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 o er 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.

e Department of Health and Human Services O ce 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. e name was changed to the Health Care Fraud Self-Disclosure Protocol (SDP).

> "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."

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.

" is 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 bene cial if it is a complex issue that OIG will have a better understanding of than

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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 Of ce 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 identi ed, but a DOJ disclosure does not. e 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 speci cally to address healthcare fraud, so reports will be reviewed by professionals who understand the industry and the speci c nature of healthcare regulations. e 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

e 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 rami cations 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 nding the total scope of the fraud.

"You don't want to disclose information that is short of the total picture because y Tm A,i 225 of(Sanizati

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 — health care 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

A special messaging system can alert hospital sta to violent incidents quickly, says Terri Mock, chief strategy and marketing o cer at Rave Mobile Safety in Framingham, MA. Hospitals must create emergency preparedness plans, use communication tools so sta can act quickly, and provide a channel to report violent incidents.

Hospitals must establish mutual aid agreements with police, eng 4 and sta using multiple communication channels so they are immediately aware and know how to respond.

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Protect Peer Review Privileges, or Risk Serious Consequences

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.

" e 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

• 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 speci cs of the policies that are in place, additional insurance or other adjustments may be needed."

HIPAA Concerns

As the pandemic abates, tele-healthcare 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 gener ally 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. " is-re axed standard should not be expected to last, and providers should be cogni zant of whether the platforms they use satisfy HIPAA."

e doctrine of informed consent was rst recognized as the patient's right to control the healthcare he or she received. e 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.

" e 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 su cient 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."

cases because of the jurisdictional issues and due to the more limited nature of care o ered 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.

" is 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.

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

" is 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 o ers 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 e orts 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 pro cient in the technical aspects of the platforms they use.

• e 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 ensur

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was tolled by either the patient's legal disability or the discovery rule. e discovery rule stops the clock for statute of limitations defenses to when the plainti 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 plainti s appealed. e appellate court reversed the trial court's ruling, holding there was a genuine issue of material fact regarding when the patient became legally disabled. e 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 plainti leave to le the amended complaint and denied plainti 's motion for leave to le her amended complaint based on the law-of-the-case doctrine.