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INSIDE

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Take the Right Steps to Speed Resolution of Malpractice Litigation

Steps taken in the early phase of malpractice litigation can significantly affect the length of the case, with the right moves resulting in a faster, cheaper resolution. On the other hand, missteps and oversights can draw out the case, costing more in legal fees and more on the eventual settlement.

The risk manager, in-house counsel, and top administrators can encourage and facilitate the steps that effectively streamline the resolution of a case — or they can discourage them and inadvertently lengthen the process.

The best way to resolve a case quickly is to obtain an expert review early on, says **Kelli L. Sullivan**, JD, shareholder with Turner Padget in Columbia, SC.

"[Obtain a review] as soon as you possibly can," Sullivan says. "As soon as you know there is a claim, and can get your records together, get that expert in to look at everything and give you an assessment of where you stand. That tells you whether you have something to defend."

The defense attorney will have a good idea of the merits, but an expert review by a physician will either back up that notion or suggest more issues to explore.

"I call it a curbside consult. It might not be an in-depth review because some of the issues might not be apparent yet, but you can get a quick assessment that tells you [there is] a problem, or no, these facts don't indicate any wrongdoing by your clinicians," she explains. "Or, it might tell you that you won't really know either way until you investigate some particular areas further."

The expert used for this stage of consultation does not necessarily have to be used as an expert witness if the case proceeds to trial. Sullivan says she tries to complete the consultation within 60 days of accepting a malpractice case.

Risk managers and defense counsel might question such an early expenditure for attorney's costs and the expert

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consultation, but Sullivan says it always is a good investment. If an early review shortens the review window by six months, it could save the defendant $20,000 in legal expenses.

With that assessment, the defense may be better able to determine whether to focus on damages or causation. The better insurance companies require this type of review early in the process, Sullivan notes.

Defense counsel and healthcare organizations often keep two or three physicians on standby to provide these quick assessments as soon as a lawsuit arises.

"With that knowledge, you can immediately tell the carrier that you have a problem and need to look at settling. Or, you can tell them that this is complex, and they need to plan to be in it for the long haul," Sullivan says. "When you know you have a liability problem, you might want to consider early mediation and try to be done with it."

Sullivan also meets with the defendants as early as possible to review the incident and their approach to the litigation. Risk managers and in-house counsel should expect that request and be prepared to respond without delay. A key goal in that meeting is to gauge the defendant's appetite for settlement.

Another goal is to quickly gather as much information as possible. Sullivan visits the healthcare facility as soon as she can to meet with any clinicians involved with the patient's care for an initial interview. Risk managers and other administrators are not always happy when Sullivan wants to talk to the clinicians immediately, but she insists.

"I try to track down everyone who looks like they might have information and see if they still work at the facility. If they do, I hot-foot it there and talk to them," she says. "I want to know what they are going to say. Or, if they're not there, why are they not there? Did they move to Timbuktu and it's going to be hard to get their deposition? You want to know what the unknowns are."

Some insurance policies include consent clauses that require the clinician or the hospital to consent to any settlement decision. Sullivan says this can create difficulties in moving forward strategically. The expert review might suggest a quick settlement is the best choice, but defendants can sometimes refuse.

Risk managers should remember those refusals can draw out the litigation and even lead to larger payouts, and advise their clinicians or administrators accordingly.

"Let's assume you have your expert review and it's kind of negative," Sullivan says. "But you have a very strident physician or nurse or entity who insists they did nothing wrong. Then, the attorney has to spend some time working on

EXECUTIVE SUMMARY

The time and money required to resolve a malpractice case can be reduced by taking the right steps up front. Some mistakes also can extend the time and increase costs.

- Obtaining an expert assessment early is key.
- Mediation can reduce the time and costs, but know your mediator.
- Ensure medical records are complete before providing them to anyone.

the client, and that can add to the time and expense."

Offers of Judgment Can Complicate

Some issues that can extend litigation and increase costs are not completely within the control of the defendants and their counsel. Sullivan notes plaintiff attorneys often file an offer of judgment as soon as the lawsuit is filed. Without researching the case early, the defense might not be ready to respond.

"This really puts the defense behind the 8 ball," Sullivan says. "They offer what they consider to be a reasonable amount, which is not always, but it usually is, in the ballpark of reasonability. If you have not gotten your ducks in a row and don't know what the case is worth, it might take you six or eight months to get those ducks in a row. Then, your offer of judgment has expired."

State laws vary, but if a case goes to trial in South Carolina and the plaintiff is awarded more than the offer of judgment, the plaintiff receives the verdict amount, 8% interest, and costs (not including attorneys' fees). It is typical for a case to take two years to go to trial, Sullivan notes, so the interest can add up significantly.

"Let's say they put in an offer of judgment for $200,000, which you think is too high, so you don't respond to it — it's off the table, it's gone. Two years later, they get a verdict for $300,000," Sullivan explains. "Not only are you paying the $300,000, but you are paying 8% interest on that $300,000 for two years. That $300,000 just turned into $350,000."

Sullivan is in a similar situation with a nursing home malpractice case that was delayed by an appellate issue with an arbitration clause. Sullivan was not on the case when the plaintiff's counsel filed an offer of judgment for only medical expenses two years ago, but she is now handling the defense. The case will not be ready for trial for another year. Sullivan now must explain to the defendant that even if the jury reaches a verdict equal to the original judgment offer, the defendant has to pay 24% interest on that amount.

> IF AN EARLY REVIEW REDUCES THE RESOLUTION BY SIX MONTHS, IT COULD SAVE THE DEFENDANT $20,000 IN LEGAL EXPENSES.

"Plaintiffs' attorneys are on to this tactic. It can be very effective for them if you don't do your research early and know whether you should accept that offer," she says.

Defendants can use the same tactic, Sullivan notes. When it appears the defendant is liable, the defense can make an offer of judgment protected by South Carolina's law. If the plaintiff rejects the offer and later receives a smaller verdict, that award is reduced by 8% per year.

"The only way those strategies have any teeth at all is if you do them early. The only way you can do them early is to know what you have, and the only way you can do them early is get your records and your experts quickly," Sullivan says. "That early assessment puts you in a position to either make that offer of judgment or to accurately assess the other side's offer."

Early investigation reveals the strengths and weaknesses of a claim. This can hinge on the actions risk management takes after notification of an adverse event, says **Carol Michel**, JD, partner with Weinberg Wheeler Hudgins Gunn & Dial in Atlanta.

An in-depth assessment may proceed after a claim is made, but the results of that investigation will improve when risk management has reacted appropriately to any initial report of a mishap or unexpected outcome. That is not always possible when the claim involves an alleged injury that was unapparent at the time, but Michel urges risk managers to fully document any reported adverse events in anticipation of a possible future claim.

The key question is if a legitimate claim of negligence exists. That will guide the strategy moving forward.

"Then, you will determine whether to defend and take the posture that you're going to take the case to trial vs. acknowledging an error and developing a strategy to resolve the case," Michel says. "I've had the full gamut, including where we identified the issue before the patient or family, and we acknowledged that things weren't done correctly. We went about working to find a resolution."

It is crucial to notify defense counsel as soon as possible when a claim is expected or has been filed, Michel says. Any delay means the defense team will fall behind the plaintiff in terms of assessing the merits of the case, obtaining experts, and researching the facts.

"Another thing that can extend the length and cost of litigation is engaging with the opposing party without the guidance and assistance of counsel, because you may not appreciate the nuances of the law, discovery

rules, and what the opposing side is entitled to get," Michel explains. "Unnecessary finger-pointing, with the defendant saying, 'It's not me, but it's everybody but me,' can expand and protract the litigation as well."

