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INSIDE

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New Noncompete Rule Requires Reevaluation of Healthcare Agreements

A recent decision by the Federal Trade Commission (FTC) changes how healthcare organizations can limit the activities of employees after they resign or are terminated, requiring a review of any noncompete agreements currently in place and policies that require them..

The FTC voted to approve a final rule banning noncompete agreements nationwide, effective 120 days after the decision is published in the *Federal Register*.

The decision is being challenged in court.

The FTC determined that noncompetes create an unfair method of competition, violating Section 5 of the FTC Act, says **Khaled John Klele**, JD, partner with the Riker Danzig law firm in Morristown, NJ. With one exception, the new rule means that existing noncompetes are void as of the effective date, and the FTC specified that employers must notify current and past employees that the employer will not enforce existing noncompetes.

> "'NONCOMPETE CLAUSES KEEP WAGES LOW, SUPPRESS NEW IDEAS, AND ROB THE AMERICAN ECONOMY OF DYNAMISM ...'"
> — LINA M. KHAN, FTC CHAIR

The one exception is existing noncompetes with senior executives. Those noncompetes can remain in force, the FTC says. A "senior executive" is defined as an employee in a "policy-making position" earning more than $151,164 per year.

Once the rule is in effect, an employer cannot enter into new noncompetes, even with senior executives. The FTC calls noncompetes a "widespread and

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AUTHOR: Greg Freeman
EDITOR: Jason Schneider
EDITOR: Mike Gates
EDITORIAL GROUP MANAGER: Leslie Coplin
ACCREDITATIONS DIRECTOR: Amy M. Johnson, MSN, RN, CPN

often exploitative practice imposing contractual conditions" that prevent employees from taking a new job or starting a new business.

"Noncompete clauses keep wages low, suppress new ideas, and rob the American economy of dynamism, including from the more than 8,500 new startups that would be created a year once noncompetes are banned," FTC Chair **Lina M. Khan** said in announcing the rule. "The FTC's final rule to ban noncompetes will ensure Americans have the freedom to pursue a new job, start a new business, or bring a new idea to market." The FTC rule is available online at https://bit.ly/3wm1XQD.

Nondisclosure Still OK

A noncompete provision prevents a person from working for a competitor post-employment, whereas a nonsolicitation provision would prevent soliciting a former employer, client, or employee, Klele explains. Meanwhile, a nondisclosure agreement prevents disclosing confidential information.

The FTC rule bans the noncompete provision, but there are certain exceptions, he says. The most important one is the sale of business exception, he says.

"No entity that operates in the healthcare space wants to buy a practice just to have the physician open a new practice across the street to compete with you. I think healthcare organizations are going to have to look at these agreements and determine how important they are to them," he says. "There aren't many exceptions, and a lot of these agreements that are litigated are very fact-specific. You also still have the non-solicitation and non-disclosure provisions that are not impacted by this FTC rule."

The FTC rule on noncompetes could be a significant issue for healthcare entities that have confidential or strategic information they wish to keep from competitors, Klele says.

The U.S. Chamber of Commerce and other business groups sued the FTC in the U.S. District Court for the Eastern District of Texas the day after the noncompete ban was announced. The lawsuit claims that noncompete clauses "benefit employers and workers alike — the employer protects its workforce investments and sensitive information, and the worker benefits from increased training, access to more information, and an opportunity to bargain for higher pay." The lawsuit challenging the FTC is available online at https://bit.ly/44rGnGY.

"The crux of it is whether the FTC had the authority to issue this rule in the first place," Klele says. "I think to maintain the status quo — because this will be impactful to the industry, and not just to healthcare but to really all industries — the court will stay the

EXECUTIVE SUMMARY

The Federal Trade Commission effectively banned noncompete clauses, which commonly are used in healthcare. Employers will have to notify employees that their noncompetes are no longer valid.

- The rule is being challenged in court.
- Nondisclosure agreements are still valid.
- There are some exceptions to the noncompete ban.

rule. Maintaining the status quo is the purpose of filing an injunction, until there's a final decision on the merits."

Assess Dependence on Noncompetes

An example of a healthcare organization using a noncompete is a scenario in which a health system contracts with a radiology group but terminates that agreement, then tries to employ the individual radiologist directly. The group would then try to enforce the noncompete that the radiologist signed. Hospitals and health systems should assess their current dependence on noncompetes, in anticipation of the rule eventually being finalized even if there are legal stays for some time, Klele says.

"I would look at the noncompete that they have in place to see how it is impacted by the FTC ruling and prepare for an eventual loss by the groups challenging the rule," he says. "If the court does deny the stay, then the rule obviously will go into effect. And then organizations will have to issue the notice to employees that is required by the rule to tell them that they're not enforceable." Trade secrets can still be protected by non-disclosure agreements, so organizations also should review them to make sure that they are providing adequate protection for those areas, he says. ■

SOURCE

- Khaled John Klele, JD, Partner, Riker Danzig, Morristown, NJ. Telephone: (973) 451-8451. Email: kklele@riker.com.

CMS Moving to Address Patient Harm with Additional Measures

Centers for Medicare & Medicaid Services (CMS) is planning to introduce additional requirements to improve patient safety, and risk managers would be wise to anticipate how those new measures might affect their operations.

Dora Hughes, MD, acting chief medical officer and acting director of the CMS Center for Clinical Standards and Quality, recently said during a public event in Baltimore that CMS is working with other Health and Human Services (HHS) branches to develop a 10-point patient safety strategy that will be announced later this year. The strategy may include new patient safety-related conditions of participation and value-based payment measures.

On April 10, 2024, CMS issued the fiscal year 2025 Medicare hospital inpatient prospective payment system (IPPS) and long-term care hospital prospective payment system (LTCH PPS) proposed rule. The proposed rule outlines the adoption of a new Patient Safety Structural Measure (PSS Measure) as part of the Hospital Inpatient Quality Reporting (IQR) Program and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, explains **Robert E. Slavkin**, JD, an attorney with the Akerman law firm in Orlando, FL.

The proposed PSS Measure is part of CMS' National Quality Strategy, launched in 2022, with a goal of achieving optimal health and well-being for all individuals, Slavkin says.

The proposed rule is available online at https://go.cms.gov/3UIhGTv.

Participating acute-care hospitals in the Hospital IQR Program that do not submit required quality data to CMS regarding measures selected by the HHS secretary will see payment reductions by CMS, he says. In the proposed rule, CMS discusses seven new proposed quality measures, one of which is the PSS Measure.

Slavkin says the purpose of the PSS Measure is to assess whether hospitals are prioritizing patient safety by requiring hospitals to attest to whether they engage in evidence-based best practices within each of the following five domains: leadership commitment to eliminating preventable harm; strategic planning and organizational

EXECUTIVE SUMMARY

Centers for Medicare & Medicaid Services is planning to introduce new requirements intended to promote patient safety. Scores will be tied to reimbursement.

- Failure to affirmatively attest to each measure could have reputational harm and potential financial consequences.
- Hospitals will need to determine their level of commitment to the measures.
- Compliance may require additional capital and staff.

policy; culture of safety and learning health system; accountability and transparency; and patient and family engagement.

