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INSIDE

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Reporting Misdeeds: How and When to Use Disclosure Protocol

Once a risk manager realizes the organization may have violated laws or regulations, the best course of action might be to report the violation instead of hoping no one will discover it. Self-disclosure can offer many advantages that result in lesser penalties and other consequences. But it is important to know when to report and how to do it advantageously.

The Department of Health and Human Services Office of Inspector General (OIG) updated its Provider Self-Disclosure Protocol Nov. 8, 2021, says **Lori A. Rubin**, JD, partner with Foley & Lardner in Washington, DC. The name was changed to the Health Care Fraud Self-Disclosure Protocol (SDP).[1]

Most of the changes were technical, but the update provides an opportunity for healthcare risk managers to review the protocol and understand how to implement it when necessary.

In addition to disclosing through the OIG-SDP, healthcare organizations can disclose directly to the Department of Justice (DOJ), Rubin says. Each option presents pros and cons.

> "THE OIG HAS MADE CLEAR THAT THEY DON'T LIKE WISHY-WASHY STATEMENTS ABOUT HOW THE GOVERNMENT MIGHT PERCEIVE THIS AS FRAUD, BUT WE DON'T THINK IT'S FRAUD."

"This requires a very careful consideration of whether to disclose, what to disclose, and where to disclose," Rubin explains. "You have to consider a lot of factors, including the complexity of the healthcare issues. Disclosing to the OIG might be more beneficial if it is a complex issue that OIG will have a better understanding of than

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DOJ. It's also worth considering relationships with the U.S. Attorney's office."

The need for a speedy resolution is another concern, as OIG might move faster than DOJ.

An internal investigation is the first step to determining whether to report and how, Rubin says. For example, Stark violations should not be disclosed through the OIG-SDP because there is a separate Stark disclosure protocol. Some overpayments to the government may require only a repayment and not a fraud disclosure.

Higher Fines from OIG

One substantive change in the recent OIG-SDP revision involved the minimum amounts required to settle under that protocol. Since the minimum amounts were increased, kickback issues require a minimum settlement of $100,000. Other issues are $20,000. That is important because organizations sometimes think they should self-disclose in case an issue constitutes fraud, but it is not certain.

"The OIG has made clear that they don't like wishy-washy statements about how the government might perceive this as fraud, but we don't think it's fraud. They don't look kindly on those," Rubin says. "If you're going through self-disclosure with OIG, you should expect to settle the case. You should not expect to have to admit liability, but you should expect some settlement rather than a dialogue about the nature of the arrangements."

Self-disclosing healthcare fraud directly to DOJ offers protection from False Claims Act (FCA) liability, Rubin notes. DOJ routinely releases FCA liability with self-disclosure, meaning the government will not sue the discloser for the conduct in scope, including for treble damages and penalties.

OIG disclosure does not provide the same level of assurance. OIG-SDP says a disclosing party can request a release under FCA, but it is not standard in settlements, Rubin says.

A DOJ disclosure also may result in a lower settlement amount. OIG typically uses a minimum multiplier of 1.5 times the single damages for settlement, but DOJ does not settle self-disclosed cases for a defined multiplier.

Downsides to DOJ Disclosure

One downside to DOJ disclosure is the 60-day report and return obligation is not automatically triggered, Rubin notes. The OIG-

EXECUTIVE SUMMARY

Self-disclosure of healthcare fraud could prevent some problems. There are two primary routes for self-disclosure.

- The Department of Health and Human Services Office of Inspector General recently updated its Provider Self-Disclosure Protocol.
- Disclosure to the Department of Justice offers protection from the False Claims Act.
- Any disclosure must be fully transparent.

SDP automatically suspends the obligation to report and return an overpayment within 60 days after an overpayment is identified, but a DOJ disclosure does not. The DOJ must obtain approval from CMS and OIG to suspend the 60-day report and return obligation.

Rubin also notes the OIG-SDP is designed specifically to address healthcare fraud, so reports will be reviewed by professionals who understand the industry and the specific nature of healthcare regulations. The same may not occur with DOJ disclosures.

If you self-disclose through either path, it is important to cooperate with the investigations, Rubin says. Self-disclosing and then resisting or not cooperating with the investigation will encourage a poor outcome.

Can Avoid Whistleblowers

The FCA and the potential for whistleblowers spurred many more healthcare organizations to consider self-disclosure, says **Gabriel L. Imperato**, JD, partner with Nelson Mullins in Fort Lauderdale, FL. Self-disclosure epitomizes the idea of managing risk. He explains to clients that self-disclosure, when appropriate, can be a way to retain more control over the outcome of a fraud investigation.

"You determine a certain scope of conduct from which you negotiate a price to get a release from the government agency for False Claims Act liability," Imperato says. "You don't have to worry about a whistleblower raising that issue and you having to deal with it in an external way, which will involve greater risk, greater money, and greater ramifications for the organization."

Once an organization decides to self-disclose through any route, it must be transparent, Imperato says. It is a terrible idea to confess to only a small part of the problem in hopes it will prevent investigators finding the total scope of the fraud.

"You don't want to disclose information that is short of the total picture because you don't want to be accused of concealing something that the enforcement agency or regulatory agency would consider to be relevant," Imperato says. "You could turn a routine matter into something much bigger because now you have them suspicious of your methods and motives." ■

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Workplace Violence on the Rise; COVID-19 Partly to Blame

Always a challenging problem, workplace violence in healthcare settings has worsened recently as the many stresses of the pandemic push staff, managers, patients, and family members to the breaking point.

The incidence and severity of workplace violence has increased profoundly in the last two years, says **Bette McNee**, RN, NHA, clinical risk management consultant at insurance broker Graham Company in Philadelphia.