Asserting positions unsupported by medicine or the law also can draw out the process, Michel says. Taking a position that cannot be supported when pressed at deposition or at trial can greatly extend the time required for resolution and the ultimate cost of the experience.

"Taking the position that you are going to deny and defend at all costs can result not only in the case drawing out longer, but also in new claims being brought as well as punitive damages being asserted," Michel says. "The overarching position needs to be one of trying to identify specifically what the correct legal and medical issues are and addressing those, without expanding the scope to other issues that really did not play a role in the case, but which plaintiff's counsel can try to make it about more than just this particular plaintiff."

Throughout the investigation, any money spent up front usually is a good investment, says **Bradley P. Blystone**, JD, shareholder with Marshall Dennehey in Orlando, FL. That includes attorney time spent on the initial assessment, expert review, and meeting with the defendants to discuss options. The initial assessment is not written in stone and can change when new information is gathered, but it is important for everyone to be on the same page.

"So many of the insurers look to save money on attorney's fees, and sometimes they balk at spending the time to do a thorough review, but you can save so much more money in the long run by thoroughly investigating your case than you ever can by trying to skimp on attorney's fees," he says.

Blystone also advises hospitals to ensure medical records are certified complete before disclosing them to anyone. Electronic medical records can be efficient for the clinicians in the hospital system, but compiling them in an electronic form that can be transferred to an outside party can be challenging. Trying to print them is even worse.

"If you produce a record initially and then find out that something was missing, like a nurse's notes or a doctor's order, then you've created a problem that is going to introduce misunderstandings and doubts that will take time and money to sort out," Blystone warns. "It leads to all kinds of situations down the road where they try to hit you with creating false evidence or spoliation of evidence. It doesn't look good when you say, 'This was supposed to be included in the record, and we just forgot it.'"

Early resolution of malpractice claims result from informal settlement negotiations, formal mediation, or successful motion practice, says **Elizabeth E. Baer**, JD, attorney with Eastman & Smith in Toledo, OH. In cases where the plaintiff likely will prevail in establishing a breach of the standard of care, or in cases where negligence by the care provider is reasonably disputed but damages are substantial, early settlement discussions can help lower both litigation costs and the settlement amount.

"In cases where early resolution is warranted, it is preferable to undertake formal mediation over informal settlement discussions. An experienced mediator can be very effective in facilitating discussions that lead to a reasonable compromise," Baer says. "Know your mediator. If possible, select a mediator who has successfully negotiated prior settlements with defense counsel. When defense counsel has a rapport with the mediator and is perceived as credible, a case can be postured more aggressively."

In a mediation, defense counsel can focus on a reasonable compromise of damages without acknowledging liability, Baer says.

Many mediators were once in private practice. Knowing the details of this practice is important, so ask other attorneys their experience with a particular mediator, Baer suggests.

Undertaking mediation with a mediator with a "plaintiff's bend" can be counterproductive and costly. Additionally, know your opposing counsel.

"Some plaintiffs' attorneys recognize that a mediation is a bit

of a game of chess that begins with an excessively high demand and an excessively low first offer," Baer says. "Other plaintiff's attorneys are easily offended by the excessively low first offer, which can negatively impact progress and lead to a higher settlement."

Defense counsel should hold frank discussions with the claims adjuster who will be authorizing settlement, Baer explains. While the adjuster may be reluctant to disclose an exact amount they are willing to pay to settle the case, it is important to understand the settlement range before mediation.

However, even if early settlement discussions are entertained, certain information is critical to assessing the value of the case, Baer says. First, if a suit has been filed, the plaintiff's deposition should be taken to ascertain credibility and sympathy, and to explore damages.

Consider Settlement Before Depositions

If liability is a concern, it can be beneficial to discuss settlement before the depositions of the defendant physicians and expert witnesses, Baer says. Documentation confirming all claimed economic damages must be available.

"[Regarding] economic damages, it is important to know state law on any applicable damage caps and evidentiary rules on a defendant's ability to refute medical bills with the amount actually paid and accepted in full by a care provider," Baer explains. "The amount accepted in full payment typically is significantly lower than the amount billed and can be a tool for reducing settlement."

Deposing expert witnesses is costly to the plaintiff, thus increasing their settlement posture, Baer notes. In cases concerning a breach of the standard of care, defense counsel often is better able to posture the case where the details of the experts' testimony is unknown to the other side.

Discovery expenses in medical negligence can be significant and can drive up the cost of settlement.

> CLAIMS OF MEDICAL MALPRACTICE ARE THE TORTS LEAST SUSCEPTIBLE TO EARLY RESOLUTION, GIVEN THE NATURE OF THE CLAIMS NORMALLY ASSERTED IN THIS TYPE OF LITIGATION.

"An additional tool for early resolution is to conduct a settlement meeting prior to any exchange of discovery or depositions. In this meeting, the parties agree that information is being exchanged only for the purposes of settlement and cannot be used as evidence in trial," Baer explains. "While the meeting may be recorded or taken down by a court reporter, witnesses are not given an oath. This type of meeting can be productive pre-suit, or in the very early stages of a lawsuit."

Not only are discovery costs cheaper, but the parties may avoid taking a position based on emotional frustration, anger, or grief, she says. These emotions often are heightened as a case progresses.

The defendant should know whether his or her insurance policy is a consent policy or a non-consent policy, Baer says. A consent policy requires the defendant's consent before any settlement discussions can take place. However, once a defendant has consented, the insurer has the ultimate say in the amount of the settlement offer.

In a non-consent policy, the insurer can proceed with settlement discussions without consent of the insured. Typically, the defense attorney and the insurance company decide the timing of mediation and selection of a mediator, without input from the defendant, Baer explains.

Early Resolution Might Not Be Possible

Claims of medical malpractice are the torts least susceptible to early resolution, given the nature of the claims normally asserted in this type of litigation, says **David Richman**, JD, partner with Rivkin Radler in Uniondale, NY.

In most other cases, easily determined facts often drive determination of liability. This makes it simpler to reach a resolution — and to do so faster, Richman says. In contrast, claims of medical malpractice are determined by the provider's adherence to a standard of care: what the standard of care was, whether the treatment at issue adhered to that standard, and, if not, whether that failure caused or contributed to the injury.

"Both the question of the standard and whether the treatment met the standard is often the focus of the dispute and not an issue that is generally determinable at the outset of litigation," Richman notes.

Moreover, complicating the question is the role of medical judgment in explaining a physician's actions in rendering treatment, Richman explains. The law provides that if a jury finds the physician's exercise of medical judgment was reasonable under the circumstances, the physician cannot be held liable for injuries claimed to have occurred because of the treatment at issue.

The question of the exercise of medical judgment also is not easily determined at the outset of litigation.

"In determining the fundamental questions — what the standard of care was, whether there was a possible deviation from that standard, and whether the physician's treatment reflected a proper exercise of judgment — a great deal of investigation and discovery is needed," Richman says. "Chief among that investigation and discovery is the deposition of the physician in order to fully and properly assess the reasoning behind the treatment rendered and whether it can be said the treatment met the standard of care."

In addition, all the plaintiff's medical records are needed to assess not only the question of negligence, but the question of causation, Richman notes. Causation hinges on whether the claimed injuries were caused by the treatment at issue, or whether other factors were present.

"All of these issues, in turn, need to be fully assessed by an expert in the provider's field as well as other experts who might be in a position to comment upon the causality question," he says. "The retention of experts early in this type of litigation is rarely of any benefit, as the information that the expert will need to opine upon will not be available."

All these issues and tasks weigh against seeking an early resolution of a claim unless the injury is not in dispute and a blatant mistake was made (e.g., a surgeon operates on the wrong limb or removes the wrong tissue and admits to the error).