Hospitals will be able to achieve a total PSS Measure score ranging from zero to five, Slavkin says. Each of the five attestation domains includes five attestation statements. A hospital must be able to provide a "yes" or "no" response to every attestation statement within a particular domain to receive a score of one for that particular domain, he says. "For example, if a hospital is only able to attest that it is in compliance with four of the five attestation statements within Domain 5, Patient & Family Engagement, the hospital will receive a score of zero points for Domain 5," Slavkin says.

Coming in 2025

CMS proposes to begin the PSS Measure attestation requirement for the calendar year (CY) 2025 reporting period, which impacts a hospital's fiscal year (FY) 2027 payment determination under the Hospital IQR Program, he explains. The proposed rule provides that a hospital would submit the PSS Measure data annually through the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN). Hospitals currently report quality measure data through this portal on a monthly or quarterly basis, depending on the measure, Slavkin notes.

"Hospitals participating in the Hospital IQR Program will be able to satisfy the reporting requirements of the PSS Measure so long as they provide yes or no responses to each of the five domains," Slavkin says. "Hospitals receive credit merely for reporting their measures, regardless of whether they successfully implemented the requirements within a specific domain."

However, Slavkin explains that the proposed rule provides that, beginning in fall 2026, CMS would publicly report the hospital's PSS Measure score (a total score of 0 to 5 points), on an annual basis on Care Compare (https://www.medicare.gov/care-compare/).

"Hospitals, therefore, face potential reputational harm if they are not able to affirmatively attest to compliance with each domain," he says.

In addition, CMS value-based purchasing programs use selected quality measures to reward providers for the quality of care they provide, Slavkin says. Therefore, another potential ramification of a low PSS Measure score is that if the PSS Measure is used by value-based purchasing programs to determine the quality of care provided by hospitals, a low PSS Measure could impact hospital reimbursement under the value-based purchasing programs, she says.

Hospitals Must Decide about Domains

The practical impact on hospitals and health systems is that they will need to decide whether they want to ensure they satisfy each of the proposed domains of the PSS Measure, says **Danielle C. Gordet**, JD, associate with the Akerman law firm in Miami, FL.

"So long as hospitals comply with submitting whether they are in compliance with each measure they will be in 'compliance' with the reporting requirement," Gordet says. "However, failure to affirmatively attest to each measure could have reputational harm and potential financial consequences."

Gordet notes that the PSS Measure currently is only part of a proposed rule, but she expects that it will be finalized and likely will not change dramatically from its current form. Although hospitals are not required to affirmatively respond to compliance with each domain, doing so is in the best of interest of hospitals to avoid potential reputational harm and other financial impacts, she says.

"Therefore, we recommend hospitals begin preparing now to ensure they are able to satisfy each element of each domain, once or if the PSS Measure is finalized," she says.

To prepare for the strong possibility that the proposed PSS Measure will be finalized, Gordet says hospital risk managers should work with hospital leadership to prepare a task force approach to ensure implementation of all the attestation statements within each attestation domain.

For example, one of the five attestation statements within Domain 2 (Strategic Planning & Organizational Policy) requires the hospital to confirm whether the following is true: "Our hospital has implemented written policies and protocols to cultivate a just culture that balances no-blame and appropriate accountability and reflects the distinction between human error, at-risk behavior, and reckless behavior."

"Implementation of this statement will require the Human Resources Department, Risk Department, Compliance Department, and C-suite leadership to all work together to ensure that the hospital will be on the same page moving forward and to ensure all departments are part of the creation of these new policies, if a hospital does not already have these policies in place," Gordet says.

Aiming to satisfy all of the domains is in the best interests of patients, but hospitals will find the requirements challenging, Gordet says. Many different departments and executive leaders will need to work together within each hospital if their goal is to affirmatively attest to every domain, she says.

"In addition to taking up a substantial amount of staff time to ensure affirmative attestation, some of the requirements may also require hospitals to spend additional capital to reach the goal of affirmative attestations," Gordet says. "For example, depending on a hospital's current capabilities, it may need to contract with third parties to implement some of the required items, such as implementation of an annual hospital-wide survey regarding a culture of safety using a validated instrument, and implementation of a patient safety metrics dashboard."

All Hospitals Under Same CCN

As an added layer to the work ahead, hospital systems that strive to be able to affirmatively attest to the five domains must ensure that all of the hospitals within the system that report under the same CMS Certification Number (CCN) are able to satisfy all of the same domains, Gordet says. A hospital system will not receive a score of 1 for a particular domain unless each of its CCN hospitals also are able to provide affirmative responses to that particular domain.

"Hospitals will face challenges if they want to be able to affirmatively attest to satisfaction of all of the domains," she says. "Affirmative attestations will likely not be possible unless the hospital has sufficient resources to ensure its employees can handle the additional obligations required by many of these domains, such as ensuring the hospital has a dedicated team to conduct event analysis of serious safety events."

Slavkin says the new PSS Measure could have a positive impact on the care that hospitals provide to their patients. CMS clearly has a vision to improve the quality and safety of healthcare for everyone, she says, and CMS will continue to put quality measure requirements on hospitals, such as the PSS Measure. These measures likely will become more rigorous each year, he says.

A necessary tool for implementation is not only buy-in from the C-suite, but also ensuring the effectiveness of the hospital's risk and compliance programs, he says. Without effective programs, these measures will not be able to be implemented. Slavkin says this is why it is important to for risk and compliance programs to be reviewed regularly to determine their effectiveness.

"Hospitals that ignore the need to focus on improving quality now will be left in a panic as these types of measures continue being rolled out by CMS," Slavkin says. "Hospitals that take active steps now to improve quality will have the most success moving forward." ■

SOURCES

- Danielle C. Gordet, JD, Akerman, Miami, FL. Telephone: (305) 982-5609. Email: danielle.goret@akerman.com.
- Robert E. Slavkin, JD, Akerman, Orlando, FL. Telephone: (407) 419-8438. Email: Robert.slavkin@akerman.com.

Safety II Framework Aims to Improve Safety, Eliminate Useless Tasks

A better approach to patient safety can eliminate much of the useless and redundant tasks that burden clinicians and do little to avoid harm, says a researcher who encourages risk managers to consider the natural tendencies of people in the workplace. Human relationships should be a primary focus in patient safety efforts, says **Edward R. Melnick**, MD, MHS, interim research section chief and associate professor of emergency medicine at Yale School of Medicine in New Haven, CT. Melnick is co-author of a recent commentary in *Mayo Clinic Proceedings* promoting this approach.

Attention to human relationships can help eliminate some problems that contribute to the high rates of physician burnout while also protecting patient safety, he says.

The commentary advocates moving from the traditional approach to safety, which they call Safety I, to a framework called Safety II, in which a systems-based approach looks at safety as the presence of resilience rather than a system with no errors.

EXECUTIVE SUMMARY

An approach called Safety II calls for more focus on human factors in preventing patient harm. It also can help eliminate unnecessary tasks that burden clinicians.

- Human beings should be seen as the greatest safety resource.
- Human factors engineers should be included in all safety improvement.
- Moving to Safety II may require disruptive leadership.

"It is based on the understanding that errors can and will always occur, no matter how well a system is designed," Melnick and his co-authors wrote. "Rather than attempting to eliminate all errors, we should instead focus on creating systems that are able to not only anticipate and avoid error, but also adapt and recover from errors in a way that supports and leverages human capacity."