"I've never seen worse workplace violence in healthcare, particularly bullying and hostility with co-workers and with patient families. The stress level is just ridiculous," McNee laments. "Everything has come together to create this incredible stress for everyone coming to work. We're getting so many increasing complaints and concerns about workplace hostility and harassment from managers."

McNee and her colleagues are advising risk managers to review their workplace violence policies to ensure they clearly define workplace violence to include bullying, intimidation, and harassment. Many such policies were written to address only physical violence, usually from patients or family members, and do not cover the incidents brought on by stress and pandemic trauma.

"We're suggesting that hospitals use examples in their policies, training sessions, and newsletters of interactions that constitute workplace violence and will not be tolerated. Physical violence, of course, is a major concern, but people have to

understand that there are other types of interactions that are prohibited by your policy," McNee says. "The prompt follow-up to complaints and violations is extremely important for managers and supervisors. Since many of these interactions are observed by co-workers, it is important to teach them that they have an obligation to report violations they witness."

Part of the problem was employers were at a loss for how to help overworked and overstressed staff members cope, simply because they have not seen this type of industry-wide overload before, McNee says. It turns out singing songs, providing free meals, and offering yoga classes did little to help staff cope.

Healthcare organizations must try to determine the root causes of all types of workplace violence and devise ways to address those underlying issues. Managers and supervisors can be trained to identify overstressed staff and intervene in meaningful ways before violence occurs.

"The healthcare industry has so much to deal with now, but helping your employees address stress and improve their ability to cope will help the hospital improve their outcomes with every other priority," McNee says.

Isolation and other frustrations generated by the pandemic has prompted a surge in clinical aggression and behavioral health issues, says **Lisa Terry**, CHPA, CPP, vice president for vertical markets — healthcare with Allied Universal Security Services in Santa Ana, CA. Those issues usually manifest first in the emergency department (ED).

"We hoped that after the vaccines were available things would calm down a bit, but it really hasn't," Terry says.

An effective workplace violence prevention program should include numerous partnerships among a wide variety of stakeholders, Terry says. The workplace violence prevention (WPV) team or committee should be a cross-functional and diverse group dedicated to a culture of safety.

Internal partnerships include security, patient safety, nursing, compliance, risk management, and human resources, Terry says. External partnerships include regulatory, compliance, and consulting organizations such as The Joint Commission (TJC). TJC released WPV prevention standards that took effect Jan. 1, along with a free webpage that includes a host of tools to assist healthcare organizations strengthen their culture of safety.[1] *(See the story in this issue for more information on the TJC standards.)*

"The Joint Commission wants to see that you have a workplace violence management plan, a program that is overarching and includes all the elements of your workplace violence efforts. What many hospitals are not doing is an actual community vulnerability assessment," Terry says. "That includes looking at your environment, what kind of access there is, and if it should be improved. The emergency department needs to be accessible but in a way that keeps everyone safe."

Data management and analysis also can help hospitals act in a proactive way rather than only responding to incidents, Terry says.

While statistics show workplace violence is declining in the workforce overall, it has become an epidemic in the healthcare arena, says **Paul Baratta**, segment development manager for healthcare with Axis Communications, a Boston-based company that provides security technology to healthcare institutions. Data from the Bureau of Labor Statistics show 73% of all workplace assaults happen in the healthcare space.[2]

"Some of this is due to acceptance of some levels of both verbal and physical violence by medical staff and empathy toward patients and family members under extreme stress," Baratta says. "One factor that has become evident is that the level of violence has increased and physical assaults are continuing to increase."

TJC Standards on Violence

There is less acceptance of this form of workplace violence by hospitals that have been mandated to protect patients, staff, and visitors by TJC and create written workplace violence policies and procedures, he says. These are to include reporting and support to staff that have been assaulted both verbally and physically. What was once "part of the job" has become less acceptable to staff and especially administrators who have seen the cost of these incidents, Baratta says.

The Occupational Safety and Health Administration (OSHA) has also joined TJC in mandating safety and the reduction of workplace violence, with the possibility of OSHA findings, TJC Sentinel Events, and fines, Baratta notes.

"The OSHA guidelines and mandatory procedures have gone one step further to include long-term care and skilled nursing residential facilities, as well as clinics. OSHA found that 20% of all workplace violence injuries happen in healthcare and over 50% of healthcare workers suffer all assaults," he says. "There are many factors that lead to this: working with violent people; extended wait times in emergency

departments; poor environmental design and lack of access control; poorly lit corridors; and prevalence of firearms, knives, weapons, and legal and illegal narcotics. These are just some examples of what causes an increase in violence."

The hospital emergency room is the "great unknown." Often, patients present with a history of violence or are under the influence of narcotics or suffer from mental behavior issues and staff are mandated to help them, Baratta says. This often leads to physical and verbal assaults against staff.

Staffing has become an issue in healthcare, with a lack of people wanting to handle patient watches and security departments having a difficult time hiring officers, Baratta says. Turnover is also an epidemic in healthcare security, at the same time medical staff are overtaxed with the pandemic and care of patients, he says.

A lack of facilities for behavioral patients also has led to increase in violence and does not seem to be improving, Baratta notes.

Train in MOAB

One major issue is a lack of proper training in management of assaultive behavior (MOAB) at all levels of staff, Baratta says. At a minimum, ED staff should all be trained in MOAB techniques, he says.

"OSHA now mandates this training, along with management commitment to worker safety; a full review of all hazards; and security technology to include video, access control, and audio. OSHA has also mandated reporting and other mandatory training, so all hospital administrators should be up to date on their recommendations and mandatory policies and guidelines," Baratta says. "About 85% of hospitals have instituted a program to reduce workplace violence. The U.S. Department of Labor has also issued guidelines and has recognized workplace violence in healthcare."

