Board (NTSB) and Commercial Aviation Safety Team (CAST) have done to improve safety for those fields for more than 25 years.

Like NTSB and CAST, the NPSB would provide expertise to study the causes of errors and create recommendations and solutions to prevent future harms, says **Karen Feinstein**, president and CEO of the Jewish Healthcare Foundation and Pittsburgh Regional Health Initiative, and the spokesperson for the NPSB Advocacy Coalition.

The effort to create the NPSB began in 2021 when a coalition of leading healthcare organizations and experts began advocating for it in response to growing concern over medical errors and patient safety. In December 2022, Rep. Nanette Barragán, D-CA, introduced HR 9377 to establish the NPSB.[1]

Feinstein says the coalition continues to grow as more organizations become aware of the need to improve patient safety. "There is a lot of recognition that the workforce shortage and the rates of error in most of the categories of patient safety are rising, and that they're not unrelated. With a number of experienced professionals — nurses in particular — leaving, we have more opportunity for error," she explains. "But as we have more opportunity for error, more nurses and doctors are just getting stressed and burnt out, so that's exacerbating the workforce shortage and the loss of experienced nurses and doctors, which then increases the opportunity for harm. It's kind of cyclical."

HR 9377 is a big step forward, Feinstein says, but she wishes there were more vocal support from the biggest names in the healthcare community, like the American Hospital Association and the American Medical Association. So far, they have not expressed any opposition to the proposal, but they also have not been active in supporting it and lobbying legislators, Feinstein notes.

Any reluctance to push the NPSB proposal might be due to the fact many patient safety improvements would involve upgrading or altering infrastructure like electronic health records and medication dispensing systems.

"Any hesitancy to do what needs to be done is because there will be a cost. You're not going to redesign systems and have it be free," Feinstein says. "We've got to get a better response from our electronic health records and other prompts because they're being ignored right now. People are just overwhelmed. What we hear from doctors and nurses is that if they didn't ignore those prompts, they would go crazy, couldn't do their jobs, and other patients would die."

EXECUTIVE SUMMARY

Advocates are pushing for the formation of a National Patient Safety Board. The board would be patterned after safety agencies in the transportation and aviation industries.

- A bill in Congress would create the board.
- The bill might not pass without bipartisan sponsorship.
- A board could address chronic underreporting of safety events.

For example, a solution must be found that alleviates the pressure on clinicians while prohibiting a dispensing system to provide two drugs with potentially deadly interactions, Feinstein says. Such solutions require a commitment to invest already-scant resources. Feinstein notes that might be why leaders are not vocal in their support of a NPSB that would pressure healthcare organizations to make those changes.

Feinstein notes Finland is well regarded for its emphasis on patient safety. The country created an agency similar to the NPSB concept. That agency investigates significant medical errors and other patient safety events, submits recommendations based on those findings, and requires hospitals to report annually for 10 years on their progress in implementing the improvements. Finland also requires medical students to take courses in safety science, quality engineering, systems theory, and other subjects related to patient safety.

"My son-in-law's a surgeon, and I think he got half an hour on infection control, and nothing on those other topics," Feinstein says.

Bill May Not Pass

HR 9377 may not succeed, says **Robert Andrews**, JD, CEO of Health Transformation Alliance in Washington, DC, which oversees the strategic direction of more than 50 major corporations to fix the U.S. healthcare system. Andrews served in the U.S. House of Representatives for 24 years.

"We think the congresswoman's bill is a step in the right direction, but in a House that's controlled by Republicans, it's unlikely that the bill will become law without Republican sponsorship," Andrews says. "I don't know if this would get 60 votes in the Senate. But I don't think it moves out of the House without Republican sponsorship. That's not a reflection on the merits of the bill. It's a reflection on the realities and the way the House works."

Andrews suspects there has not been much objection to the bill from the healthcare industry because a bill introduced by a minority member does not have much chance of succeeding. The industry is probably not paying much attention to it for that reason, even though the NPSB would create more regulatory oversight — and no industry is eager to see that happen, he says.