The commentary is available online at https://bit.ly/3JDLL02.

"Safety I is kind of the older model for risk management and improving safety, in which you look often for the root cause of an error, uncover what that cause was, and try to fix that part of the system. Then you can prevent a future error with the Swiss cheese model for setting up a system where human error is more likely to be caught by another member of the team or the system itself," Melnick says. "No one is saying that that's going away, but certainly medicine historically has had a culture of blame and pointing out the errors of the human in the system. So Safety II is sort of flipping that a little bit, in terms of thinking more about how humans are actually the failsafe and that the system itself is imperfect as currently designed."

Recognize Human Limitations

Healthcare organizations should be building systems that recognize human limitations but also their ingenuity and ability to be creative and to stop errors before they happen, he says. As opposed to seeing the human being as the source of error, Phase II emphasizes that human beings are the best resources for preventing that error, he says.

"I work in the emergency department, in the ER and our resources are vast but also at the same time limited. In so much of what I do, there's opportunity for error at every step of the way, and based on my training, I'm catching a lot of it but also some of it is just the system is really not designed to catch everything," Melnick says. "So, I'm doing a lot of creative thinking to try to get the right care for the right patient in that moment. It's kind of counter to that Safety I of 'let's just build the system so that people don't make mistakes' if more people are bending over backwards to help the system to succeed."

In addition, Safety II encourages the elimination of repetitive tasks and data entry that yield little for patient safety, he notes. Safety II encourages the design of systems that address not just the complexity of medicine but the complexity of the environment that medicine is delivered in, and what the role of the human plays in that environment, he says.

"What is the role of a human? Can we design an idea that might work, and before we deploy it, really engineer it in a human-centered way where we understand what the user's needs are?" he says. "We need to build for those needs, test it, iterate upon it make it better, before deploying it."

Integrate at Local Level

The concept of human engineering applies in many ways throughout the healthcare process, he says. Just the simple act of navigating through a hospital can be complicated for someone who is healthy and has a good sense of direction, but Melnick says a patient who needs to make it to a doctor's appointment may have much more difficulty.

"It's not just what they're trying to do for one individual patient but how do they provide that care within the practice environment and balance the needs of that individual patient with the needs of the group of patients that they're working with, and the team that they're a part of," he says. "It's about thinking of that big picture in terms of the humans needs, function, and then the system itself."

Melnick says human factors engineering should be more integrated at the local level within individual health systems. He notes that when building healthcare devices, a human factors engineer will be involved, but that should be the case for many other projects and risk management activities within a hospital or health system.

"Having a human factors engineer as a member of the local team, fully embedded into the team, is probably something that will eventually percolate into the world," he says. "It's tough because that sort of thing is up-front investment, and, right now, healthcare systems are still recovering from financial hardship from the pandemic. I'm a little bit skeptical that we're going to see change soon unless people recognize the need to make that sort of investment."

The move to Safety II and the incorporation of human factors engineering may require some disruptive leaders who are willing to invest in the change, Melnick says. "As a leader of a healthcare system, you want to be the place where patients want to go and you want that patient experience to be really exceptional," he says. "You also want the best and brightest in your staff and clinicians. Being in a work environment where things are built for them to thrive should be a priority. ■

SOURCE

- Edward R. Melnick, MD, MHS, Interim Research Section Chief and Associate Professor of Emergency Medicine, Yale School of Medicine, New Haven, CT. Email: edward.melnick@yale.edu.

Stigmatizing Language Can Lead to Diagnostic Errors, Patient Harm

Stigmatizing language is inappropriate in healthcare and can easily seep into documentation and verbal communication. One of the worst effects of such comments is that it can lead to diagnostic errors and other threats to patient safety, according to recent research.

Stigmatizing language is widespread throughout medical documentation and more likely to be found in the records of some patients, says **Katherine Brooks**, MD, clinical lead for information guidance with the San Francisco Department of Public Health and clinical mentor with the University of California-Berkeley UCSF Joint Medical Program. The problematic language is more likely to be found in the records of Black patients, those with public insurance, and patients with certain comorbidities, she says.

Brooks and her colleagues recently investigated associations between stigmatizing language and errors in the diagnostic process. Their research is available online at https://bit.ly/3Uu464W.

Their analysis drew on the data of a larger study of patients who were hospitalized on internal medicine services and who had either died or required intensive care early in the course of their hospitalization — within the first 48 hours. About a quarter of those patients had a diagnostic error.

Reviewers identified any stigmatizing language in the patient's chart and found that there was more stigmatizing language found in the charts of Black and homeless patients. The bias toward stigmatizing language in those groups had been documented earlier.

"We went on to try to correlate this with the clinical outcome, which has really not been done in the literature so far. This association intuitively makes a lot of sense, but we don't really know the exact mechanism," Brooks says. "We know that provider biases have a huge influence on patient care, particularly the diagnostic process, which is quite cognitive. And there is the opposite effect in which providers are seeing stigmatizing language documented in the chart and that's leading them to have a different level of investment or level of care for that patient."

There is not a lot of work being done in this space, and any real progress will require culture change, Brooks says. The current generation of trainees coming out of medical school has a much greater awareness and knowledge of inequities in medicine and, particularly, how identity affects a lot of clinical processing, Brooks says.

"This is, thankfully, improving. I think a lot of it also has to do with providers being better trained in understanding how the cognitive process and understanding that we are prone to errors," he says. "I think what's a little bit newer is a move towards training clinicians to understand how their own social biases also impact their clinical reasoning and at times their care." ■

EXECUTIVE SUMMARY

Stigmatizing language in patient records is more common in some demographic groups. The language is connected to diagnostic errors and poor outcomes.

- Black people and homeless people were more likely to be stigmatized.
- The language can affect how clinicians see their patients.
- Newly trained clinicians may have a better approach.

SOURCE

- Katherine Brooks, MD, Clinical Lead for Information Guidance with the San Francisco Department of Public Health and Clinical Mentor with the University of California-Berkeley UCSF Joint Medical Program, San Francisco, CA. Email: katherine.brooks@ucsf.edu.

Falls Remain a Leading Safety Problem, Still Need Attention

Risk managers must not let their guard down on the perennial patient safety concern of falls, looking to the proven methods of prevention and the sometimes simple steps that can have significant effect.

Much of fall prevention relies on helping patients and their family members understand the risk of falls and the potentially severe consequences, says **Karen Curtiss**, BCPA, founder and executive director of The Care Partner Project, based in Chicago. Part of the mission is to equip patients and families with quick, downloadable checklists that they can follow to help them manage healthcare, along with resources for hospitals to improve fall prevention. Resources are available at https://thecarepartnerproject.org/.

"When we talk about falls, I don't like to call them errors because that's a blaming word. I prefer calling them cracks in care or gaps in care," she says. "The ones that happen most often are the most preventable. The one and only thing we're ever taught about healthcare is if someone you love is in the hospital or the emergency room, you just show up at their bedside. But none of us really has a clue what to do."

When family members are educated about falls, they can actually pitch in for patient safety, Brooks says. That education can be as simple as pointing out how much of the equipment and furniture in the room is on wheels and may not provide a reliable hold for an unsteady patient. "It's a simple thing of just talking about and being aware of the risk for falls, and what will help you, and what won't," Curtiss says. "It's also about giving people permission to ask for help, assuring them there is no shame in asking for help."