Some acoustic analytics can be deployed to monitor for aggressive behavior, glass breaks, gunshot detection, and alarm notification, Baratta notes. Many hospitals are exploring the use of sound analytics and artificial intelligence to help stop an assault before it escalates into a serious incident where staff are injured.

"Being proactive by using video, audio, and analytics can help reduce workplace violence with better response by both staff and security officers," Baratta says. "Although not perfect and difficult to determine if someone or their family will become violent, proactive measures with video and audio have been shown to reduce workplace violence."

TJC, OSHA Expect Hospitals to Address Violence

The Joint Commission (TJC) recently updated its standards for preventing and addressing violence in the healthcare workplace.

TJC noted in 2018 healthcare and social service workers were five times more likely to experience workplace violence than all other workers — and that was before the pandemic added additional stress to both patients and staff. Although incidents likely are underreported, violence in healthcare setting comprises "73% of all nonfatal workplace injuries and illnesses requiring days away from work," TJC noted in announcing the revised standards. *(An explanation of the revised standards is available online at: https://bit.ly/3nb7HER. Additional TJC resources on workplace violence are available online at: https://bit.ly/3qZpLTv.)*

The Occupational Health and Safety Administration (OSHA) does not use specific standards for workplace violence, but the General Duty Clause requires employers to provide their employees with a place of employment that is "free from recognized hazards that are causing or are likely to cause death or serious physical harm."

OSHA noted, "The courts have interpreted OSHA's General Duty Clause to mean that an employer has a legal obligation to provide a workplace free of conditions or activities that either the employer or industry recognizes as hazardous and that cause, or are likely to cause, death or serious physical harm to employees when there is a feasible method to abate the hazard. OSHA has developed Enforcement Procedures and Scheduling for Occupational Exposure to Workplace Violence, which provides guidance and procedures to be followed when conducting inspections and issuing citations related to the occupational exposure to workplace violence." *(*Enforcement Procedures and Scheduling for Occupational Exposure to Workplace Violence *is available at: https://bit.ly/337pR3w. Additional OSHA resources on workplace violence are available online at: https://bit.ly/33dRqbt.)* ■

A special messaging system can alert hospital staff to violent incidents quickly, says **Terri Mock**, chief strategy and marketing officer at Rave Mobile Safety in Framingham, MA. Systems are available that can notify staff using multiple communication channels so they are immediately aware and know how to respond.

Hospitals must create emergency preparedness plans, use communication tools so staff can act quickly, and provide a channel to report violent incidents and anonymous tips.

"By deploying a personal safety app that can easily be downloaded onto phones, healthcare organizations can put emergency plans, contacts, and safety tools right into the hands of their staff," Mock says. "Adopting these more agile communication technologies give employees multiple ways to report violence, and help hospital administrators improve conditions for those on the frontline. Likewise, ensuring hospitals work with police, fire, emergency managers, and others in the community will be crucial to ensuring a swift and collaborative response." ■

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Protect Peer Review Privileges, or Risk Serious Consequences

A hospital's peer review protection often prevents attorneys from potentially using damaging information in court, but that protection can be forfeited.

Peer review is an important tool healthcare organizations use to prevent future patient harm by identifying issues, conducting investigations to determine the root causes, and fixing those root causes before they can cause further harm, says **Callan G. Stein**, JD, partner with Troutman Pepper in Boston.

The peer review privilege is critical because it allows physicians and medical professionals, whose medical expertise make them uniquely qualified to know best how colleagues should act, to conduct the investigations themselves while maintaining confidence. Absent the peer review privilege, hospitals and medical centers would have to rely on another privilege to maintain confidence. For example, they would have to engage legal counsel in every instance to take advantage of the attorney-client privilege, Stein says.

All 50 states and the District of Columbia currently have peer review privilege statutes on the books, Stein says. The application of, and limitations for, the peer review privilege will vary by state.

State peer review statutes and some federal statutes, such as the Healthcare Quality Improvement Act of 1986, generally provide levels of immunity to those who participate in the peer review process, Stein says. That means they cannot be sued or otherwise held liable for their statements or actions that were part of the peer review process.

"State peer review statutes also typically protect the confidentiality of peer review processes," he explains. "This encourages the open exchange of ideas and open communication during peer review without the participants fearing that their statements will later be used against them, for example, in litigation."

This protection goes both ways. In a malpractice suit, peer review materials cannot be used by either the plaintiff patient or the defendant physician or facility.

Follow the Statute

To protect patient safety investigations, the most important thing is to follow the applicable federal or state peer review statute as strictly as possible.

Most statutes explain the circumstances in which the peer review protections will apply, including defining what does and

does not constitute a "peer review committee," Stein says. For an investigation to enjoy peer review protection, it must, at a minimum, be conducted by one of these committees or another body to whom the statutory protections apply.

"In addition, often times peer review statutes will make clear that the peer review privilege only applies to actions taken for specific purposes; for example, the evaluation or improvement of the quality of healthcare being provided," Stein explains. "It should be well documented that any patient safety investigation is being conducted for one or more of these purposes, and the findings of the investigation should, in fact, be used for those purposes. Put another way, a hospital or facility claiming the peer review privilege over a patient safety investigation should be prepared to demonstrate how the investigation helped improve patient care, for example."

If the hospital or facility uses a specific, documented process by which a patient safety investigation must be conducted, it should first ensure the stated process complies with the applicable peer review statutes, Stein says. If the process is compliant, Stein advises following that process as strictly as possible.

"Plaintiffs and other parties seeking to vitiate the peer review privilege frequently seek to exploit even minor deviations from documented procedures," he explains.

Peer review protection can be forfeited through errors on the part of the healthcare entity, Stein cautions.