> ANY RELUCTANCE TO PUSH THE NPSB PROPOSAL MIGHT BE DUE TO THE FACT MANY PATIENT SAFETY IMPROVEMENTS WOULD INVOLVE UPGRADING OR ALTERING INFRASTRUCTURE LIKE ELECTRONIC HEALTH RECORDS AND MEDICATION DISPENSING SYSTEMS.

If such a bill ever looked like it might pass both the House and the Senate, the healthcare industry might respond by saying there already is plenty of safety oversight and requirements from CMS, The Joint Commission, the FDA, and state departments of health, Andrews notes. They might also cite the existing legal system for malpractice compensation.

Andrews says he does not necessarily agree with those counterclaims and believes the NPSB would create consumer knowledge and transparency that does not exist. He envisions the NPSB putting an emphasis on patient safety so hospitals would market by promoting their good scores and high standards, helping patients find the safest options for care.

"I'm old enough to remember when the auto industry fought airbags ferociously. They depicted airbags as the end of the American auto industry. Of course, they weren't," Andrews recalls. "Airbags were required, and now they market airbags in car ads. Airbags went from being what the industry saw as oppressively expensive to being a marketing tool. I'd like to see that happen with safety standards."

Challenging Corporate Limits

An NPSB could help break through some of the corporate mindset that hinders efforts to improve patient safety, says **Gary Warren**, CEO of ivWatch, an IV patient safety company in Newport News, VA. Warren says perception of the issue is framed by two comments he heard in recent years from hospital executives.

In the first, a chief financial officer at a prominent hospital told him, "We generally don't collect data on things that are going to cost us money to fix." The second was made by the chief medical officer of a large hospital network, who said, "Our business model is to provide the least

amount of healthcare for the most amount of money."

"These comments haunt me every time I walk into a hospital. They are appalling but define the battle between patient safety initiatives and the financial model of our healthcare system," Warren laments. "The first casualty of this battle is and has been accurate reporting and recordkeeping. The first step in solving a problem is admitting you have one, and hospitals underreport medical errors because they have a strong financial incentive to maintain the status quo."

An NPSB would be a welcome development, but to align with the charter of the NTSB, mandatory and consistent reporting of events needs to be the foundation, Warren says.

IV access is one procedural area the newly formed NPSB should include in their focus, Warren says. More than 80% of patients admitted to hospitals undergo this seemingly simple and common procedure. However, significant complication rates lead to drug dosing errors, skin necrosis, scarring, compartment syndrome, and even amputation in severe instances.

For a specific example of why NPSB oversight is needed, Warren says one can look at the administration of radiopharmaceuticals via an IV placement. Radiopharmaceuticals contain radioactive isotopes and are used in nuclear medicine for procedures like bone scans, heart scans, and cancer treatments. They are regulated by the Nuclear Regulatory Commission (NRC). The NRC has yet to make the extravasation (accidental delivery outside the vein) of radiopharmaceuticals a required reportable medical event.[2]

"Instead, just this year, the NRC, 'in working with stakeholders,' decided that it would be up to the patient to report the missed delivery of radioactive drugs and any complications that occur in the future," Warren notes. "To make an analogy with the NTSB, this would be like requiring the passenger of a plane to report a crash or it never happened. The healthcare reporting system is broken."

The problem of IV infiltration and extravasation spans more areas than nuclear medicine, Warren notes. The delivery of chemotherapy agents, antibiotics, dextrose, and vasopressors all cause injuries when delivered outside the vein. Even worse, the therapeutic effect of the drug is diminished or removed because every IV infiltration and extravasation is a drug dosing error. For example, a stroke patient needing clot-busting drugs does not receive the therapeutic benefit because of a misplaced IV.

"They die. It's never reported," Warren notes. "Then, there are certain patient populations such as neonates that have over 50% of their IVs fail. That's over 50% of the patients with drug dosing errors."