Healthcare organizations should address the defensiveness among care providers in talking about disclosing risks to patients and families, she says. Some of the defensiveness comes from frontline clinicians who feel like, as with so many other patient safety efforts, all the work falls on their shoulders, she notes.

"This defensiveness gets in the way of having good conversations about some very simple and effective patient safety practices," Curtiss says.

Curtiss' father suffered a fall that eventually led to his death after complications, and the experience illustrates how conveying simple information can prevent a tragedy. He had been switched to a new medication which could cause dizziness and a drop in blood pressure.

"They could have simply said, 'Look, this is a new medication and here's some things that we need to watch out for, and you need to be sure that somebody's with you when you're on the move until we see how this medication affects you," Curtiss says. "My dad was a really, really smart person and he was great at following directions. He was such a compliant patient and just that one little conversation would have made all the difference.

Some Patients More Vulnerable

Elderly, impaired, and disabled individuals experience an especially serious risk of falling in the healthcare setting, says **Richard F. Cahill**, JD, vice president and associate general counsel with The Doctors Company, a malpractice insurer based in Napa, CA. Such incidents often diminish the reputation of the facilities, following negative social media posts, he notes. "Preventable injuries are rarely defensible. Patients, vendors, and others visiting a clinic office, hospital, ambulatory care center, or testing complex who fall and sustain physical harm may initiate litigation to recover monetary damages," Cahill says. "Not uncommonly, patients may claim that there was inadequate supervision or support by clinic personnel prior to the incident constituting medical negligence. A lawsuit involving such allegations may thereby trigger the provider's professional liability coverage."

Alternatively, an individual who sustains injuries from a fall may allege that the property was inherently dangerous or defective, which may have been avoided through the implementation of simple measures, he says. In this situation, the general liability policy for the clinic would ordinarily respond to provide counsel for defending the action and pay the indemnity in the event of a settlement, adverse jury verdict, or arbitration award, he says. Cahill says healthcare providers and facilities are strongly encouraged to undertake these proactive measures to prevent falls from occurring in the first place, thereby limiting potential financial exposure:

- Routine inspections of equipment, including elevators, escalators, treadmills, examination tables, support railings, public restrooms, and common areas, as well as the overall condition of the premises, will help to identify problems that can be corrected in a timely manner.
- Periodic ergonomic risk

EXECUTIVE SUMMARY

Falls remain a significant threat to patient safety. Sometimes simple conversations and interventions can reduce falls.

- Communicate with patients and family about fall risks.
- Watch for common causes like medications and dementia.
- Round more frequently than the standard two hours.

assessments by third-party experts promote greater safety and often achieve consistency with prevailing community standards.

• Records detailing maintenance efforts, including sweep sheets and repair orders, generally will demonstrate due diligence and a concern for the well-being of guests attending the premises, enabling counsel to present a more defensible case to the finder of fact, should the matter proceed to trial or hearing.

• Similarly, medical offices should consider developing a protocol for assessing patients, especially the elderly, infirm individuals, or persons presenting with a physical limitation, disability, or other impairment at the earliest available opportunity to be better prepared to prevent a fall from occurring. Offices should appropriately document the medical records of any individuals so assessed.

"Office policies related to facilities maintenance and patient assessments, as well as staff members' implementation of those policies, should be periodically audited for compliance and updated as necessary to help ensure best practices are being followed," Cahill says. "It is also recommended that healthcare offices maintain a post-fall protocol detailing steps to be implemented to ensure that prompt medical care is provided."

New Environment Risky

Patients placed in any new environment with unfamiliar surroundings will be susceptible to a certain amount of confusion, which can lead to falls, says **Anna ten Napel**, PhD, RN, NP, vice president for regulatory affairs and performance improvement with Catholic Health in Long Island, NY.

Also, the units they are admitted to often are busy hubs, requiring the attention of staff, who then are not always able to monitor each patient's needs every minute, she says. Additionally, many patients tend not to wait for staff assistance getting out of their beds or needing to walk or use the facilities, she says. These factors combine to increase the risk of an untoward event, such as a fall.

"At Catholic Health, we're addressing these issues upfront by carefully explaining that a hospital environment is different than their home and providing guidance on how best to avoid any accidents," Napel says. "We ask them to recognize their vulnerabilities and review and sign a Fall Prevention Agreement. This fosters the patient's active participation in our safety strategy."

> "COMMON CAUSES OF FALL ARE MUSCLE WEAKNESS, MEDICATIONS, AND NEW ONSET OF DIAGNOSIS. THE MOST EFFECTIVE PREVENTION STRATEGIES INCLUDE MEDICATIONS AND REHAB SERVICE."

Catholic Health looks at each patient's individual needs, screening all for fall risk. It has invested in tele-sitter technology to keep a watchful eye on patients and is sharing best practices with other hospitals across the country to reinforce its fall prevention programs, Napel says.

"Our own best practice tools are built into our electronic medical record platform, providing alerts to notify staff of patients who are categorized as high risks for falls," she says. "That prompts us to pay closer attention to those patients' needs. Most recently, we've introduced micro-learning, where our staff watch short vignettes that reinforce our grasp of preemptive fall prevention."

Napel notes that there is no single strategy to prevent falls. A multifaceted, multilayered approach to ensure safety, always recognizing that each patient will have their own specific needs, will yield the best results in avoiding patient falls, she says. "As falls can be devastating, it is critical that all resources be applied in the prevention of patient falls," she says. "Innovation and technology are certainly vital, and yet, at Catholic Health, we always come back to listening to our patients, really engaging with them to understand their needs, and making them partners in their own care."

Follow Prevention Strategies

Falls always will be a risk in healthcare settings because patients are more frail than other adults in the community, says **Ken Sha**, program director at Excel at Woodbury for Rehab and Nursing in Woodbury, NY. They often have chronic conditions, such as osteoporosis, balance, vertigo, heart and lung conditions, and difficulty walking along with issues with memory, active daily leaving, and being in a new environment, he explains. Common causes of fall are muscle weakness, medications, and new onset of diagnosis, Sha says.

The most effective prevention strategies include multiple factors, such as medications and rehab services — physical, occupational, speech, and recreation therapy. In addition, Sha recommends these fall-prevention strategies:

- Assess patients after any fall to identify risk factors and medical conditions.
- Educate staff on environmental safety.
- Have proper, durable medical equipment in place, such as grab bars, raised toilet seats, lower bed heights, and proper ambulation devices.
- Use appropriate devices, such as bed alarms and chair alarms, for cognitive issues.
- Incorporate exercises and rehabilitation to improve patient strength, static and dynamic balance, endurance, and walking abilities.
- Anticipate patients' needs.
- Maintain a toileting schedule.
- Incorporate group activities for supervision and education on safety and proper body mechanics.

Sha advises against the use of physical restraints because studies show that they do not reduce falls.