Avoid Bad Faith Charge

One common way parties seek to sever the peer review privilege is by claiming the party seeking to enforce it engaged in bad faith during the peer review process, Stein says. The term often applied in this context is that of a "sham peer review," in which the participants are alleged to have acted out of bias, personal animus, or some other non-medical reason. If such bad faith is proven, it will defeat a claim of peer review privilege.

"Another somewhat common argument to overcome the peer review privilege is a claim that certain comments or actions were taken outside the peer review setting," Stein says. "The privilege only applies to the peer review setting, the boundaries of which are often defined as the duration of a meeting of a peer review committee."

Peer review records also typically do not enjoy privileged protection in federal lawsuits alleging discrimination or other civil rights violations, Stein notes.

The most important thing to remember about confidentiality protections afforded to patient safety investigations by state law is they represent an exception to the strong policy in favor of allowing patients to access information about their own treatment, says **Mark R. Ustin**, JD, partner with Farrell Fritz in Albany, NY.

"They tend to be limited. You want to make sure that any disclosures occur only in the context of formal proceedings eligible for protection, and you have to pay close attention to any exceptions to those protections," Ustin explains. "For instance, sometimes the statements of a malpractice defendant will not be afforded the same protection as statements of other individuals investigating the alleged malpractice. Once the privilege is forfeited in one place, that can lead a court to determine that it was forfeited elsewhere, forcing the disclosure of statements or documents that you never thought would be subject to disclosure."

Hospital Acted Too Quickly?

Acting in haste can threaten peer review privilege, says **Christopher J. Kutner,** JD, partner with Rivkin Radler in Uniondale, NY.

The privilege, created by statute in most states, is rationalized by the need for confidentiality in promoting a complete and candid peer review, Kutner says. But one court in Pennsylvania decided the privilege was not available because the formality required by statute to afford the protection was not followed.[1]

"The lesson to be learned is that statutes affording privilege must be followed to the letter if the hospital will intend to use privilege as a shield," he says.

In a case involving infant deaths following an outbreak of adenovirus, the lower court in Pennsylvania ordered the release of information because a formal meeting to commence the peer review did not occur as required, Kutner explains. Balancing the need to follow the applicable peer review statute to the letter against the urgency of commencing an immediate investigation to avoid further patient harm may be the key issue on an appeal.

"It is certainly understandable, especially when involving the deaths of infants, to want to investigate immediately to avoid further loss of life," Kutner says. "In present day, with extensive technology available to gather individuals for a meeting on short notice, there is no excuse for not commencing the investigation as required, especially understanding

that infants died and there would most surely be lawsuits."

Investigators may have concluded the hospital was liable for failure to adequately sanitize ophthalmic equipment used in the neonatal unit or the hospital did everything reasonable to sanitize the equipment, or something in between, Kutner explains.

Privilege is afforded based on broad principles. Privilege will be afforded if peer review action is taken in the reasonable belief the action was in furtherance of quality of care, after a reasonable effort to obtain the facts of the matter, after reasonable notice and hearing procedures are afforded to the physician involved or after such other procedures are fair to the physician under the circumstances, and in the reasonable belief the action was warranted by the facts known after such reasonable efforts to obtain the facts.

"In the Pennsylvania case, there was certainly urgency to determine if a quality-of-care issue existed and to immediately remediate, but that could have been done after the formalities required to kick off the review were performed," Kutner says.

When a statute affords protections such as a privilege from discovery, and the statute is not followed to the letter of the law, courts are constrained in their ability to extend the privilege. Had the judge granted the privilege and that issue appealed, the appellate court would likely have reversed the lower court and ordered the release of information.

"The lesson in these peer review cases is to follow the applicable statute, bylaw, or otherwise to the letter, or courts will be constrained for upholding the privilege," Kutner says. ■

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Stay Vigilant About Malpractice Risks with Telemedicine

The dramatic increase in the use of telemedicine is raising concerns about the potential for malpractice issues related to this form of caregiving, with some experts cautioning a wave of lawsuits could be on the way.

Adherence to key principles of patient safety and risk management can reduce the risk.

Few lawsuits focused specifically on care delivered by telemedicine have been filed, and some attorneys are surprised, says **Tom Davis**, MD, FAAFP, a practicing physician, consultant, and expert witness in St. Louis. There always is a delay after new technology is widely adopted, but some legal experts expected more lawsuits by now, he says. It may only be the lull before the storm.

The consensus in the legal community is the delay is simply because the liability attorneys do not know how to value these claims, Davis says. Plaintiff's attorneys appear to be holding on to complaints until they can determine valuations, but that is not an indicator that telemedicine has been unusually free of medical malpractice allegations.

"When one or two brave souls file claims, their peers can look at that and see how to value these cases, and then it will be a flood of cases coming. Attorneys hear people say it appears there has not been much actionable related to telemedicine, and they chuckle at that because they think it is going to be the alpha and omega of tsunamis once the claims start," Davis says. "Don't take the lack of filings as being reassuring in any sense. It's a new thing, and once they come, boy, are they going to come."

Failure to Diagnose

Failure to diagnose will be one of the most likely allegations, Davis predicts. Healthcare organizations should be extremely conservative in how they use telemedicine and resist encouragement from the business office to maximize patient volume through the technology.

By its nature, telemedicine allows for much less meaningful interaction with and assessment of the patient, Davis says. What might be immediately obvious in a traditional office visit might go overlooked or

require much more inquiry through telemedicine. For that reason, Davis' threshold for telling a patient to go to urgent care or call 911 during a telemedicine encounter is much lower.

"The telemedicine services don't like it because they like to advertise that you can get the same care through telemedicine as you can get in person, which we all know is a lie," Davis says. "When a patient gives you a symptom that is even the least bit concerning, they have to have an in-person visit — automatically, no question. That's just about patient safety."