Warren says he and his colleagues constantly hear hospital leaders say, "Our hospital does not track our IV infiltration rates," or "We do not have that problem in our hospital," or "I don't have time to report that event; it's just some swelling." That is where the friction begins and why a NPSB is so important, he says. No one wants to get in trouble — no one wants to be held accountable.

The statistics do not lie, yet there is minimal reporting on this everyday problem. "When you look at the clinical research available around IV infiltrations and extravasations, the mean infiltration incidence rate is 23.9%. Our own research from 50 ivWatch hospital evaluations exposed a 24.1% infiltration rate, which matches the published literature," Warren explains. "If a hospital was required to report its infiltration rates publicly and reported a major outlier, for example, at 3%, that should be an immediate red flag to audit that hospital because there are two scenarios here. Either they are significantly underreporting their data, or they have solved a serious healthcare crisis and it needs to be celebrated by the world so every hospital can replicate their policies."

Warren notes that if one plane crashes, the NTSB acts. But in medicine, people say, "It's a small percentage, so it's OK."

"The problem is a small percentage of a really big number is still a big number. Additionally, people are not percentages," Warren says. "As such, I support the formation of the NPSB, but I believe the battle begins with fixing reporting issues." ■

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Patient Objections to Caregivers Create Difficult Situations

Healthcare organizations could find themselves in a difficult position if a patient or family member refuses care from a clinician because of race, sex, or sexual orientation. If the situation arises, the law is clear even if following it will make the patient or family upset.

Sometimes, patients prefer a male or female caregiver or state they are uncomfortable with a clinician or aide who is of a certain race, sexual orientation, or religion. Accommodating the patient in these situations runs the risk of violating labor laws, says **Tom Harrington**, JD, principal with The Employment Law Group in Washington, DC.

Researchers found patients often requested providers of the same gender, race, or religion. The decision on whether to accommodate the patient usually fell to the physician, and female physicians were more likely to say yes.[1]

The 1964 Civil Rights Act (CRA) and Title VII of the act prohibits employers from basing decisions about job assignments, promotions, or other terms of employment on the person's status in a protected category, Harrington says. The protected categories include race, gender, national origin, disability, and age.

The question of whether sexual orientation or identity is a protected category was in dispute for many years, but the Supreme Court recently ruled Title VII does protect people from discrimination based on these categories. Making an assignment based on the discriminatory preferences of a patient would be in violation of those laws, Harrington says. Even if an employee does not know about the accommodation at the time, he or she may find out later and claim the discrimination adversely affected their job status.

Objections to care provided by transgender clinicians or aides spurred the United Kingdom's National Health Service to publish guidance warning patients could be found guilty of discrimination if they refuse care from a transgender medical professional. Healthcare leaders were told patients have no right to be informed about a healthcare worker's assigned sex at birth.[2]

"It would likely be discriminatory for the patient to refuse to be treated or cared for by a trans person, unless clear and evidenced clinical harm may result to the patient," officials wrote.

The U.S. Equal Employment Opportunity Commission has not addressed the issue, but Harrington says he can conceive of difficult circumstances if a patient objects to care from a transgender individual.

It is common for hospitals to accommodate a request from a woman who prefers a female caregiver for intimate care, Harrington notes, but if a patient objects that a transgender caregiver was born male, it might be difficult to satisfy the patient.

"That is the one thing I can think of where it's a complicating factor. If you want a doctor of the same gender for privacy reasons, how does that affect somebody who's trans and whether you view them as the same gender as you or have a different gender than you?" Harrington asks. "But I'm not aware of any changes to the laws that would cover that."

The conservative approach would be to support the caregiver and not comply with the patient's request. "If the hospital accommodates that type of request, I think they potentially have some liability because clearly you're treating a trans female as if she is not really female," Harrington says. "That would expose the hospital to potential liability, or at least to lead to some litigation."

Policies Needed

Organizational policies and guidelines are necessary for these situations, says **Talya Van Embden**, JD, an attorney with Kaufman Dolowich Voluck in Fort Lauderdale, FL.