Use Appropriate Rounding

Falls are an unfortunate outcome that are never fully preventable, but they can be mitigated, says **Christopher E. Brown**, JD, partner with the Kaufman Dolowich law firm in Orlando, FL. In the hospital and long-term care setting, the best prevention strategies are to assess the patient upon admission to the facility, familiarize the patient with the environment, maintain a call light, and ensure the patient is competent in the call light's use, he says. It also is useful to keep hospital beds and wheelchair brakes in the locked position at all times, use non-slip footwear with the patient, and ensure handrails are in place in all private bathrooms, he says. Appropriate rounding by hospital personnel also can go a long way to avoiding these falls. While the industry standard is to round every two hours, more frequent rounding and patient observation can avoid situations where an individual feels compelled to move without assistance, Brown says.

"In regard to liability, it is important and necessary to document all assessments and interventions that have been implemented for the patient. This needs to be done immediately and has little to no effectiveness if completed after a fall has occurred," Brown says. "Rounding, including the time and individual who performed the service, should also be documented contemporaneously in the medical chart." ■

SOURCES

- Christopher E. Brown, JD, Partner, Kaufman Dolowich, Orlando, FL. Telephone: (407) 789-0230. Email: cbrown@kaufmandolowich.com.
- Richard F. Cahill, JD, Vice President and Associate General Counsel, The Doctors Company, Napa, CA. Telephone: (800) 421-2368.
- Karen Curtiss, BCPA, Founder and Executive Director, The Care Partner Project, Chicago. Telephone: (847) 208-6074. Email: karen.curtiss@carepartnerproject.org.
- Anna ten Napel, PhD, RN, NP, Vice President, Regulatory Affairs and Performance Improvement, Catholic Health, Long Island, NY. Telephone: (716) 706-2112.
- Ken Sha, Program Director, Excel at Woodbury for Rehab and Nursing, Woodbury, NY. Telephone: (516) 692-4100.

State Laws Affect Privacy Compliance; Data Tracking Also a Concern

New state privacy laws can affect hospital operations but might be overlooked when the focus is on HIPAA compliance. Risk managers and compliance officers should make sure they are complying with both obligations, says **Sharon R. Klein**, JD, partner with the Blank Rome law firm in Los Angeles.

Enforcement from the Federal Trade Commission is a new issue, since it focuses on tracking of online data that is not necessarily protected health information (PHI).

"When you're thinking about healthcare, you think about the federal acts like HIPAA. But from a state law perspective, you have these new comprehensive privacy laws that are applying to not-for-profits, and of course a lot of healthcare is not-for-profit," she says. "New Jersey, Colorado, Delaware, and Oregon have privacy laws that directly affect hospitals, so you have that combination with some of those state privacy laws that do extend to PHI."

Many of the state laws focus on mobile apps and consumer health, such as health trackers that count daily steps. That is not PHI covered by HIPAA, but it still can create problems for healthcare providers, Klein says.

"So why is that a problem? It's a problem because HIPAA does not have a private right of action. You're not going to get a class action under HIPAA," she explains. "But under the state laws, you have the [attorneys general] who can bring regulatory action, and you have the threat of individual plaintiffs in class actions against healthcare institutions. That's like a sea change."

As onerous as HIPAA privacy and security and breach obligations can be, they largely are enforced by the Office of Civil Rights and not the private plaintiffs' bar, Klein says. The possibility of state action and class action lawsuits brings an additional level of risk.

"Most of my clients, hospitals and physician groups, are using mobile devices and digital apps. You need to really understand that and try to avoid online tracking," she says. "Think of that as the pixels that follow you around, and cookies and geolocation. And post-Dobbs, the Supreme Court decision, there is a concern over reproductive rights and the protection of sensitive information on where that person lives. That is getting a huge focus in healthcare."

The FTC warned hospitals after Dobbs last year that they were going to look at online tracking and geolocation as a regulatory priority, Klein says.

"To the extent you're collecting that data, they're going to require a specific consent for sensitive data. Now, why is that a sea change? Because under HIPAA, traditionally if you're talking about treatment, payment and operations, you don't need a patient consent," she says.

Healthcare institutions that collect certain kinds of like data, including geolocation data, may need to go back to their patients and get consent, she says.

"It used to be that [Health and Human Services] was the main enforcer on the federal side," Klein says. "Now we're seeing the Federal Trade Commission is getting into enforcing privacy on healthcare information." ■

SOURCE

- Sharon R. Klein, JD, Partner, Blank Rome, Los Angeles, CA. Telephone: (949) 812-6010. Email: sharon.klein@blankrome.com.

Review Cyber Risk Insurance, Brace for Transparency Issues

Pay attention to your policies for cyber insurance or data liability when they come up for renewal or if you are in the process of obtaining them, advises **J. Malcolm DeVoy**, JD, partner with the Holland & Hart law firm in Las Vegas.

"Look at them closely [when] considering getting coverage and maybe have counsel take a look at them, because the terms might be more porous than they appear," DeVoy says. "These tend to be pretty expensive policies that can cost over $100,000 without being a particularly large organization. So you would think that you would have better coverage than you actually do."

DeVoy urges healthcare leaders to be proactive in assessing their cyber liability coverage.

"Don't assume that the insurance policy is going to cover you. Don't just have your normal attorney read it over. Not that they're not smart people, but it might be worth asking specifically for coverage counsel to give an opinion about it," he says. "Ask, 'Will I be protected if this were to happen?' and lay out some common scenarios."

DeVoy also advises healthcare organizations to brace for the Biden-Harris administration to push more transparency, as it has done with respect to nursing facilities, and specifically skilled nursing facilities.

"I think that there are certain economies of scale where you can really only run these facilities if you have a number of them. But there's more transparency requirements that took effect with respect to disclosure in the ownership of real estate investment trusts, common ownership, going up the stream of ownership through these facilities, their management companies, the entities that own the real estate in some way, to some degree," DeVoy says.

Once you have a big enough set of information, it is not that far to see how the government can tee that up for further action, she says.

"That could be administrative review, or they could realize that there's commonality of ownership where a problem at one facility can suddenly spread to other facilities," he says. "The premise is that, if the ownership of this one facility is doing it wrong, maybe the commonly owned facilities have other problems. And that's besides the antitrust issues that could arise." ■

SOURCE

- J. Malcolm DeVoy, JD, Partner, Holland & Hart, Las Vegas. Telephone: (702) 669-4636. Email: jmdevoy@hollandhart.com.

HEALTHCARE RISK MANAGEMENT™

CME/CE INSTRUCTIONS

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CME/CE QUESTIONS

1. **What did the Federal Trade Commission ban, with some exceptions, recently?**

   a. Noncompete clauses
   b. Non-disclosure clauses
   c. Privacy agreements
   d. Employee performance minimums

2. **What is Centers for Medicare & Medicaid Services planning to introduce later this year?**

   a. 10-point patient safety strategy that may include new patient safety-related conditions of participation
   b. 10-point patient quality improvement strategy that may include conditions of participation applicable only to the largest hospitals
   c. 5-point labor rights strategy that may include limits on working hours
   d. 5-point communications strategy that may include requirements for more broad disclosure of quality ratings

3. **What is a key component of the Safety II strategy?**

   a. Incorporating more technology to improve patient safety
   b. Focusing on human beings as the greatest resource for patient safety
   c. Developing more standards and guidelines for clinicians
   d. Requiring more nurse participation in patient safety efforts.

4. **What does Karen Curtiss, BCPA, founder and executive director of The Care Partner Project, say is an important way to help reduce falls?**

   a. Conduct an annual investigation of fall rates and causes.
   b. Bring in outside consultants for a fresh perspective.
   c. Base prevention efforts mainly on national statistics.
   d. Communicate with patients and family members about risks and prevention.