"So, too, might be the case where a radiologist or a pathologist improperly interprets a study or tissue sample and is unable to explain the error," Richman says. "In those instances, however, the provider is often unwilling to admit a mistake and pushes back against early resolution."

Richman says the latter issue is related to another factor weighing against early resolution: the provider's unwillingness to admit a mistake. Many insurance policies require the physician to give written consent to settle before the carrier may enter settlement negotiations.

Even in policies where no consent is required, most carriers will tread lightly because of the reporting requirements imposed by the National Practitioner Data Bank and similar reporting requirements imposed by state governments, Richman says. These reporting requirements can damage the reported physician, both in attracting new patients and gaining approval from insurance carriers who have the right to decline a physician if it feels the provider's claims history is less than stellar.

"Because of these reporting requirements, many physicians are reluctant to agree to allow the carrier to settle without making a maximum effort to structure a defense. Most carriers will abide by the physician's demands whether or not the physician has a consent policy," Richman says. ■

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Improving Patient Handoffs Helps Reduce Malpractice Claims

Patient handoffs affect safety, although it is possible malpractice risk is a downstream effect. A large study of malpractice claims revealed a direct relationship between the quality of patient handoffs and claims.

Researchers at Boston Children's Hospital reviewed 498 medical malpractice claims, selected at random from Candello, CRICO's national medical malpractice collaborative. Of the cases that involved communication failures, 40% included a handoff of care.

Of those cases involving patient handoffs, 77% likely were preventable with a handoff tool developed by the I-PASS Patient Safety Institute. Additionally, malpractice cases involving communication errors were more expensive to defend, with a cumulative payout of $58 million vs. $39.1 million for cases in which communication errors were not a factor. *(An abstract of the study is available at: https://bit.ly/3ATq0Eb. Another earlier study showing the effectiveness of improved handoffs can be found at: https://bit.ly/3GnJQbK.)*

The I-PASS handoff program has been associated with improving patient safety by reducing miscommunications, medical errors, and injuries due to medical errors. The program uses a uniform structure for verbal and written communication, based on the I-PASS mnemonic: illness severity, patient information, action list, situational awareness and contingency plans, and synthesis by receiver. *(More information on I-PASS is available at: https://bit.ly/3Gv2vTf.)*

Research Establishes Direct Link

The cases resulting in malpractice claims are only a small subset of all cases involving harm related to a patient handoff, so the effect of improving handoffs likely is greater even than what the research revealed, says **Kate E. Humphrey**, MD, MPH, a pediatric hospitalist at Boston Children's Hospital and the lead author of the study.

The tie between communication failures and malpractice claims has been established previously, but this research draws a direct link between a particular form of communication failures — patient handoffs — and malpractice claims, says **Christopher P. Landrigan**, MD, MPH, co-founder of the I-PASS Patient Safety Institute and chief of general pediatrics at Boston Children's Hospital.

"This study has built on previous research to clarify that link to claims, and, importantly, it also identifies some strategies and approaches that might mitigate or avert them," Landrigan says.

Another important facet is that researchers studied not only the communication failures among critical care providers, but also between providers and patients and families.

"We saw a significant impact on patients and families in those gaps in critical, key pieces of information that can mitigate that risk," Humphrey says.

The communication failures at handoff fell into several categories, explains **Melissa Sundberg,** MD, MPH, co-author and emergency medicine physician at Boston Children's Hospital.

"Most of the failures involved information that was not passed on appropriately, but we further looked into whether it was related to a medication, radiology, lab study, or other information that was not passed on," Sundberg says. "They covered a broad range of specific types of information, but most of them involved an omission of some type when communicating with other providers or the patient and family."

Severity of Illness Often Missed

Humphrey notes a common omission was the severity of the patient's illness along with contingency planning, which could be important for a family member

EXECUTIVE SUMMARY

The quality of patient handoffs directly affects malpractice claims. A standardized handoff system can significantly improve patient safety.

- A large proportion of communication-related claims involved handoffs.
- Handoffs often involve failure to adequately communicate the severity of illness.
- Contingency plans also often omitted or conveyed inadequately.

caring for the patient at home. Another omission was the actual diagnosis.

The team explored potential interventions that may have averted some of the claims in the study, particularly whether the I-PASS system would have helped.

"For the large majority of handoff-related errors that we found, it was judged that it most likely would have averted the claim or mitigated it," Landrigan says. He notes I-PASS focuses on two common omissions in the cases studied — severity of illness and contingency plans.

"That is by design because even a decade ago, when we were building I-PASS, it was clear in the literature that those were two elements we should focus on," Landrigan says. "It is particularly interesting to see in this malpractice data set that those were two elements that fell down most often as patient information was being passed off."

Sundberg says the research further confirms healthcare organizations should use some type of formal communication in patient handoffs.

"It is important to consider whether you have a structured way to communicate information not only between providers, but also to families," Sundberg says. "Consider a way to have structure throughout the organization so that you might ensure some of these situations don't lead to adverse events and near-misses."

The direct link between patient handoffs and malpractice claims might prove useful to risk managers when seeking support from administration and clinicians for improvement programs.

"The risk management community has an incredibly important role in driving patient safety improvements across hospitals. Because of the high cost of malpractice claims, there a lot of resources in that system that can be turned toward potentially preventing these adverse events," Landrigan says. "When studies like this come out that identify discrete sources of harm as well as potential strategies to avert them, it would be great if risk management could partner with the clinical sector to drive those strategies forward." ■

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Handoffs Shown to Improve Patient Safety

Handoffs are a crucial moment in a patient's care, when poor communication can lead to errors and harm, says **Marian Altman**, PhD, RN, CNS-BC, CCRN-K, clinical practice specialist with the American Association of Critical-Care Nurses (AACN).

As evidence of the importance of effective handoffs, Altman notes The Joint Commission (TJC) requires hospitals to develop a standardized process for handoff communication regarding patient information.

"Handoffs are key to making sure that each patient receives consistently high-quality care, from provider to provider, from shift to shift, and from unit to unit," Altman says.

"A handoff is a transfer and acceptance of patient care responsibility achieved through effective communication," TJC noted. "It is a real-time process of passing patient-specific information from one caregiver to another, or from one team of caregivers to another for the purpose of ensuring the continuity and safety of the patient's care."

This definition was part of TJC's *Sentinel Event Alert* 58: Inadequate hand-off communication. *(The alert is available at: https://bit.ly/3HyE88l.)* TJC cited study results that estimated communication failures in U.S. hospitals and medical practices were at least partly responsible for 30% of all malpractice claims, resulting in 1,744 deaths and $1.7 billion in malpractice costs over five years.

"Communication errors are the No. 1 cause of sentinel events in a hospital. Handoffs are important to prevent errors of omission, and also provide structured communication between providers," Altman says. "A poor patient handoff can contribute to vital information being forgotten or missed, leading to delays in care, extended hospital stays, and confusion. Poor handoffs may also result in nursing overtime. Poor handoffs also may affect a patient's

perception of quality, thus affecting HCAHPS [Hospital Consumer Assessment of Healthcare Providers and Systems] scores."

Most hospitals use standardized tools and methods to facilitate handoffs, Altman says. These can include forms, checklists, and mnemonics such as SBAR (situation, background, action, response) and I-PASS (illness severity, patient summary, action list, situation awareness, and synthesis by the receiver).

"The tool alone is not a solution," Altman notes. "How individuals use them is the true measure of their effectiveness. Skilled communication during handoffs ensures that each clinician feels confident that the patient is in good hands."

A face-to-face handoff, instead of a paper handoff, is encouraged to allow the receiver to ask clarifying questions. It also is important to have uninterrupted time during the handoff.