Healthcare organizations should ensure a zero-tolerance policy for discrimination, then work to educate its employees as to what a zero-

EXECUTIVE SUMMARY

Sometimes, patients object to a particular caregiver based on race, gender, or other factors. Employers must respond carefully to avoid discrimination charges.

- Some accommodation is acceptable for modesty concerns.
- Employers are obligated not to restrict assignments based on certain factors.
- Labor laws can be violated even if the employee does not know at the time.

tolerance policy means within the constraints of the duty to provide care. Healthcare entities must ensure their employees are not subjected to discrimination or bias on the job, regardless of the source.

Hospitals should only respond to reasonable requests, such as a female sexual assault victim requesting a female clinician, and deny requests that appear to be based solely on discriminatory means.

"Patient reassignment requests based on bigotry pose an ethical dilemma for healthcare entities that does not lead to black-and-white solutions," Van Embden says. "When faced with such a demand, healthcare entities should understand that federal law requires employers to protect employees from discrimination regardless of the source — including customers, patients, visitors, or even vendors."

Van Embden notes that in 2010, the U.S. Court of Appeals for the Seventh Circuit decided the case of *Chaney v. Plainfield,* involving a Black certified nursing assistant prohibited from caring for a white resident who requested no Black caregivers. The court rejected the nursing home's assertion its deference to the patient's expressed preference was "reasonable" and held a patient's racial or sexual preference is not a defense to treating employees differently.[3]

In 2016, U.S. District Court for the Eastern District of Michigan ruled even a brief abridgment of an employee's rights is actionable, Van Embden says. This case involved a respiratory therapist who was unable to care for a hospital patient whose record indicated he wanted no Black caregivers. The court held that Section 1982 protects a non-white person's enjoyment of all benefits, privileges, terms, and conditionals of an employment relationship, and that assignments based on race constitute an adverse employment action because such assignments affect the terms and conditions of employment.[4] ■

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Study Shows Importance of Effective Medication Reconciliation

A recent study from Brigham and Women's Hospital in Boston illustrates some of best tactics hospitals can use for improving medication reconciliation.

Updating and verifying a patient's medication lists and orders is critical to ensuring patient safety and optimizing care, but it can be challenging in a hospital environment, says lead author **Jeffrey L. Schnipper**, MD, MPH, research director of the Brigham's Division of General Internal Medicine and Primary Care, a professor of medicine at Harvard Medical School, and principal investigator of the second Multi-center Medication Reconciliation Quality Improvement Study (MARQUIS2). The recent work is a new analysis of data from the second study.

The first lesson from the study is the importance of taking the best possible medication history in the ED before the patient is admitted, Schnipper reports. The information obtained in the ED tends to be more accurate and complete.

"Once the patient is upstairs, the admission orders have been written. It's much harder to take a history at that point, and then retrospectively fix the admission orders that were based on incorrect history that was originally taken," Schnipper explains. "Getting it right the first time and doing it as early as possible before the admission orders are written is the goal, which generally means doing it while the patient is still in the emergency department. That is really key."

Another important finding is a best-possible medication history in the ED should be combined with discharge medication reconciliation, especially in the highest-risk patients. At discharge, this is usually by a pharmacist to reduce discrepancy rates, especially for those that are going to be harmful to patients.

"We know when patients leave the hospital, they're going to a less monitored setting. Mistakes that are made at that point may not be detected for a while until they cause patient harm," Schnipper says. In the ED, the medication history can be taken by pharmacy technician rather than a pharmacist, he notes.

Improving medication reconciliation can require systemwide interventions, Schnipper says. These may include improving the medication reconciliation module in the electronic health record, better access to preadmission medication sources, and training providers on how to take the medication history.

"The two things that we found most successful were making changes to the electronic health record, and then doing what we call 'measurevention,' which is basically catching errors in real time and fixing them before they reach the patient," Schnipper explains. "A few sites were particularly good at that. It does take resources to do this well, but these errors are occurring every day in our hospitals — and at quite alarming rates. The only reason we don't notice them more often is that we're not good enough in measuring."