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

Virginia Supreme Court Orders New Trial in Medical Malpractice Case After Trial Court Refuses to Give Jury Instruction About Alternative Causes

*By **Damian D. Capozzola**, Esq.*
The Law Offices of Damian D. Capozzola
Los Angeles

***Jamie Terrence**, RN*
President and Founder, Healthcare Risk Services
Former Director of Risk Management Services (2004-2013)
California Hospital Medical Center
Los Angeles

News: Recently, the Virginia Supreme Court ordered a new trial in a medical malpractice case in which a woman was awarded $1.6 million. The plaintiff claimed that she suffered a seizure and fell after her physician failed to treat her low blood sodium. The trial saw multiple experts testify on both sides of the issue of causation — a key element in proving any negligence lawsuit.

The defendants (hospital and doctor) argued that the plaintiff's fall could have been caused by several other factors, rather than malpractice. They asked the court to instruct the jury that, if there were multiple possible causes of the plaintiff's injury, then the jury should return a finding that defendants were not liable. The trial court refused, and the jury ultimately found for the woman and awarded her $1.6 million in damages.

The verdict was affirmed by the Court of Appeals. However, on appeal to the Virginia Supreme Court, the court found that the trial court erred by refusing to give the defendants' proposed jury instruction on the issue of alternative causation to the jury. In its opinion, the Virginia Supreme Court clarified the law on jury instructions with reference to longstanding legal principles. It overturned the Court of Appeals and remanded the case for a new trial.

ON APPEAL TO THE VIRGINIA SUPREME COURT, THE COURT FOUND THAT THE TRIAL COURT ERRED BY REFUSING TO GIVE THE DEFENDANTS' PROPOSED JURY INSTRUCTION ON THE ISSUE OF ALTERNATIVE CAUSATION TO THE JURY.

Background: The plaintiff sought medical treatment at the defendant hospital for abdominal pain and nausea, where the defendant doctor diagnosed her with hyponatremia, a condition characterized by low blood sodium levels. Despite this diagnosis, the plaintiff claimed she was not informed of it and was discharged without proper instructions regarding her condition.

At trial, several experts testified on both sides regarding the cause of the plaintiff's fall and subsequent injuries. Paramedics and physicians, serving as expert witnesses, differed in their opinions, with some attributing her condition to a hyponatremia-induced seizure and the experts of the defendants claiming that alternative causes, such as medication side effects or a mechanical trip and fall, were responsible for the woman's head injury.

The jury instructions provided by the court included those addressing proximate cause and multiple causation. The jury instruction that the judge gave explained that "[t]here may be more than one proximate cause of an injury," but if "the negligence of a defendant proximately caused injury to [the

plaintiff], then the negligence of that defendant is a proximate cause of [the plaintiff]'s injury even if there were other acts or omissions that caused her injuries."

The defendants proffered a different instruction. They wanted the judge to instruct the jury that "[i]f you believe from the evidence that the injury to [the plaintiff] might have resulted from either of two causes, for one of which [the defendant doctor] might have been responsible and for the other of which [the defendant doctor] was not responsible, and if you are unable to determine which of the two causes occasioned the injury complained of, then the plaintiff cannot recover."

On appeal to the state's Court of Appeals (the intermediate reviewing court), the trial court's decision was affirmed, but on the grounds that the defendants waived their argument that the injury was caused by a mechanical trip-and-fall by raising it for the first time on appeal. But the Virginia Supreme Court disagreed, first ruling that the defendants did not waive the issue for appeal, and then ruling that the refusal of the trial court to give the defendants' instruction to the jury was reversible error. The Virginia Supreme Court held that defendants' proffered jury instruction — that the jury must find for the defendants if they cannot determine which cause occasioned the plaintiff's injury — was the correct instruction.

The Virginia Supreme Court centered its ruling on legal fundamentals. It explained that, to establish negligence, the evidence must show that the defendant's actions were the cause of the injury. This is straightforward enough. But in situations where the evidence reasonably shows that there may have been more than one cause of the injury, the trial court must instruct the jury that if it believes there may be alternative causes of the injury, they should return a verdict for the defendant. The Virginia Supreme Court found that jury instructions should be given if they correctly state the law and are supported by evidence presented during the trial.

During the trial, the evidence did suggest that factors beyond the defendants' alleged negligence could have caused the plaintiff's injury. These included the plaintiff's medication and the possibility of a mechanical trip and fall. The Virginia Supreme Court held that there was more than a "scintilla" of evidence presented suggesting that factors other than the defendants' alleged negligence could have led to the plaintiff's injury, such as the potential side effects of the plaintiff's medication, drugs the plaintiff was given, or a trip and fall.

What this means for you: Jury instructions are a critical part of a trial. After all the evidence has been heard and the witnesses have testified and the lawyers for both sides have given their closing arguments, the judge instructs the jury on how to deliberate. The jurors receive a series of instructions. Many are commonplace instructions given in most or all trials, but some — and usually the ones on the issues pivotal to the particular case — are specially drafted by the parties in an effort to spin the law to their own advantage. The judge must decide in such circumstances whether to give the jury both, one, or none of the competing instructions. The judge's decision in such circumstances is critically important to both the verdict outcome at trial and protecting the integrity of the trial on appeal.

This case also highlights the importance of expert witnesses. Often called "the battle of the experts," complex medical actions often rely heavily on expert witnesses to prove, or contest, a medical negligence case. Expert witnesses are required to establish the standard of care that physicians must meet to discharge their duties to patients, who can become plaintiffs when they feel that the physician failed to meet that standard. In this case, the expert witnesses were focused on the issues of causation: Was it the defendant doctor's failure to correctly diagnose the plaintiff who was the cause of her injury, as the plaintiff's experts opined, or was there some other cause of her injuries?

In cases where there are a multitude of expert witnesses testifying persuasively on similar topics, the decision to use one of two competing jury instructions becomes all the more important. Even an attentive, perceptive jury can be left unsure of what to believe, and how to apply their beliefs concerning what the evidence showed in rendering a verdict. Juries need the direction of the court to properly instruct them on the law.

For defense practitioners and defense-side experts, the Virginia Supreme Court's ruling may be encouraging. If the defense can offer plausible, believable expert opinions on different theories of causation, it may mean the difference between a $1.6 million verdict and a victory for the defense. Or, at least, defense-side practitioners can be reassured that the jury will be instructed to reach verdicts for the defense if it cannot determine the true cause of injury among multiple competing theories. Sowing that doubt about the plaintiff's theory of causation is crucial.

For plaintiff practitioners and plaintiff-side experts, this case highlights the importance of persuasive testimony on the element of causation — opinion testimony that is strong enough to rule out alternative causation theories. Although this case is yet to be retried in the trial court, this decision raises the bar for plaintiffs. It

is critical not only for the plaintiffs to offer persuasive causation testimony, but they also must effectively rule out alternative causes of the injury. That is a tall order when faced with competent defense counsel with persuasive experts. Rebuttal testimony and effective cross-examination become all the more important as well. The jury must feel comfortable ruling out alternative causes that will sink the plaintiff's case. ■

REFERENCE

- Decided on April 4, 2024, in the Supreme Court of Virginia, Case No. 230199.