AACN regularly studies patient handoffs, Altman notes, which established the AACN Clinical Scene Investigator Academy in 2012, as a hospital-based nurse leadership and innovation training. ■

SOURCE

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Control Factors That Influence Insurance Premiums

Insurance premiums are influenced by many factors. Some factors are out of the insured healthcare organization's control, but hospitals can earn lower premiums by showing a concerted effort to improve patient safety and lower risk.

The insurance market had been soft for about 20 years. But hospitals have seen premium increases averaging 20% over the past two years, says **Steve Kahl**, senior managing director of the healthcare practice with risk management and insurance provider Gallagher in Denver.

Those rate increases hit at the same time as the pandemic, which sharply reduced the elective procedures that can comprise about 65% of any hospital's bottom line.

"It made the hard market all that much more difficult," Kahl says. "For larger institutions, underwriters are looking mainly at loss history and loss severity to come up with a premium, so risk mitigation strategies are key. Risk managers seeking to reduce that premium are looking at the kinds of policies and procedures they can put in place after a loss to prevent that from recurring. If they can do that, it's going to have a long-term impact on the premiums they're going to pay."

A healthcare organization seeking to reduce premiums or minimize increases needs to highlight its organizational successes, Kahl says. Show strategic growth initiatives and illustrate how the hospital improved patient safety and minimized the risk of adverse events.

Data showing the positive effects of these initiatives will be useful for the underwriters, Kahl explains. Analytics and claims benchmarking can identify emerging trends that affect premiums.

"Tell a really good narrative up front to highlight your underwriting submission, move it to the top of the pile, get it noticed by the various underwriters so that they get a little bit excited about what you're doing as an institution. Then, they can get aggressive in their underwriting position on your organization," Kahl says. "There are a lot of great success stories to tell right now because healthcare organizations are re-energized about enterprise risk management [ERM]. There is a new push for a more cohesive ERM strategy within the institution, and if I find that my healthcare clients are engaged in that, I make sure I am highlighting it."

EXECUTIVE SUMMARY

A healthcare organization's practices can significantly affect its malpractice insurance rates. Controlling the right factors can lower premiums.

- Risk mitigation tactics are a major driver in premiums.
- Premiums have increased sharply over the past two years and probably will continue to rise.
- Underwriters can be influenced by participation in recognized risk reduction programs.

Adopting the Communication and Optimal Resolution (CANDOR) process also will attract underwriters' attention, Kahl says. *(More information on CANDOR is available at: https://bit.ly/34CWYNl.)* CANDOR often can lead to an earlier resolution, result in a lower payout, and even lead the patient or family to decide against litigation.

"That's another good area to talk about. Underwriters — and, in particular, the claims folks within our carriers — are excited to hear that that's the approach you're taking," Kahl says. "There are no immediate rate credits for that, but if it helps get to an early resolution of a difficult claim, there is going to be a longer-term impact on the premiums you pay."

Risk managers should strive for a direct relationship with their insurance representatives and underwriters, Kahl says, as that will give them a better understanding of what drives the insurers to reach the final premium.

The insurance marketplace has tightened in recent years with the exit of big players like Swiss, Re, Zurich, Hallmark, and CNA from the healthcare marketplace. Rates will be higher than normal for a while until more insurers arrive and build further capacity, Kahl says. That makes captive insurance programs more attractive for many healthcare organizations.

"The ones that haven't formed captives in the past are now really pushing their leadership to consider it. It helps them assume more risk, and it provides for a stronger investment strategy," he says. "The premiums you pay into your own captive tend grow at a robust rate."

If a healthcare organization is unhappy with the stated premium, all is not lost, Kahl says. When you have reason to think you deserve a lower premium, and evidence of your risk mitigation strategy and ERM culture to prove it, the hospital can work with its broker to push for a lower premium.

That does not guarantee the broker can produce a better premium. But the relationship with the broker should be strong enough that you can ask why.

"At the end of the day, as your broker, I want to be able to tell my client that we've tested the marketplace, we've gone to every carrier that has an appetite for your risk, and we didn't settle for the first quote we got," Kahl says. "The goal should be for the healthcare organization to put its best foot forward, for the broker to do his or her best in finding an optimal program structure, and for all parties to be comfortable that they achieved the best result." ■

SOURCE

- **Steve Kahl**, Senior Managing Director, Healthcare Practice, Gallagher, Denver. Phone: (303) 889-2624. Email: steve_kahl@ajg.com.

Nurses Risk Consequences for Spreading Misinformation

Risk managers may need to counsel nursing staff on how they could expose themselves to professional consequences if they spread health misinformation online, particularly with much attention on what people post regarding COVID-19.

Nurses who post misinformation could be subject to disciplinary action from their nursing boards, in addition to other results, says **Georgia Reiner**, MS, CPHRM, risk specialist for the Nurses Service Organization in the Healthcare Division of Aon's Affinity Insurance Services in Philadelphia.

"When you are online, it's easy to see how objective facts tend to be less influential than something that appeals to your emotions and your personal beliefs. This allows relatively small groups to shape the conversation around public health issues like COVID, vaccines, and masking," Reiner says. "We've noticed that nurses, like everyone else, are vulnerable to these influences, and we've seen nurses numbering among those who are using social media and other types of public forums to share misinformation about issues related to COVID."

However, unlike most other people online, nurses must provide information to the public that meets professional standards, Reiner says. Nurses tend to be among the most trusted professionals of any type, and those who use their credentials to position themselves as a trustworthy source of health information are obligated to share information that is truthful and backed by scientific research.

"Failure to do so is an ethical failure and can damage public trust. In the case of misinformation about COVID, it can be harmful to society as a whole," she says.

The National Council of State Boards of Nursing (NCSBN) recently made clear nurses are accountable for information they provide to the public. That means nurses who spread misinformation could be subject to discipline by their state boards. *(The NCSBN statement can be found at: https://bit.ly/3HyMeOD.)*

A state board of nursing may respond to misinformation with statements of concern, fines, probation, or suspension or revocation of the nurse's license.

"Depending on the gravity of the situation, nurses could be placing their careers in jeopardy by posting misinformation online," Reiner says.

Hospitals and other nurse employers also may discipline nurses for distributing health misinformation, subject to their policies and procedures related to the use of social media and other forms of distribution, Reiner says. That is especially true if the nurse is using his or her credentials as an employee of the hospital to spread misinformation.

"If the nurse identifies as an employee of the organization, that can, in turn, damage the public's trust in the employer as well," Reiner says. "In addition to warning employees about these consequences, they can help educate them about how to spot misinformation and avoid sharing it online."

Employees may defend themselves by saying they are using social media on their own time, but their nursing licensure and their status as employees of the hospital create an obligation that is not held by other private citizens.

"The nursing license alone creates an expectation that you will not communicate incorrect health information, but when you share your credentials, and even your employer, then that activity clearly becomes the purview of your employer as well," Reiner says. "As far as your online presence being your personal business, that stops when you bring in your credentials and your workplace." ■

SOURCE

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Abnormal Vitals Linked to Unanticipated Death After ED Discharge

By Stacey Kusterbeck

More than half of 129 patients who died unexpectedly after they were discharged from EDs exhibited abnormal vital signs at the time.[1] Each patient had presented to an urban academic ED between 2014 and 2017, and died within seven days after they went home.

"The findings should perk up the ears of ED providers and remind them to take a second look at if discharge is safe, or if rapid follow-up or admission should be considered," says **Richard Hoang**, MD, the study's lead author and trauma team leader at Sunnybrook Health Sciences Centre in Toronto.