For most hospitals, applying the lessons from the study probably would require hiring more pharmacy technicians. In some markets, it is harder to find those employees than others. Many hospitals are employing dedicated transition of care pharmacists (TOCs), Schnipper says.

"What's interesting about this group of people is that they are in some ways easier to hire than your typical inpatient pharmacist because the skill set that you need to be a quality control pharmacist is often the skill set that community pharmacists have — the ability to know medications really well, talk to patients, counsel them," Schnipper notes. "We've actually had an easier time hiring TOC pharmacists. We recently hired 20 new TOC pharmacists, and they've all been from the community setting and are really enjoying the job." ■

REFERENCE

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SOURCE

- **Jeffrey L. Schnipper**, MD, MPH, Research Director, Brigham's Division of General Internal Medicine and Primary Care, Boston. Email: jschnipper@bwh.harvard.edu.

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CME/CE QUESTIONS

1. **What does Jaime L.M. Jones, JD, say is one recent change in False Claims Act enforcement?**

   a. The Department of Justice (DOJ) is conducting more of its own analytics research now instead of waiting for violations to be reported.
   b. The DOJ is relying more on whistleblowers to report fraud and abuse.
   c. The DOJ is focusing more on large health systems and less on smaller healthcare organizations.
   d. The DOJ is more lenient with entities that self-report overpayments.

2. **What did the United States Supreme Court determine in *United States ex rel. Polansky v. Executive Health Resources, Inc.*?**

   a. The DOJ can move to dismiss a whistleblower action at any time, including after it has decided not to intervene.
   b. The DOJ cannot move to dismiss a whistleblower action after it has decided not to intervene.
   c. Whistleblowers must withdraw their lawsuits if the DOJ decides not to intervene.
   d. Whistleblowers may not withdraw their lawsuits even if the DOJ decides not to intervene.

3. **According to Robert Andrews, JD, why is the bill in Congress to create the National Patient Safety Board unlikely to pass?**

   a. The healthcare industry is not sufficiently motivated to improve patient safety.
   b. The healthcare industry is aggressively lobbying against the bill.
   c. In a House controlled by Republicans, it is unlikely that the bill will become law without Republican sponsorship.
   d. In a Senate controlled by Democrats, it is unlikely that the bill will become law without Democratic sponsorship.

4. **Who does Jeffrey L. Schnipper, MD, MPH, say can take patients' medication history in the ED?**

   a. Pharmacist
   b. Pharmacy technician
   c. Registered nurse
   d. ED physician

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

Failure to Inspect Patient After Cesarean Section Leads to Cardiac Arrests and Hysterectomy, $8 Million Award

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News: A Pennsylvania jury awarded $8 million to a patient and her husband for a physician's failure to perform a proper post-cesarean section inspection, resulting in the patient twice experiencing a cardiac arrest and requiring an emergency hysterectomy.

Initially, the physician attempted a vacuum extraction when the baby's heart rate began to drop, but eventually resorted to an emergency cesarean section. The surgery was successful, but the patient's vital signs soon deteriorated sharply. A different physician found significant blood accumulation in the patient's abdomen, requiring an emergency hysterectomy.

After a trial, the jury found the physician who performed the cesarean section negligent for failing to perform proper postoperative procedures. The jury awarded the patient and her husband $8 million for pain and suffering and the loss of society, comfort, and companionship. The outcome of this case serves as a stark reminder of the critical importance of postoperative care and the potential risks and complications associated with emergency procedures.

Background: The patient was 39 weeks pregnant with her second child when she went into labor on Dec. 10, 2013. The baby's heart rate began to slow, so the physician attempted delivery using a vacuum extractor. When the vacuum did not work, the physician performed an emergency cesarean section, and successfully delivered the child.