Ohio Appellate Court Refuses New Trial for Patient Plaintiff with Errors in Record on Appeal

News: Recently, an appeals court in Ohio affirmed a verdict finding a defendant group of doctors not liable for medical malpractice in failing to detect a woman's cancerous tumor. After the jury reached a verdict for the defendants, the plaintiff argued that her lawyer should have been allowed to impeach the defendant pathologist who she accused of failing to detect her cancerous growth. However, the appellate court found that the appeal failed for several reasons. First, the trial court judge did not err in preventing the plaintiff's attorney from impeaching the defendant pathologist with reports from other patients. Second, however, and more fundamentally, the appellate court noted that the plaintiff did not have a full transcript of the trial for the appellate court to review. Without a transcript, the appellate court found that it was simply unable to determine if the trial court had erred in its decision to prevent the woman from offering the evidence she wanted.

The case is a reminder of the basics of what evidence will be allowed to make it in front of a jury, as well as the procedural and administrative fundamentals of appeals, all of which can become critically important for any doctor or medical administrator involved in litigation.

Background: The plaintiff underwent a surgery to have her thyroid removed. The defendant pathologist who examined the plaintiff's thyroid did not detect a malignancy in the woman's thyroid. However, a few years later, the plaintiff had another surgery on her neck to remove a growth, and that pathologist found a cancerous growth. The pathologist also determined that the plaintiff's thyroid cancer was, in fact, present in the slides of her 2015 visit to the previous pathologist. Cancer also was found in the woman's lung after additional testing. The woman sued the first pathologist and his employer for medical malpractice for failing to detect the cancer in 2015.

During the trial, the plaintiff's attorneys sought to impeach the defendant pathologist after he testified that he had not ever made a similar error in missing a cancerous growth. As it happens, the pathologist had treated two other relatives of the plaintiff, and the plaintiff's attorney had the pathologist's reports from those treatments, which purportedly showed that the pathologist had missed cancerous growths in those instances as well. The plaintiff's attorney argued that this showed the pathologist's untruthfulness and sought to impeach the pathologist on this basis.

The trial court refused to allow impeachment on this basis, because bringing in those other reports could cause the jury to question whether the defendant pathologist was negligent in those cases as well. Whether the pathologist was negligent in those cases was not relevant to the issues in this case, the court determined. The trial court also did not allow the plaintiff's attorney to ask his client, the plaintiff, about her relatives' experiences with the pathologist.

After the jury returned a verdict for the defendant pathologist, the plaintiff made a motion for a new trial, and then appealed the denial of that motion. The plaintiff appealed on the grounds that the trial court erred in prohibiting the plaintiff's attorney's efforts to fully explore the other purported acts of negligence and impeach the defendant pathologist.

However, the plaintiff's attorney submitted an incomplete trial transcript on appeal. On that basis alone, the appellate court found that it could not decide the issue of error on an incomplete record, and explained that it was the appellant's obligation to include a transcript that allows the reviewing court to do its job. The court also found that the plaintiff did not show that any error of the trial court rose to the level of requiring a new trial anyway, because no "substantial right" of the plaintiff was affected by excluding the evidence relating to the reports. The appellate court also found that it was not an error for the trial court to prevent the plaintiff's attorney's line

of questioning about previous missed cancer diagnoses.

What this means for you: Attorneys attempt to "impeach" witnesses to draw their credibility into question in front of the jury. An attorney can impeach a witness with a document or other piece of evidence that shows that the party may not be entirely honest when testifying. In this case, the attorney for the plaintiff sought to impeach the credibility of the defendant pathologist for his testimony that he could not recall previous instances in which he missed a cancer diagnosis. The trial court judge rejected the attempt to do so for a couple reasons, chief among them that it would be prejudicial for the jury to hear about unrelated cases of missed cancer diagnoses.

Trial courts have a gatekeeping role of permitting the jury to consider only relevant evidence. Even where evidence may be relevant, a trial court still must exclude it if it would be unfairly prejudicial to one of the parties. That is what happened here. The trial court found that, even if the pathologist had missed previous cancer diagnoses and denied it, it would be too prejudicial to him to allow the plaintiff's attorney to ask him about previous instances where that occurred, because he is not on trial for those previous instances. Allowing the jury to hear that what the doctor is accused of has happened before may lead them to believe that he must be liable in this instance as well. But technically that is not relevant in determining his liability here. However, that the doctor had missed diagnoses would be a fact that is hard to forget when jurors begin their deliberations. The trial judge therefore excluded it, and the appellate court affirmed.

The court exercised its gatekeeping role again when it prevented the plaintiff's attorney from asking other pathologists about the reports. The plaintiff's attorney wanted to make the point that the hospital group should be held liable as a whole, and to establish that, sought to raise the issue that the hospital group had been negligent with respect to its policies concerning reviewing cases. Here, the trial court rejected this attempt because doing so would be to introduce evidence of "subsequent remedial measures." Subsequent remedial measures are actions that a party takes after an accident or negligent incident to prevent it from occurring again. The policy against allowing evidence of those measures in front of the jury is to encourage, or at least not penalize, a party when it fixes a negligent condition. The legal system recognizes that we are all better off when people or companies are encouraged to repair, fix, and correct negligent conditions. Here, the court noted that, if the defendant doctors group made changes to their policy following a missed cancer diagnosis, that would be a subsequent remedial measure that should not make it in front of a jury.

Also worth noting is the court's ruling that, even if there was an error made by the trial court, it does not automatically entitle the plaintiff to a whole new trial. Courts recognize that no one is perfect, even trial court judges. For that reason, any error by the trial court will only get the appealing party a new trial if it affects the party's substantial rights. In other words, the appellate courts give the trial courts some leeway in recognition that there are a lot of decisions that the trial court must make. It would be unreasonable to expect the trial court judge to get every decision right every time during the course of a trial, especially when those decisions involve evidentiary rulings. The trial court judge may make several hundred evidentiary rulings over the course of a trial.

Lastly, this case is a reminder of the importance of the sometimes mundane administrative requirements for an appeal. Here, the appellate court noted that it did not even have the ability to review the appellant's legal arguments in full, because the appellant did not attach all of the relevant portions of the trial transcript. Including a full record on appeal is one of many requirements to make a successful appeal. In this case, the appellate court did not seem to think that the plaintiff had much of an argument on the merits. But for those cases where practitioners have excellent grounds to appeal an evidentiary ruling, step one is to make sure that you file the appeal correctly.

Regardless of the legalities, the medical group has a responsibility to its patients to use their peer review process to assure that the members within the medical group continually meet the accepted standard of care for the particular specialty involved. Although peer review records are (with some exceptions) generally held to be privileged and confidential, for the purposes of patients' safety and mitigation of potential events, the medical group has a responsibility to take peer review activities seriously and stand by the decisions reached by their internal review. Questionable outcomes or lack of qualified review staff can be referred for outside peer review. Remediation also can be outsourced in some instances. ■

REFERENCE

- Decided on March 29, 2024, in the Court Of Appeals Of Ohio, Ninth Appellate District, County Of Lorain, Case No. 23CA011969.