The lack of sensory feedback with telemedicine could increase the risk of failure to diagnose, says **Christopher J. Ryan**, JD, an attorney with Dickinson Wright in Ann Arbor, MI.

"The provider is not able to palpate an area to recreate pain, for instance, and that is an important diagnostic tool in some cases. That could lead to a failure to diagnose," Ryan says. "If the provider gets the sense that they could get a more complete picture by bringing patient in, they should do that. There should not be any hesitation because it is inconvenient."

Ryan agrees an increase in telemedicine malpractice cases is on the way, and urges risk managers to review policies and procedures that can mitigate the risk.

"It wouldn't hurt to include documentation on why the provider felt that telemedicine was appropriate for this visit," Ryan says. "It could be a good risk management approach to have the provider attest to why this particular patient and type of care is appropriate and safe with this technology. That may include the risks of having the patient come into a facility during a pandemic, or other risks associated with a physical visit."

Telemedicine also will play into one truism about why patients sue. It is well known patients are less likely to sue doctors with whom they feel they have a relationship and who care about their welfare, and more likely to sue those they do not know and who seem indifferent.

"It's much more difficult to communicate empathy, compassion, that you're a nice person through an iPhone screen than it is in person," Davis says. "When you see me in person, I'm going to give you a fist bump or a handshake, chat with you, ask about your family — all of which makes our encounter less efficient but much better overall. There are ways to make up for that in telemedicine, but the physician has to be taught that. I have yet to find a health system that is interested in engaging their clinicians in the right way about that."

Larry Hansard, MSM, area director for the healthcare practice of Gallagher, a commercial risk management and insurance brokerage in Washington, DC, confirms he has seen few malpractice claims related to telemedicine. In the past six years, his company has provided telemedicine insurance coverage for more than 70 clients, including some of the largest telemedicine providers, accounting for millions of telemedicine visits every year.

"In that time, I have seen one paid malpractice claim. Frankly, it was kind of an anomaly," Hansard says. "It was a therapist who used some bad judgment and got involved with a patient. It had very little to do with telemedicine, and all about a very misguided individual."

However, insurance carriers are reporting an uptick in claims. Hansard believes the difference is his clients are mostly referred by law firms specializing in telemedicine, and the healthcare providers use top-notch risk management controls for their telemedicine operations.

It is likely the number of cases of patient regulatory complaints and medical malpractice allegations that involve this type of care will increase, says **Katea M. Ravega**, JD, partner with Quarles & Brady in Indianapolis.

Ravega advises focusing on these mitigation tactics:

- Ensure accurate and complete medical records for each telemedicine visit. In addition to complying with the laws about recordkeeping, ensuring a correct and thorough record of the encounter can help support the basis for the provider's care decisions.
- Stay current on changes in standard of care, diagnostic tools, and exam methods using telemedicine technologies. This area of law and practice is changing rapidly, and clinicians are frequently innovating new ways to examine patients remotely. In addition, Ravega says, restrictions on conditions that can be treated via telemedicine, requirements related to mode of technology or establishment of valid provider-patient relationships also evolve from time to time.
- Continue to provide the same high-quality care via telemedicine that would be provided in person, including recommending patients go for an in-person visit when it is called for, and document those recommendations.
- Maintain all required licenses for the healthcare providers, and establish to prevent anyone from accidentally engaging in unlicensed practice.
- Monitor enforcement actions, settlements, and legal changes in the states where patients are located to ensure adjustments are made to comply with new requirements over time.

• Incorporate telemedicine compliance tactics into the overall compliance program, including policies and procedures, training, and internal auditing and monitoring processes.

"An additional item that is sometimes overlooked when providers initially begin to provide care via telemedicine is to review the insurance policies to ensure that the malpractice coverage includes care provided via telemedicine," Ravega says. "Depending on the specifics of the policies that are in place, additional insurance or other adjustments may be needed."

HIPAA Concerns

As the pandemic abates, telehealthcare may recede as well, but it is unlikely to return to pre-pandemic levels as both providers and patients have enjoyed its convenience, says **Christopher Tellner**, JD, partner with Kaufman Dolowich Voluck in Blue Bell, PA.

While this area of the law is in its infancy, there are several established principles of which healthcare providers and patients should be aware. Telemedicine technology must be compliant with HIPAA, state-based laws regarding health information, and informed consent requirements, Tellner notes.

Regarding telemedicine, the threat of a HIPAA violation may be heightened due to the threat of hacking or impermissible third parties eavesdropping on a telemedicine visit.

"While a provider's responsibilities under HIPAA do not change generally when engaging in the practice of telemedicine, certain aspects of HIPAA have been relaxed during the COVID-19 pandemic, particularly the security rule requirement that the telecommunication platform used meet certain technical security requirements," Tellner says. "This relaxed standard should not be expected to last, and providers should be cognizant of whether the platforms they use satisfy HIPAA."

The doctrine of informed consent was first recognized as the patient's right to control the healthcare he or she received. The doctrine has since been extended to include the patient's right to control his or her health information, Tellner says. Over the years, several elements have been held to encompass a patient's informed consent.

"The patient must have the capacity to make decisions on their own behalf, which includes the mental capacity to understand the decision the patient is making. A patient must be given sufficient information that would enable a reasonable patient to understand the decision the patient must make, and to understand the possible consequences of that decision," Tellner explains. "Due to the less formal nature of telemedicine, informed consent may be overlooked during the provision of telemedicine. However, informed consent requirements are no less stringent when providing virtual care than in the provision of in-person care, and cannot be overlooked."