Following the surgery, the mother's vital signs deteriorated. She went into cardiac arrest, requiring a round of chest compressions and resuscitation measures. Another physician opened the patient's incision and found nearly three liters of blood had collected in her abdomen. After a "massive hemorrhage protocol" was ordered, the second physician began an emergency hysterectomy, joined by an OB/GYN and gynecologic oncologist during the surgery. Although the patient survived, she suffered another cardiac arrest.

> ANOTHER PHYSICIAN OPENED THE PATIENT'S INCISION AND FOUND NEARLY THREE LITERS OF BLOOD HAD COLLECTED IN HER ABDOMEN.

The patient and her husband sued all four physicians and the hospital, alleging although the delivering physician performed a bilateral extension of the uterine incision during the cesarean section, she failed to recognize the left uterine artery was bleeding profusely because it was "completely transected" following the delivery. The plaintiffs further argued although the surgical team noted and repaired the damage to the right uterine cavity, there was no indication the physician or her team inspected the left uterine artery despite the bilateral incision. The plaintiffs also alleged the three other physicians who provided post-cesarean care failed to recognize warning signs, such as the patient's abnormally low blood pressure,

elevated pulse, and other indications of intra-abdominal hemorrhage.

The jury found the delivering physician failed to properly diagnose and treat the uterine rupture, failed to provide the patient with adequate pain medication, and failed to properly monitor the patient's postoperative condition. The jury awarded the plaintiffs $8 million in noneconomic damages: $5.5 million for pain and suffering and $2.5 million for loss of society, comfort, and companionship. The delivering physician was liable for 100% of the damages. The court ordered the damages to be paid by the physician's employer under vicarious liability.

What This Means for You: This case serves as a stark reminder to medical professionals about the critical importance of closely monitoring patients after surgery and preparing to intervene promptly if complications arise. The incident underscores the significance of knowing the risks and potential complications associated with emergency cesarean sections.

In this case, the physician attempted vacuum-assisted delivery before the emergent cesarean section. This also is a high-risk procedure that is discouraged unless most other options for a successful vaginal delivery have been attempted. It also indicates the infant's head probably was wedged within the pelvic arch with possible cord compression causing the deceleration of the infant's heart rate. With these complications occurring simultaneously, it can be safely assumed the delivering physician was under a great deal of stress. The delivering physician could have called on other team members for immediate assistance before the injuries occurred. Physicians often are reluctant to ask for assistance until after the most critical and high-risk tasks have been attempted. This heroism or martyrdom behavior is dangerous to the patient, the physician, and the healthcare facility. It is fortunate other physicians stepped in once the injuries were taking their toll and they saved the patient's life. But physicians need to recognize their own limitations, especially during stressful and unexpected circumstances. They, like their patients, should reach out for help.

One of the key takeaways from this case is the need for medical professionals to be vigilant in postoperative care. The jury found the physician liable for negligence due to her failure to properly diagnose and treat the patient's rupture of her left uterine artery. This demonstrated a lapse in the physician's attention to detail and thoroughness. This oversight led to the accumulation of a significant amount of blood in the patient, cardiac arrest, and need for an emergency hysterectomy.

The verdict also sheds light on the willingness of juries to impose significant awards for noneconomic damages. Despite the absence of any economic damages, the jury awarded $8 million solely for pain and suffering and the loss of society, comfort, and companionship experienced by the patient and her husband. This serves as a reminder that juries are willing to assign significant noneconomic damages when medical professionals fail in their duty of care.

However, the case also shows juries may likewise carefully consider who should not be held liable for medical negligence. The plaintiffs sued not just the delivering physician — they also sued three other physicians who were involved in the postoperative care or the emergency hysterectomy. The plaintiffs alleged the three other physicians also failed to recognize the patient's condition had deteriorated significantly, including hemorrhaging. The jury found the other three physicians were not liable for any medical negligence. Although the verdict form does not list the jury's reasons for their decision, the verdict does suggest they weighed the evidence, assigned liability, and assessed significant damages against only whom they believed truly at fault. It supports the notion that juries recognize the individual roles and responsibilities of each physician and evaluate their actions independently.