Pneumonia was the most common cause of death. Recurrent themes among the patients included multiple complaints or comorbidities, acute progression of chronic disease, and a history of recurrent falls.

Other common factors included patients with multiple ED visits, patients who had been admitted recently, or patients for whom no repeat vital signs were recorded. ED providers failed to admit high-risk elderly patients, missed diagnoses, and failed to consider infectious etiology.

"Hopefully, this encourages clinicians to consider repeating vital signs prior to discharg[ing] their patients," Hoang says. ■

REFERENCE

1. Hoang R, Sampsel K, Willmore A, et al. Remember that patient you saw last week: Characteristics and frequency of patients experiencing anticipated and unanticipated death following ED discharge. *CJEM* 2021;23:767-771.

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CME/CE QUESTIONS

1. **What does Kelli L. Sullivan, JD, say should be the priority when faced with a malpractice claim?**

   a. Make an offer of judgment immediately.
   b. Obtain an expert review.
   c. Investigate the plaintiff's background.
   d. Estimate a budget for the defense.

2. **What does Bradley P. Blystone, JD, advise regarding medical records released in relation to a malpractice claim?**

   a. Make sure the records are complete before providing them to anyone.
   b. Make sure the records are properly redacted before providing them to anyone.
   c. Notify the recipients the records may be amended at a later date.
   d. Notify the recipients the records are final and will not be amended or supplanted at a later date.

3. **According to the recent study on patient handoffs and malpractice claims from Boston Children's Hospital, what was one common communication failure at the handoff?**

   a. Failure to provide contact information
   b. Failure to identify previous adverse events affecting the patient's condition
   c. Failure to fully communicate the severity of the patient's illness
   d. Failure to specify future plans for follow-up.

4. **What does Steve Kahl suggest as a way to obtain the lowest insurance premium?**

   a. Highlight your organization's successes.
   b. Stay with the same insurance broker every year.
   c. Shop around for a new insurance broker every year.
   d. Avoid providing information not specifically requested.

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Upon completion of this educational activity, participants should be able to:

1. describe the legal, clinical, financial, and managerial issues pertinent to risk management;
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3. identify solutions to risk management problems in healthcare for hospital personnel to use in overcoming the challenges they encounter in daily practice.

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

Appellate Court Revives Lawsuit Against Hospital for Harvesting Organs Despite Objections

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Tara Aleagha
Pepperdine School of Law, 2022

News: A California appeals court has revived a father's suit alleging a hospital and an organ donor network conspired to harvest his daughter's organs despite his objections. The father contended the trial court should have considered the full scope of the hospital's actions, not just the harvesting procedure, when deciding whether the claims could go forward.

In November 2017, the hospital declared the plaintiff's daughter brain dead due to strangulation injuries. The plaintiff strenuously objected to the withdrawal of life support and harvesting of his daughter's organs, wanting to preserve any evidence of foul play. The hospital obtained consent from the plaintiff's ex-wife and withdrew life support. Some of the daughter's organs were harvested by the donor network, with the assistance of the hospital.

The plaintiff sued the hospital and donor network for intentional infliction of emotional distress. The defendants argued their conduct was not outrageous, nor was it directed at the plaintiff. The trial court agreed, and dismissed the case.

THE PATIENT'S MEDICAL RECORDS INDICATED THE DEFENDANTS PLANNED TO HARVEST THE PATIENT'S ORGANS WITHOUT THE PLAINTIFF'S CONSENT.

On appeal, the plaintiff argued the trial court erred by failing to evaluate the full range of defendants' outrageous conduct, which began when the defendants formed a plan to recover his daughter's organs without obtaining his consent and continued when the defendants effectively ejected him from the hospital when he objected to any organ donation, and concluded with the removal and donation of her organs and tissue without his permission.

The plaintiff contended he and the patient's mother, as the surviving parents, possessed co-equal rights to determine the disposition of their daughter's remains. He alleged the defendants were aware he suspected foul play in his daughter's death and that he did not want her body disturbed before an autopsy was performed. The appeals court reversed the dismissal, ruling the plaintiff sufficiently alleged the defendants intentionally inflicted emotional distress on him. The justices pointed to recorded evidence the hospital intended not to tell the plaintiff about harvesting his daughter's organs until after it was completed, even though the hospital was well aware that he objected.

Background: On Nov. 17, 2017, the plaintiff's daughter was admitted to the hospital in a deep coma due to strangulation injuries. The plaintiff believed the injuries were not an accident, and a result of foul play. The hospital staff initially informed the plaintiff his daughter might survive.

Six days later, the medical staff informed the plaintiff his daughter was brain dead. The plaintiff demanded a second opinion. However, the medical staff told informed him a second opinion had been obtained, and he would not be allowed to obtain his own second opinion.

Representatives of an organ donation network approached the patient's mother about donating the patient's organs and tissues after death. The plaintiff, who wanted to preserve evidence of possible foul play, objected to withdrawing life support and harvesting organs or tissue, and refused to consent to donation. The plaintiff requested an autopsy; he believed harvesting the patient's organs would cause inaccurate results. Additionally, the patient had never signed any instructions regarding the donation of her organs or tissues after death.

The patient's medical records indicated the defendants planned to harvest the patient's organs without the plaintiff's consent. They also indicated they would not tell the plaintiff about the organ harvesting until it was completed.

When the plaintiff protested the removal of life support and harvesting of his daughter's organs, the hospital called security. He was given only three minutes to say goodbye to his daughter and leave the hospital. The hospital withdrew the patient's life support, and she died Nov. 24, 2017.

The plaintiff filed suit, alleging the hospital and donor network conspired to harvest his daughter's organs without his consent. The trial court granted the hospital's motion to dismiss, ruling the hospital's action of removing the patient's organs was not directed at the plaintiff, since he was not present when it happened.

On appeal, the appellate court found the trial court had interpreted the law too narrowly, stating the court should consider the defendants' entire course of conduct toward the plaintiff, not just the organ removal procedure. The justices added these actions were taken toward the plaintiff when he was emotionally vulnerable, and the defendant hospital flagrantly denied the plaintiff access to his daughter before she died. They also found the hospital and donor network's conduct extreme and outrageous, and believed their actions to be deliberate, intentional, and directed toward the plaintiff. Specifically, the apparent lack of thought or sensitivity toward the plaintiff's wishes constituted a reckless disregard.

What this means to you: This case shows the standard of review for a plaintiff's success on a claim of intentional infliction of emotional distress against a hospital.

The cause of action for intentional infliction of emotional distress includes these elements: extreme and outrageous conduct by the defendant with the intention of causing, or reckless disregard of the probability of causing, emotional distress; the plaintiff's suffering severe or extreme emotional distress; and actual and proximate causation of emotional distress by the defendant's outrageous conduct.

In this case, the plaintiff contended the defendants' conduct was more than the harvesting of his daughter's organs — it also included defendants secretly deciding to recover and donate her organs without obtaining his consent, effectively ejecting him from the hospital when he objected, and proceeding with removing and donating her organs and tissue over his objections. The removal and donation of his daughter's organs is not the only conduct relevant to a determination of "extreme and outrageous."

As the patient's co-parent, the plaintiff possessed statutory rights concerning the disposition of the patient's remains and the donation of her organs. The plaintiff strenuously attempted to exercise his statutory rights when he became aware of the defendants' plans to take his daughter off life support and harvest her organs. The plaintiff alleged he made clear to the hospital that he wanted his daughter to remain on life support until an autopsy could be performed, that he did not want any of her organs or body parts removed, and that he did not consent to organ removal.