State Lines May Complicate

Every healthcare practitioner is governed by a state licensing board and is subject to state licensing guidelines, notes **Abbye Alexander**, JD, partner with Kaufman Dolowich Voluck in Orlando. A major, unclear legal issue courts nationwide are grappling with is the effect of a health practitioner's provision of remote care and on the standard of care applicable to that particular practitioner.

Practitioners may be located in different states than patients. There will be different malpractice laws, standards of care, immunity provisions, statutes of limitations, or damage limitations in the practitioner's state than the states in which their patients are receiving the virtual care.

"This issue becomes more complicated by the common exclusion in malpractice insurance policies regarding unlicensed activities engaged in by the practitioner, which could be implicated if the practitioner is engaging in a practice within the scope of his or her license in the state they are providing care, but the location where the patient is receiving care is outside the scope of the practitioner's license," Alexander says. "We can anticipate an increase of litigation in this area. Litigation that arises in this area should be monitored."

Practitioners should understand the geographic scope of their patients to better ensure the care provided is permissible across jurisdictional lines.

"Malpractice concerns can have serious, disastrous impacts on providers and patients alike. This fact has not changed in light of the shift toward telemedicine, but telemedicine poses different malpractice dynamics than the in-person provision of care," Alexander says. "Health providers should discuss malpractice concerns specific to telemedicine with legal counsel and malpractice insurance carriers to ensure compliance with evolving regulations and standards of care, and to ensure coverage in the event of a telemedicine malpractice incident."

Determining the standard of care becomes complicated in telemedicine

cases because of the jurisdictional issues and due to the more limited nature of care offered by telemedicine, says **Henry Norwood**, JD, attorney with Kaufman Dolowich Voluck in Orlando. A practitioner likely cannot provide the same level of care via telemedicine they could by physically examining a patient.

"This would suggest that the standard of care provided to the patient is lower and the burden is higher on the practitioner to show that the proper standard of care was met, and will likely result in an increase of malpractice lawsuits," Norwood says.

The American Medical Association (AMA) has issued guidance on the standard of care to which practitioners should hold themselves in the practice of telemedicine.[1]

"This guidance, while not conclusive on the legal issue of the standard of care applicable to telemedicine malpractice cases, may be relied on as persuasive authority in the area," he says.

Norwood offers this summary of the key recommendations in the AMA telemedicine guidance:

• Inform patients about the limitations of the patient-provider relationship and the services the provider can competently provide via the telemedicine platform.

• Advise patients how to arrange for follow-up care, if necessary.

• Encourage patients to inform their primary care providers of the patients' virtual visits.

• Providers engaging in virtual care must hold themselves to the same professional standards applicable to the provision of in-person care.

• Providers must recognize and actively take efforts to overcome the limitations of telehealth technology in the course of the care they are providing, such that any deviation of care between telehealth care and in-person care is diminished.

• Providers must be proficient in the technical aspects of the platforms they use.

• The same standards apply equally to providers engaged in the prescription of medications.

• Informed consent should be tailored to the patient-provider interaction, considering the telehealth nature of the interaction.

Additional guidance from the AMA and other professional organizations likely will be issued as telehealth remains a primary form of care in the years to come, Norwood says. A practical understanding of this guidance can aid practitioners to avoid malpractice concerns in the course of their practice.

Ensure Tech Is in Order

On the issue of misdiagnosis in telehealth, it is best that healthcare providers ensure their receiving equipment is fully functioning so there are no complications, glitches, or sound or picture barriers to their telehealth visit, says **Savera Sandhu**, JD, partner with Newmeyer Dillion in Las Vegas. A best practice is to use secure technology with historically successful communication, picture, and recordkeeping.

Some healthcare providers have used common FaceTime or video chat platforms due to limited regulatory measures during COVID-19, but that may lead to insufficiencies and liability.

"Another recommendation is that a second person is with the provider, such as a nurse, a physician assistant, or a resident. That way, there are two sets of eyes and ears to confirm the medical issues and recommend a treatment path," Sandhu says. "It is always good to repeat the patient's comments, confirm the accuracy of their complaint, and record them. In the world of oncology, diagnosing cancer is critical, so a recommendation for an in-person visit should be given if there is even the slightest chance of a potential cancer concern." ■

REFERENCE

1. American Medical Association. Ethical practices in telemedicine. https://bit.ly/3zHdszj

SOURCES

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HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **What is one advantage of using the OIG Health Care Fraud Self-Disclosure Protocol?**

   a. It automatically offers protection from False Claims Act liability.
   b. It specifically covers healthcare fraud, so reports will be reviewed by professionals who understand healthcare regulations.
   c. Fines are reduced by half for self-disclosure.
   d. Self-disclosed fraud reports are not made public.

2. **What does Paul Baratta say is happening with workplace violence?**

   a. Workplace violence is declining in the workforce overall, but it has become an epidemic in healthcare.
   b. Workplace violence is increasing in the workforce overall, but it is decreasing in healthcare.
   c. Workplace violence has decreased in the workforce overall, but has not changed in healthcare.
   d. Workplace violence has not changed in the workplace overall or in healthcare.

3. **What does Callan G. Stein, JD, say is the most important thing to protect patient safety investigations?**

   a. Follow the applicable federal or state peer review statutes as strictly as possible.
   b. Do not publicly release information from the investigation.
   c. Do not enter evidence from the investigation during litigation.
   d. Create a new safety committee for each investigation.

4. **What does Tom Davis, MD, FAAFP, say is the primary reason few telemedicine-related malpractice lawsuits have been filed?**

   a. Telemedicine yields few actionable allegations for malpractice.
   b. Pandemic regulations limited the potential liability for telemedicine.
   c. Plaintiffs' attorneys do not yet know how to value the cases.
   d. Patients tend to develop a closer and more trusting relationship with physicians through telemedicine.