Finally, this case emphasizes the importance of meticulous documentation. A surgeon's postoperative note is one of the most critical documents in the medical record when a case is litigated. Yet it is often the most hastily written, leaving holes where crucial information is omitted or inaccuracies where misinformation is added. Accuracy takes patience, and patience takes time. It is time well spent for both physician and patient. Here, the plaintiffs took advantage of the lack of notes or records indicating the delivering physician ordered or conducted a postoperative inspection of the left uterine artery. Although contemporaneous notes may not have given the defendant a strong argument considering the accumulation of three liters of blood in the patient's abdomen, the lack of notes may have emboldened a jury that was determined to award damages to the plaintiffs. Accurate medical records and clear, concise notes — particularly in emergency situations — play a crucial role in establishing a comprehensive record of patient care and can serve as vital

evidence in case of any subsequent disputes or legal proceedings.

By maintaining a high standard of care, diligence in postoperative monitoring, documenting actions thoroughly, and staying informed about the risks associated with emergency procedures, medical professionals can strive to prevent similar incidents, ensure the well-being of their patients, and avoid costly lawsuits and blemishes on their records. ■

REFERENCE

- Decided June 2023 in the Montgomery County Court of Common Pleas, Pennsylvania, Case No. 2014-27658.

Medical Malpractice Action Failed When Expert Testimony Did Not Comply with Statute

News: An appeals court affirmed a trial court's decision that a physician was properly disqualified as an expert witness. The witness failed to strictly satisfy state law statutory requirements for expert witnesses who testify on the standards of care owed by non-physician healthcare providers.

In this malpractice lawsuit, the plaintiffs alleged nurses caring for their mother failed to notify her surgeon of the signs and symptoms of her internal bleeding, ultimately leading to her death. However, the plaintiffs' expert witness was disqualified from testifying because he did not possess the requisite experience supervising, teaching, or instructing nurses in identifying and reporting signs and symptoms of postoperative internal bleeding required by state statute.

This case clarifies physicians who wish to testify as experts on the nursing standard of care may need the requisite experience supervising, teaching, or instructing nurses in the specific area of the standard of care at issue. It also highlights the importance of retaining qualified experts in medical malpractice cases from the outset. The plaintiffs' case was unsuccessful because their expert witness was disqualified; therefore, they had no one to testify to the standard of care and whether the defendant breached that standard.

Background: In October 2013, a patient underwent surgery to remove her left kidney. Several days later, while recovering in the hospital, she suffered from internal bleeding and died. The plaintiffs, her children, filed a complaint alleging the nurses fell below the standard of care by failing to identify and notify the patient's surgeon of the signs and symptoms of her internal bleeding, including her low blood pressure, elevated heart rate, and decreased urine output. They alleged the nurses were responsible for monitoring the patient's condition and notifying her surgeon of any changes but failed to identify or notify the surgeon of patient's internal bleeding until it was too late.

The plaintiffs submitted an affidavit from a physician who testified the nurses had breached the accepted standard by failing to identify and give notice of the signs and symptoms of the patient's postoperative bleed. The defendant medical center sought to disqualify the physician's opinion, arguing he was unqualified to render nursing standard of care opinions because he had not supervised, taught, or instructed nurses as required by the state statute. The defendant also moved for summary judgment, noting that without the expert, the plaintiffs could not offer anyone to establish the standard of care.

The plaintiffs argued that although an expert witness must be in the same profession as the defendant, the state statute still permits a physician to qualify as an expert as to non-physician providers, such as the nurse defendants, if the physician has supervised, taught, or instructed such non-physician providers. The plaintiffs argued their expert witness was qualified as an expert given his two decades of medical experience, which included several lectures he had given to nurses on nursing documentation, expectations regarding the standard of care, and communicating effectively with physicians. The plaintiffs also noted their expert was chair of a medical center's "quality control council."