While deprivation of a statutory right usually is insufficient to be "extreme and outrageous" conduct, the plaintiff alleged the defendants did more than merely deprive him of his statutory rights. The complaint alleged they engaged in such deprivation by barring the plaintiff from being physically present with his daughter as she faced death. The defendants acted over time, despite knowing the plaintiff's particular vulnerability to such conduct, and over the plaintiff's protestations about the conduct in question.

The defendants knew the plaintiff was in a dire emotional state but disregarded the bona fide basis of his refusal to donate his daughter's organs. The continuing course of defendant's conduct was extreme and outrageous, the appellate court ruled. The justices considered the full scope of defendants' conduct: the defendants conspiring to harvest the patient's organs and tissue without the plaintiff's consent, their ignoring his objections to any organ removal and effectively ejecting him from the hospital, and carrying out their plan of harvesting organs and tissue.

Probate laws usually are clear about the rights of patients and families facing these issues. If the patient is a juvenile, parents are the decision-makers unless a court has determined otherwise. If the patient is an emancipated adult, or at or above the age of consent, unable to make healthcare decisions, and lacking an advance directive, then the spouse, significant other, parents, or other individual with whom the patient lives becomes the decision-maker. Consent from one of these individuals is required for organ donation, unless the patient has indicated on their driver's license or

by some other legal means that they wished to donate their organs. The only time a hospital can make that decision on behalf of the patient is if the patient is unrepresented. In that case, the hospital must create a policy describing this process of consent. A team of uninvolved individuals, including community members, clergy, and the hospital CEO, make the unanimous humanitarian decision to consent on behalf of the patient. In this case, with appropriate representation from parents, donation without their consent is not permitted.

Withdrawing life support from a patient declared brain dead by two physicians following policies meeting licensing and accreditation standards is a different situation. Families, loved ones, spouses, children, other physicians, and friends cannot stop the removal of life support. Most hospitals allow families time to gather and say goodbye, but the hospital is bound by law to remove the patient from life support. A patient whose brain has ceased functioning, except for the brain stem that keeps the heart beating and some respiratory functions working, is, in fact, dead. The only reason to maintain the body on life support is to harvest organs for donation. The pleas from the family that the patient's death involved foul play would have been up to the coroner's office. Had the coroner intervened, the office would have mandated an autopsy long before any consideration of organ donation. These are complex issues that keep risk departments constantly seeking opinions from their peers, their in-house counsel, and the courts. But the rules are in place, the policies have been written, and the answers can be found. Involving counsel as soon as such issues appear is strongly advisable. ■

REFERENCE

- Decided Jan. 31, 2022, in the Court of Appeal of the State of California Fifth Appellate District, Case No. F080109.

Appeals Court Denies Hospital's Objection to Expert Witness Report

News: In March 2017, a man sought emergency treatment after a toolbox fell and crushed his hand while he was working as an auto mechanic. The box slashed open his left thumb, causing a 6 cm cut and a bone fracture in the tip of his thumb that extended to the next bone. An emergency physician (EP) treated the patient's injury and instructed him to follow up with an orthopedic specialist in two days. The specialist recommended surgery, which was scheduled for March 16. However, the surgeon canceled the operation and performed a drainage procedure when the surgeon discovered an infection in the patient's hand.

The patient filed a malpractice lawsuit, claiming a breach in standard of care, noting the delay in treatment led to permanent injury to his thumb. The plaintiff's expert witness report claimed the hospital failed to staff a hand fellowship-trained surgeon for immediate consultation, and failed to immediately recommend the patient visit the specialist. The defendants objected, arguing the expert witness was not trained as an EP. The trial court did not allow the expert witness to testify, but an appeals court overturned the objections to the report, ruling the expert witness was qualified to present opinions on standard of care in the case.

Background: On March 11, 2017, a man presented to an emergency department with a laceration and bone fracture to his thumb after a toolbox fell on his hand. An EP treated the patient's injuries and referred him to an orthopedic specialist, arranging an appointment for March 13. The specialist recommended surgery, scheduled for March 16.

During surgery, the specialist discovered the patient's hand was infected. The specialist stopped the surgery and performed a drainage procedure. The patient later underwent two additional drainage procedures. As a result, the patient experienced permanent damage to his thumb, and a 9% impairment rating.

The patient filed a malpractice suit, alleging the EP breached the standard of care by not immediately referring the patient to a hand specialist and failing to recommend emergency surgery within 24 hours of the injury. The patient's expert witness — a board-certified orthopedic surgeon — submitted a report backing these claims, stating the hospital did not have a hand fellowship-trained surgeon on call for immediate consultation.

The defendant physician and hospital objected to the report, stating the expert witness did not provide evidence of emergency medicine training, and orthopedic experience does not overlap with emergency medicine. The trial court allowed the

plaintiff time to remedy any defects in the expert witness report.

The defendants appealed, arguing the trial court abused its discretion by allowing the plaintiff to remedy the expert witness report. The appellate court affirmed the trial court's decision, noting state law does not require dismissal of a deficient report that can be fixed. The justices also noted previous courts have ruled doctors who are board certified in their field are qualified to write expert reports.

What this means to you: This case shows the importance of expert testimony in reporting the standard of care. However, the legal requirements for expert witnesses are fairly minimal. According to Federal Rule of Evidence 702, expert witnesses must possess "knowledge, skill, experience, training, or education" that will "help the trier of fact to understand the evidence or to determine a fact in issue." *(More information is available at: https://bit.ly/3GjZjtH.)* The court enforced this broad standard when it acknowledged other courts' rulings that doctors who are board certified in their field are qualified to write expert reports.

The expert witness process is the result of decades of evolution and refinement, with numerous different professionals working together. The expert witness testimony procedures in the United States demand honest, unbiased opinions about evidence, responsibility, and integrity from all professionals involved in a court case. The primary roles of expert witnesses are to provide testimony about evidence in the case and to clarify matters such as the standard of care.

The fact an expert is to remain (or should remain) impartial lends further credibility to their reports. The expert's role is to simply provide the court objective, unbiased information. The broad strokes set forth by the rules of expert testimony are largely because of the value brought by experts informing candidly and neutrally.

During testimony, many expert witnesses present a case or opinions in a way that can remove confusion about technical aspects and concepts the average judge or jury panel member will not otherwise understand. Depending on the subject matter, the case may proceed with specific experts in numerous fields to remove confusion, clarify details, and help the court understand the information.

THE APPELLATE COURT AFFIRMED THE TRIAL COURT'S DECISION, NOTING STATE LAW DOES NOT REQUIRE DISMISSAL OF A DEFICIENT REPORT THAT CAN BE FIXED.

As seen here, plaintiff's expert witness merely informed the court of the standard of care within the industry. The standard for a hospital, as reported by the witness, is for a fellowship-trained hand surgeon to be available for immediate consultation to the treating physician, and for the doctor to immediately consult or recommend a specialist. The EP did not follow these practices. The plaintiff was permitted to present his expert report because it included information on the standard of care in the industry. Because of this report, the court determined the defendants' liability due to a failure to follow the industry standard of care.

Expert witness reports are crucial for helping determine liability in a nonbiased and tactful manner. As long as experts follow the criteria set forth in the evidence code, their reports should not be suppressed for minor, correctable flaws. If written truthfully and with integrity, expert reports are invaluable, especially when setting the standard of care in a specific industry. Without this standard set forth, it would not be possible to determine liability in many cases.

Additionally, this case shows the importance of knowing and following industry standards. This litigation could have been avoided if the hospital took adequate measures to ensure the health and well-being of its patients. Often, in the hectic environment of an emergency department, practitioners can overlook providing recommendations for follow-up care. Most healthcare organizations recognize this and create standards of care for follow-up treatment in their discharge instructions. It is important to keep the medical records from the start of care with the current record. More importantly, this entire record should be reviewed by each provider.