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

Use of Defective Laser Leads to $9.7 Million Verdict Against Hospital

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News: A jury ruled against a Pennsylvania hospital and one of its neurosurgeons, finding the latter negligent for using an allegedly defective tool on a patient without securing proper consent. Jurors awarded the plaintiff $9.7 million.

In October 2015, a patient sought treatment from a neurosurgeon for a benign brain tumor. The neurosurgeon recommended laser interstitial thermal therapy (LITT), a minimally invasive procedure to destroy unhealthy tissue. However, the neurosurgeon failed to warn the patient the particular laser had not been used before for that kind of surgery, nor did he inform the patient he had never performed this procedure.

During the surgery, the outer tip of the probe broke off, releasing carbon dioxide in two eight-second blasts directly into the patient's brain, apparently causing a spike in the patient's intracranial pressure. The patient fell into a coma.

The subsequent lawsuit also alleged the neurosurgeon had only used the device in one other type of surgery, during which he had used a narrower, more fragile tip instead of a thicker one, and had ignored messages from the device's software that should have prompted him to stop.

The jury found the neurosurgeon failed to obtain proper informed consent from the patient, and his omissions were material to the patient agreeing to the procedure. The jury also found the neurosurgeon and the hospital were negligent, and the defect in the device was a cause of the patient's injuries. The neurosurgeon is liable for about $4.2 million of the verdict, and the hospital will pay about $1.5 million.

THE NEUROSURGEON FAILED TO WARN THE PATIENT THE PARTICULAR LASER HAD NOT BEEN USED BEFORE FOR THAT KIND OF SURGERY, NOR DID HE INFORM THE PATIENT HE HAD NEVER PERFORMED THIS PROCEDURE.

Background: On Oct. 16, 2015, a patient underwent LITT to treat a benign brain tumor. Previously, the patient underwent stereotactic radiosurgery for left frontal meningioma. The patient's neurosurgeon recommended LITT as treatment for the ongoing edema and worsening symptoms. There has been no report in the medical literature of the use of LITT to treat meningioma or radiation necrosis in meningioma, nor had the neurosurgeon ever performed this procedure for meningioma. The neurosurgeon did not relay this information to the patient.

After the surgery, the patient experienced problems with his memory and speech. MRIs showed residual left frontal meningioma with central necrosis and edema.

The patient further alleged the neurosurgeon negligently chose the smaller 2.2 mm outer diameter probe for the LITT procedure instead of the more

robust alternative with a 3.3 mm outer diameter probe. MRI images with contrast recorded during the procedure showed sequential development of hemorrhage and mass effect in the left frontal lobe.

On Oct. 21, 2015, the neurosurgeon informed the patient's wife and son the fiber optic cable fractured during the procedure, and an approximately 2 mm piece of plastic coating was missing from the tip of the probe. Additionally, the neurosurgeon informed the patient's family an eight-second infusion of carbon dioxide gas directly into the patient's brain occurred twice during the procedure, producing a spike in the patient's intracranial pressure. As a result, the patient fell into a coma.

The patient filed a malpractice lawsuit against the neurosurgeon and the hospital for medical negligence. He asserted a claim of battery for lack of informed consent before the procedure.

The patient also sued the manufacturer of the device used during the LITT procedure for counts of strict liability, failure to warn, malfunction, breach of implied warranty, and negligence. The patient's wife asserted a final claim of loss of consortium and companionship as a result of the procedure.

The jury found the device manufacturer 42% at fault for the injury. The manufacturer had already settled with the patient for $12.5 million. The remaining fault was apportioned at 43% for the surgeon and 15% for the hospital. The jury awarded the patient and his wife $5 million for pain, suffering, and other noneconomic losses; $3.1 million for his future medical expenses; and $1.6 million for loss of companionship.

What this means to you: This case shows the importance of informed consent in medical negligence cases and defines how strictly a court upholds the standard of care when informing a patient of the asserted risks of a procedure outside the scope of a doctor's expertise.

The main issue in this case concerns the level of informed consent. The patient was unaware of his neurosurgeon's lack of experience with this procedure in treating the patient's condition. As previously stated, there are no reports or precedents of the use of this specific device for LITT treatment of this condition. Additionally, the neurosurgeon had never performed this procedure for meningioma and did not relay this information to the patient. The patient stated he would not have undergone the procedure if he knew of its novelty as a treatment and the neurosurgeon's inexperience.

Although the court ruled the medical device manufacturer is 42% at fault, they placed the largest percentage of blame on the surgeon at 43%.

It is important to provide patients full and comprehensive information on the procedure, including how common the practice is and the doctor's experience level.

Responsibility also lies with the hospital's medical staff to know physicians' skill levels, awareness of medical devices, and to instruct physicians on proper usage of devices until they demonstrate proficiency. At that point, the physician must inform the patient about the upcoming procedures, including the physician's knowledge of medical devices. Detailed documentation of the explanations and the patient's understanding is the only reliable way to ensure fully informed consent.

Another key lesson is courts are likely to impose liability on a hospital or physician if they determine the patient did not feel adequately informed of the risks of injury following surgery. Regardless of what caused the injury, informing the patient of the commonality of the specific procedure and the

physician's personal experience with the procedure falls within the standard of care.

It is crucial to inform patients of all the attenuated risks of any procedure. It is evident from this case there are many risks in performing a procedure that is not standard and routine for treatment of a specific illness. There also is a high risk if a physician is performing a procedure for the first time. These were risks that were not related to the patient and were detrimental to the neurosurgeon's case when assessing if the patient was adequately informed. Without informing the patient of these risks, the patient could not give informed consent. ■

REFERENCE

- Decided Nov. 12, 2021, in the Court of Common Pleas for Philadelphia, case number 160803335.