However, the trial court ruled the proposed expert witness was inexperienced in supervising, teaching, or instructing nurses in identifying and reporting signs and symptoms of postoperative internal bleeding. His lectures did not involve this subject, either. Applicable state law only allows a physician to testify as an expert witness in a medical malpractice case involving a non-physician provider if they have supervised, taught, or instructed that type of provider for at least three of the past five years before the date of the alleged negligence. The plaintiffs' proposed expert witness acknowledged during the previous

five years, he had not taught at a nursing school nor supervised nurses daily.

The expert witness's testimony was crucial to the plaintiffs' case. He was the only witness they retained who could testify to this standard of care. The court granted summary judgment for the defendant. A three-judge appeals court panel upheld the ruling.

What This Means for You: This ruling is a reminder of the crucial importance of consulting with counsel and investigating statutory requirements when selecting an expert witness who is not in the same profession as the defendant. Although a physician may offer expert testimony on non-physician healthcare providers if he or she meets the statutory exception where applicable, this case suggests courts will require strict compliance with the statutory exception the physician has supervised, taught, or instructed the non-physician providers in three of the last five years. Without strict compliance with this requirement, a court will do expert witnesses no favors, even if the proposed expert has decades of experience.

This case also highlights the critical role of identifying a qualified expert witness from the beginning. The expert's affidavit was attached to the plaintiffs' complaint early in the case. By the time the case progressed to the expert's disqualification, the defendant medical center moved for summary judgment because the plaintiffs had not offered another expert to establish the standard of care. The plaintiffs' decision to retain this physician as their expert when filing the complaint sealed their fate. This serves as a reminder for both plaintiffs and defendants to ensure their chosen expert witnesses possess the relevant experience and qualifications for the case.

Although the decision is unfavorable to the plaintiffs, it is worth noting the statutory requirements for expert witnesses apply with equal force to either party in a medical malpractice case. Thus, physicians and hospitals facing litigation must not only demand plaintiffs strictly comply with statutes on the qualification of expert witnesses, but they also must ensure their own compliance when qualifying an expert. It is critical to consult with experienced counsel in the applicable jurisdiction to ensure such statutes are known.

THE STATUTORY REQUIREMENTS FOR EXPERT WITNESSES APPLY WITH EQUAL FORCE TO EITHER PARTY IN A MEDICAL MALPRACTICE CASE.

This ruling also underscores the prized attributes of potential experts — effectiveness in front of a jury, winning record, the ability to withstand cross-examination pressure, and clear communication skills — mean little if a party cannot cross the basic threshold of qualifying the expert. When considering experts, parties often focus on the finish line, but the beginning deserves as much attention to avoid a similar situation: a disqualified expert and resulting summary judgment in the defendant's favor.

It is ultimately the physician's responsibility to know his or her patient's condition. However, as the healthcare industry grew and physicians were caring for more patients, nursing responsibilities grew to meet the need by requiring patient monitoring, documentation, and reporting of observed or measured changes in symptoms and care requirements. This quickly became the standard of care in all settings where nurses are used to provide patient care under the orders of a physician or other licensed independent practitioner. Nurses assume leadership roles within these settings and possess advanced degrees that qualify them to teach other nurses and serve as expert witnesses when nurses' care is in question. With or without a degree, a seasoned nurse who has supervised subordinates and peers can offer valid testimony that often withstands whatever legal scrutiny the opposition tosses at it. Attorneys are missing opportunities by not using this resource.

Finally, physicians and healthcare providers should know the experience and qualifications necessary to testify as experts, especially when it comes to professional standards of non-physician healthcare providers. Although a plaintiff (or defendant) may be thrilled an intelligent, experienced physician with a winning track record is willing to testify on their behalf, it may be worth declining the invitation if there are doubts as to whether the expert can strictly comply with an applicable expert witness statute. It is critical to consult with experienced counsel in your state to understand any such applicable statutes, which will vary by state. ■

REFERENCE

- Decided June 21, 2023, in the Court of Appeals of Georgia, Case No. A23A0267.