Finally, if hospitals and medical professionals inform themselves adequately before any conflict, they can significantly reduce the probability of medical malpractice. Knowing and following industry standards is beneficial for all parties. Following standards of care allows for the lowest risk for the patient and the healthcare professionals. ■

REFERENCE

- Decided Jan. 13, 2022, in the Fourteenth District Court of Appeals of Texas, Case Number 14-20-00004-CV.

HIPAA REGULATORY ALERT

CUTTING-EDGE INFORMATION ON PRIVACY REGULATIONS

HIPAA Safe Harbor Offers Limited But Important Protection

The HR 7898 HIPAA Safe Harbor Law, enacted in 2021, created a "safe harbor" for HIPAA-covered entities and their business associates when potentially facing fines and other penalties under HIPAA. But there are nuances to the law that risk managers and compliance officers must consider.

The most important point may be the safe harbor law, while offering substantial protection, does not provide a true safe harbor. *(The law is available online at this link: https://bit.ly/3L6RZoK.)*

A typical safe harbor shields an entity from liability when certain conditions are met, whereas the HIPAA Safe Harbor Law only offers some protection in certain circumstances, says **Kenneth K. Dort**, JD, partner with Faegre Drinker Biddle & Reath in Chicago. The HIPAA Safe Harbor Law requires the Office for Civil Rights (OCR) to consider whether a covered entity had implemented certain technical safeguards for 12 months. If so, it allows OCR leniency in assessing the breach.

But how much leniency is undefined.

"It is very much not specific about how OCR must respond. Perhaps they will require audits by a third party every other year instead of every year, maybe for 10 years instead of 20 years," Dort says. "I've wondered if OCR comes to the table in somewhat bad faith and says, 'We're going to fine you $1 million, but now we'll only fine you $900,000,' when really they always intended to fine you $900,000."

OCR already considered the circumstances of a HIPAA breach, including what technical safeguards were in place, and other components of a privacy compliance program. Dort says he is unsure of the additional value in the Safe Harbor Law.

For an entity seeking the best treatment from OCR after a breach, Dort says the key will be proving all reasonable and prudent steps were taken to prevent the breach, making it a one-off occurrence that does not reflect negatively on the compliance program. That will require extensive documentation — and probably third-party audits.

"If you can't show that your regular practices meet the best standards in the way the statute says, OCR may not take that into account," Dort warns. "Like anything in risk management, you have to prove that you did what you say you did, or it won't matter."

W. Reece Hirsch, JD, partner with Morgan Lewis in San Francisco, agrees that even though HR 7898 was titled The HIPAA Safe Harbor Bill, it did not create a true safe harbor. The law does not provide absolute protection for HIPAA-covered entities and business associates, but it does ensure OCR will consider an organization's implementation of certain recognized security practices when assessing HIPAA penalties or other enforcement actions.

"HR 7898 is beneficial because it reflects a less punitive approach to HIPAA enforcement, recognizing the good work that healthcare organizations have been doing to prevent ransomware and other cyber threats," Hirsch says.

Because HR 7898 is not a blanket endorsement of all healthcare industry data security standards, it is important to review your security program to determine whether you qualify, Hirsch says.

HR 7898 only applies if the recognized security practices have been in place for the previous 12 months. An organization that has experienced a HIPAA security breach cannot take advantage of the law by implementing those security measures immediately before an OCR investigation.

"Be sure to formally document that your organization is applying one of HR 7898's recognized security practices in developing its security policies and procedures. You want to make it easy for OCR to see that you have applied practices that must be considered under the law," Hirsch explains. "Already, OCR has begun to specifically ask whether

an organization has implemented recognized security practices in its document requests at the start of an investigation."

"Recognized security practices" means standards, guidelines, or other approaches developed, recognized, or promulgated through regulations under statutory authorities, such as Section 2(c)(15) of the National Institute of Standards and Technologies (NIST) Act, or Section 405(d) of the Cybersecurity Act of 2015, says **Erin Dunlap**, JD, an attorney with Coppersmith Brockelman in Phoenix.

"Unfortunately, there are no regulations implementing the amendment, and there is no case law interpreting it. However, the amendment gives HIPAA entities some flexibility in determining their 'recognized security practices' so long as the practices are consistent with the HIPAA Security Rule," Dunlap says. "The amendment also makes clear that OCR cannot hold a HIPAA entity liable for not engaging in recognized security practices, and OCR cannot increase fines or the length, extent, or quantity of an audit due to a lack of recognized security practices."

Of course, a HIPAA-covered entity still must comply with the HIPAA Security Rule and implement reasonable and appropriate administrative, technical, and physical safeguards to protect its electronic protected health information.

"Historically, we've advised HIPAA entity clients to consider the NIST framework and HHS cybersecurity guidance for healthcare entities when evaluating their security measures. But now, there's a real incentive to do so," Dunlap explains. "If a HIPAA entity can demonstrate robust security practices based on these industry-recognized standards and approaches, it could result in the favorable termination of an investigation, or audit, or lower settlement amounts or penalties. If a HIPAA entity has the resources, I suggest comparing current security practices to the standards and approaches referenced in the amendment."

It may turn out the organization already has implemented "recognized security practices," or it is really close, and a few additional measures will get you there.

"For compliance/privacy personnel responding to an investigation or audit, don't forget to consider this defense," Dunlap says. "If your organization can show 'recognized security practices' for the past year, you should ask the OCR investigator to take that into consideration and close the investigation or audit — or at least grant some leniency."

The HIPAA Safe Harbor Law incentivizes healthcare providers to adopt the most appropriate security practices, but it does not provide any penalties for failure to do so, notes **William P. Dillon**, JD, shareholder with Gunster in Tallahassee, FL. In that sense, it is only beneficial — even though it is not a true safe harbor offering complete protection.

"The settlement agreements are what people sometimes fear the most after a breach because they can be so burdensome and extend for so many years after the incident, and this gives OCR the ability to back off on those," Dillon says. "It rewards those healthcare providers who are taking cybersecurity more seriously. The crazy thing is that even though HIPAA has been around so long and cyber threats are nothing new, there are still a lot of people in the healthcare arena who are just not taking the security as seriously as they should."

Some covered entities, especially smaller organizations with fewer resources, may be deficient partly because they do not understand what steps are necessary for the best protection, Dillon says. The HIPAA Safe Harbor Law is helpful in how it outlines what OCR considers the best practices.

The HIPAA Safe Harbor Law underscores the importance of ongoing documentation when dealing with OCR, says **Colin J. Zick**, JD, partner with Foley Hoag in Boston. A key benefit of the law is how it specifies exactly what OCR will consider evidence of a covered entity's best intentions and efforts toward compliance.

Regarding documentation, Zick says it is not just about the ability to pull together information when needed. Organizations need to keep that documentation up to date on an ongoing basis so it is ready at a moment's notice.

"They will ask you what your security practices are, and trying to compile that on the fly as you're dealing with all the fallout from a breach is very, very difficult," Zick says. "People may have left the company, or they're unavailable, or the files are locked up somewhere and you can't get to them. You need to have a secure and easily available summary of what you have done so that you have something very easy to hand over to the feds when they come."

The difficulty for covered entities and their business associates, especially small- to medium-size businesses, is understanding what all the requirements mean and providing the financial and human resources to prepare, implement, and monitor the complex security requirements, says **Lani M. Dornfeld**, JD, CHPC, an attorney with Brach Eichler in Palm Beach, FL.

HIPAA Security Rule compliance is not a "once and done" process, Dornfeld says. It is an ongoing and evolving process that changes over time to address various security risks and vulnerabilities identified by each business.