Appellate Court Reinstates Claims of Negligent Treatment Causing Permanent Disability

News: A three-judge appeals panel in Illinois reinstated claims by a patient with multiple sclerosis for her neurologist's negligence in treating her disorder. The treatment caused the patient's permanent disability. The trial court originally rejected the patient's amended complaint.

The patient and her mother claimed the neurologist and the clinic are responsible for the patient's progressive multifocal leukoencephalopathy (PML), a brain infection the patient alleged she contracted while undergoing treatment for multiple sclerosis. The patient alleged the doctor failed to follow a warning the medication could cause PML as a side effect if the medication is used improperly.

Because of the infection, the patient cannot function or communicate properly. A probate court found the patient legally disabled, making her mother the legal guardian of her estate. Following this ruling, the patient, through her attorneys, asked the trial court to file an amended complaint to name the patient's mother as co-plaintiff.

Defendants moved to dismiss the case on a statute of limitations defense. They also argued the case is not subject to tolling, as the patient was not legally disabled before filing suit. The trial court sustained defendant's motion for summary judgment. The appellate court later reversed the ruling, stating there is a genuine factual dispute as to when the patient became disabled and if tolling would be applicable. The appellate court urged the patient's mother to submit an amended complaint for the lower court to consider.

But when the case went back to the trial court, the neurologist took issue with what they believed was a new allegation in the patient's amended complaint, which contended the patient was disabled in November 2012 when she was diagnosed with PML. The defendants also asked the trial court to eject the patient's expert witness, who testified the patient was disabled by the time she was diagnosed with PML. They argued the patient's mother used it to contradict a "judicial admission" the patient made in her earlier complaints, which said she discovered the neurologist's mistake in June 2015.

The trial court agreed with the defendants, dismissing the witness's statements and the amended complaint. The lower court judge awarded summary judgment to the neurologist and clinic based on the facts in the previous complaint.

Background: From March 2008 to October 2012, a patient with multiple sclerosis was prescribed natalizumab to slow the progression of the disease. The patient claimed the doctor knew treating patients with natalizumab for longer than two years placed them at an increased risk for developing PML, a rare brain infection that causes severe disability.

In April 2018, a probate court found the patient was legally disabled and appointed her mother as guardian of her estate and person. The patient's mother moved to file an amended complaint and to substitute the patient's mother as plaintiff. The defendants objected, and filed a combined motion to dismiss and for summary judgment due to the statute of limitations. Defendants moved for summary judgment, arguing the patient knew her cause of action when she was first diagnosed with PML on Nov. 15, 2012, and was required to file suit no later than Nov. 15, 2014.

The plaintiffs argued a genuine issue of material fact as to when the patient discovered the injury based on the defendants' wrongful conduct. They attached a doctor's affidavit, stating the patient was under a legal disability as of November 2012, contending the limitations period

was tolled by either the patient's legal disability or the discovery rule. The discovery rule stops the clock for statute of limitations defenses to when the plaintiff reasonably could discover his or her damages.

Despite the proof of a triable issue of fact, the trial court granted defendants' motions, to which the plaintiffs appealed. The appellate court reversed the trial court's ruling, holding there was a genuine issue of material fact regarding when the patient became legally disabled. The panel ruled the lower court's ruling "directly contradicts" the previous appeals opinion.

What this case means to you: At issue in this appeal is whether the trial court erroneously vacated its order granting plaintiff leave to file the amended complaint and denied plaintiff's motion for leave to file her amended complaint based on the law-of-the-case doctrine.

The law-of-the-case doctrine is the concept that a decision by an appellate court on a legal issue is binding on both the trial court on remand and an appellate court on a subsequent appeal in the same case with the substantially same facts. Under this doctrine, legal issues decided on appeal to a court of last resort usually govern the case throughout its subsequent stages. The case law is intended to ensure lower courts follow the rulings of higher courts and to prevent relitigation of previously resolved issues, as seen here. The doctrine applies to questions of law and fact, encompassing both explicit and necessary implication decisions made by a court.

The purpose of the law-of-the-case doctrine is to protect the parties' settled expectations, ensure consistency in decisions, maintain consistency throughout the course of a single case, effect proper administration of justice, and close litigation.

In this case, the defendants argued the law-of-the-case doctrine does not apply because the trial court was trying to remedy its mistake. However, the court addressed this issue in the initial case and determined the law-of-the-case doctrine applied.

The facts indicated the trial court knew the amended complaint contained a new allegation the patient was disabled in November 2012, when she was originally diagnosed with PML. The appellate court concluded the trial court, by allowing the new amended complaint to be filed, was aware of its contents and was compelled to accept the allegations in the amended complaint. Therefore, the appellate court concluded there was no mistake to be remedied on remand, and the trial court was required to accept the amended complaint as the operative pleading.

The key takeaway is that courts do not want to relitigate an already-litigated issue. The law-of-the-case doctrine requires both trial and appellate courts to follow the rules set forth by a former appeal regardless of whether the initial court was right or wrong. In this case, the appeals court determined the trial court's ruling directly contradicted its prior holding allowing the amended complaint to be filed without limitation. The trial court was erroneous in not accepting the allegations of the amended complaint as they were pled. They disregarded the court's previous ruling and did not correctly apply the law-of-case doctrine. Because of this, the patient tolled the statute of limitations that allowed for her to try her case.

Tolling and when a patient discovers his or her injury are crucial components of any medical malpractice claim. The discovery rule allows the statute of limitations clock to run upon reasonable discovery by the patient of his or her injury. Timing of when a patient becomes disabled is a genuine issue of material fact and should be permitted. ■

REFERENCE

- Decided Nov. 16, 2021, in the Appellate Court of Illinois, Second District, Case No. 2-20-0735.