"Somebody must be minding the store," Dornfeld says. That means studying the available resources and implementing the right protection.

Dornfeld notes HHS convened a 405(d) Task Group, comprised of more than 150 information security officers, medical professionals, privacy experts, and industry leaders, as a collaboration between industry and the federal government "to align healthcare industry security practices in an effort to develop consensus-based guidelines, practices, and methodologies to strengthen the healthcare and public health sector's cybersecurity posture against cyber threats." *(Information on the task force is available at this link: https://bit.ly/3rnJI81.)*

The Task Group's first publication, *Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients*, identifies the top five cyber threats (email phishing attack; ransomware attack; loss or theft of equipment or data; insider, accidental, or intentional data loss; and attacks against connected medical devices) and 10 best practices to mitigate the top five threats. *(The report is available at: https://bit.ly/3LctyWU.)*

"In the end, covered entities and business associates will need to do more than just have written policies and procedures sitting on a shelf," Dornfeld says. "They will need to take proactive and meaningful measures to implement those policies, conduct periodic risk assessments, address and manage identified risks and vulnerabilities, monitor systems and overall compliance, ensure staff receive periodic and useful training, and properly manage any breach incident or violation."

At the top of all this must reside HIPAA privacy and security officers who possess enough knowledge and training to assist their organizations in overall HIPAA compliance initiatives, Dornfeld says. When HHS comes knocking, the organization must be prepared to prove it has adopted and implemented recognized security practices, including details of implementation, responsible individuals, training materials, and other proof the security practices meet the requirements of Section 2(c)(15) and Section 405(d).

The HIPAA Safe Harbor Law does not affect the determination as to whether a breach occurred, notes **Richard Sheinis**, JD, partner with Hall Booth Smith in Charlotte, NC. The Safe Harbor Law only comes into play after a security breach has occurred.

The entity also should be aware that simply complying with the HIPAA Security Rule likely will not be sufficient to meet the standard of "recognized security practices," Sheinis says. That will require adhering to the technical requirements specified in the law.

"Meeting the standard of recognized security practices is not easy and is not done quickly. Rather, it takes a great amount of coordination by the entity's IT professional to demonstrate in writing that the standards have been met," Sheinis says. "Keep in mind that this safe harbor does not provide automatic immunity from a finding that a security breach occurred or that a penalty should be imposed. However, it can serve as an aid after the fact, to reduce the likelihood or amount of a penalty."

The Safe Harbor Law is an incentive to entities to improve their security practices, Sheinis says. However, even if this standard is met, an entity still can be penalized for a security breach.

"If an entity never experiences a security breach, they have still benefited by having a higher level of security," Sheinis says. "Although it is difficult to prove a negative, it might just be that the higher level of security is the reason a security breach never occurred." ■

HHS Guidance Addresses HIPAA and Emergency Protective Orders

HHS recently issued guidance about HIPAA compliance when information must be released in conjunction with an extreme risk protection order (ERPO). The guidance will be useful for risk managers and compliance officers, but may present some challenges when trying to adhere to HIPAA restrictions.

An ERPO is "a court order that temporarily prevents a person in crisis, who poses a danger to themselves or others, from accessing firearms. ERPO legislation, which can vary in important ways among states, generally specifies certain categories of petitioners (e.g., law enforcement officers, family members, healthcare providers) who may apply to a court for an ERPO and includes requirements for affidavits or sworn oral statements from the petitioner or witnesses to support the application," HHS explained. *(The guidance is available online at: https://bit.ly/3omkcxV.)*

The guidance does not indicate any change in how providers should

determine whether to disclose protected health information (PHI) when a patient might be at risk of harming themselves or others, but it illustrates how these scenarios are likely to occur, explains **Breanne M. Rubin**, JD, an attorney with Eastman & Smith in Toledo, OH. The guidance notes how those situations can be addressed under existing laws.

"What is most key in the guidance is how OCR highlights that ERPO laws vary from state to state," Rubin says. "The guidance discusses how a covered entity can disclose PHI under HIPAA, and if so, what conditions apply."

The decision to disclose PHI in such a situation can be difficult, Rubin says, coming down to the discretion of the provider assessing the patient's condition, the statements made by the patient, and the likelihood of the patient acting on a threat. HIPAA allows for disclosure in these situations as long as certain conditions are met.

"HIPAA sets the floor for the minimum requirements, but there may be a state law that is more strict, in addition to other federal laws and regulations that apply to the disclosure of health information," Rubin says. "There are very strict rules regarding the release of information related to substance abuse, for example — much [stricter] than HIPAA."

The guidance is useful, particularly in the light of concerns over gun violence in the country, says **Alaap B. Shah**, JD, an attorney with Epstein Becker Green in Washington, DC. Healthcare providers may find themselves in difficult situations when a patient is considered dangerous, and the HHS guidance should help them make a lawful decision.

"People have been confused by HIPAA. It's often used as a shield, with people automatically saying HIPAA doesn't allow us to disclose anything," Shah says. "[HHS] is clarifying that there are some purposeful avenues by which you can disclose sensitive information, including mental health information records, to prevent gun violence."

However, the guidance only goes so far. It still is up to the covered entity to understand pertinent state laws and other federal laws that may limit disclosure.

"HHS is saying that there are ways to disclose this information under HIPAA, but they're also emphasizing that they are not the final word on any disclosure decision," Shah says. "They help you understand how HIPAA applies, but they're very clear that you have to explore these other avenues before making a decision to disclose."

One challenge that could result in litigation is interpreting the scope of the guidance's "minimum necessary" standard, says **Callan G. Stein**, JD, partner with Troutman Pepper Hamilton Sanders in Boston. The guidance is clear: Covered entities and business associates must limit their disclosure of PHI under ERPO laws to the absolute minimum that is necessary to accomplish the intended purpose.

"But what constitutes 'minimum necessary' will vary, not just on a case-by-case basis but on a purpose-by-purpose basis. It is not difficult to envision an individual getting upset and even taking legal action against a covered entity that discloses, under an ERPO law, more PHI than the individual believes was necessary," Stein explains. "Covered entities should be sure to carefully consider what PHI is absolutely necessary to disclose, and to document those decisions in such a way that they can be relied upon later should the need arise."

The same interpretational challenges also could arise in the context of whether a person presents a serious and imminent threat such that disclosing PHI is justified, Stein says. It is not difficult to imagine an individual challenging such a determination in court if he or she believes PHI was disclosed unnecessarily.

"Here, the guidance does provide some guardrails for providers, making clear that a provider who discloses PHI to prevent or mitigate a serious and imminent threat is presumed to have acted in good faith so long as the provider's belief is based on actual knowledge or a credible representation by someone with actual knowledge," Stein says. "Once again, providers who disclose PHI under these circumstances would be wise to carefully consider the threat of harm and, more importantly, document the facts and/or representations on which the decision is ultimately made. Providers should also be cognizant of to whom they make the PHI disclosure. The guidance permits providers to make the disclosure to anyone who is in a position to prevent or lessen the harm."

Another challenge for covered entities is navigating the maze of state ERPO laws that will differ from each other, sometimes in significant ways, Stein says. For example, the guidance noted different states may restrict who can and cannot apply for an ERPO. For example, a physician could apply for an ERPO under one state law but not another.

Covered parties will need to ensure they know what state laws apply to a given situation, and be sure to consult the laws themselves or local counsel before taking any action. They need to understand state-specific laws also extend beyond state ERPO laws.

"Certain states have enacted laws or have common law judicial decisions that will likewise impact these situations," Stein says. "For example, certain states have enhanced restrictions on the disclosure of certain types of PHI, which may still apply in the context of an ERPO." ■