HIPAA REGULATORY ALERT

CUTTING-EDGE INFORMATION ON PRIVACY REGULATIONS

OCR's Update on Online Tracking Guidance Still Tricky

The Office for Civil Rights (OCR) recently updated its December 2022 bulletin regarding the use of third-party tracking technologies by HIPAA-regulated entities "to increase clarity for regulated entities and the public." However, the clarity is questionable.

The updated bulletin potentially raises more questions than it answers, says **Angela Matney**, JD, counsel with the Reed Smith law firm in Washington, DC. Based on the updated guidance, covered entities and business associates may be required to know the subjective intent of visitors to certain webpages, she says. (The updated guidance is available online at https://bit.ly/3VSHfSI.)

If this intent cannot be determined, which Matney says almost always will be the case, regulated entities may choose to treat all identifiable information collected through these webpages as protected health information (PHI).

The guidance addresses the use of cookies, pixels, and other website analytics tools that may violate HIPAA by exposing PHI.

"This has implications for regulated entities' use of tracking technologies, including those designed to help improve patient experiences and to provide beneficial information to help allocate resources based on the needs of different populations," she says.

The updated guidance comes after the American Hospital Association (AHA) and others sued OCR over the rule restricting the use of third-party technologies. (The lawsuit is available online at https://bit.ly/3UJEx0X.) **Chad Golder**, AHA general counsel and secretary issued a statement after the updated guidance, saying "The fact that the HHS Office for Civil Rights has modified its Bulletin in response to our lawsuit concedes that the original Bulletin was flawed as a matter of law and policy. Unfortunately, the modified Bulletin suffers from the same basic substantive and procedural defects as the original one, and the agency cannot rely on these cosmetic changes to evade judicial review."

Matney explains that the portion of the bulletin at issue in the AHA suit concerned "unauthenticated webpages," defined in the bulletin as "webpages that are publicly accessible without first requiring a user to log in to such webpage." OCR acknowledges in the updated bulletin that tracking technologies on certain webpages (such as a webpage that provides information about job postings or visiting hours) do not collect PHI, she says.

"But according to the updated bulletin, if a visit to a regulated entity's website relates to an individual's health, health are, or payment for healthcare, the use of third-party trackers results in a disclosure of PHI," Matney says. "This suggests that a covered entity or business associate will need to have insight into the user's subjective intent for visiting these webpages if it plans to treat information collected through trackers as anything other than PHI."

Examples in the updated bulletin would seem to support this interpretation, Matney says. The bulletin considers two hypothetical visits to a hospital's page listing its oncology services. The bulletin states that if a student visited the page while writing a term paper on the changes in the availability of oncology services before and after the COVID-19 pandemic, information collected by tracking technologies would not be PHI, even if it identified the student, Matney notes.

On the other hand, if an individual visited that same webpage seeking a second opinion on treatment options for their brain tumor, identifiable information relating to the individual's healthcare would be PHI according to the guidance, she says. The individual's reason for visiting

the webpage would seem to be the determining factor.

"Because HIPAA-regulated entities are not in a position to know why a particular individual visits a webpage, they may choose to mitigate risk by treating all information collected through certain webpages as PHI. This means that they may have to completely discontinue the use of third-party trackers on these pages or only use trackers from vendors who will enter into HIPAA-compliant business associate agreements," Matney says. "Traditionally, many providers of popular analytics tools have refused to sign business associate agreements (BAAs), so covered entities and business associates may have limited options if they wish to use tracking tools for purposes such as improving patient experiences or helping determine how to allocate resources based on patient needs in different geographic locations."

No Useful Changes

Unfortunately, the new guidance made no real substantive changes to the original guidance, says **Kristen Rosati**, JD, an attorney with the law firm of Coppersmith Brockelman in Phoenix, AZ. It seems OCR is digging in its heels, she says, with no immediate regulatory relief in sight, while healthcare organizations struggle to comply with the guidance without impacting website functionality and operations too much.

Unfortunately, the use of online tracking by healthcare organizations carries significant risk, says **Erin Dunlap**, JD, an attorney with the Coppersmith Brockelman law firm in Phoenix, AZ. Regarding regulatory risk, both OCR and the Federal Trade Commission (FTC) have issued guidance on online tracking that set difficult standards to meet, she says. They have initiated investigations and issued joint "warning" letters to approximately 130 hospital systems and telehealth providers regarding the use of online tracking.

The FTC has imposed penalties against numerous parties related to online tracking, Rosati says, and the regulatory attention isn't limited to the feds: State attorneys general also are initiating investigations related to online tracking under their state consumer data privacy laws and/or state health information confidentiality laws, she says.

There also is litigation risk, Rosati notes. Numerous lawsuits, including several class actions, have been filed against third-party tracking vendors, hospital systems, and telehealth providers over the disclosure of website user data through online tracking. Financial risk comes into play because cyber liability insurers are issuing detailed requests for information to healthcare organizations to explain their use of online tracking, raising concerns about increases in insurance premiums, Rosati says.

"We had a small glimmer of hope that OCR would revisit its guidance when the American Hospital Association filed a lawsuit against OCR on Nov. 3, 2023, challenging OCR's original guidance on the use of online tracking," she says. "Unfortunately, OCR did not make significant revisions in response to the AHA lawsuit. The March 2024 guidance slightly retracted OCR's original position on IP addresses, stating IP addresses may constitute PHI 'in some circumstances.'"

The guidance says that the mere fact that an online tracking technology connects the IP address of a user's device (or other identifying information) with a visit to a webpage addressing specific health conditions or listing healthcare providers is not a sufficient combination of information to constitute PHI if the visit to the webpage is not related to an individual's past, present, or future health, healthcare, or payment for healthcare, Dunlap explains.

"This is not a workable distinction, as HIPAA regulated entities will not know the intent of a website user," Rosati says.

The updated guidance also encourages the use of a customer data platform (CDP), which OCR defines as "software that can combine data from multiple sources regarding customer interactions with a company's online presence to support a company's analytic and customer experience analysis." OCR explained that CDP vendors may be willing to sign business associate agreements and de-identify online tracking data before sending it to online tracking vendors like Google or Facebook, Dunlap says.

"We agree that the use of a CDP or 'middlemen' vendors is helpful for HIPAA-regulated entities to maintain some analytical capabilities to determine whether their marketing efforts through social media platforms are effective," she says. "But we have noted that HIPAA regulated entities need to 'kick the tires' to make sure the CDP vendors are appropriately de-identifying data before sending data to online tracking vendors.

In addition, Rosati notes that these vendors can be expensive and may be cost prohibitive for some organizations.

Address in Risk Analysis

OCR's updated guidance also made clear that HIPAA-regulated

entities should address the use of tracking technologies in their risk analysis and risk management process, she says, with OCR saying it is "prioritizing compliance with the HIPAA Security Rule in investigations into the use of online tracking technologies."

"This is a big heads up to HIPAA-regulated entities to accelerate their internal analysis on the use of online tracking and to integrate any remaining online tracking into the HIPAA security risk assessment process," Rosati says.

(*See the story on p. 3 for Rosati and Dunlap's recommendations for responding to OCR's guidance.*)

OCR's updated guidance only made matters worse for covered entities, says **Jeremy Mathis**, vice president of client success with Fathom, a digital marketing agency based in Cleveland, OH, that works with health systems across the country, and former communications and social media strategist at University Hospitals in Cleveland.

"The OCR's update sought to 'increase clarity for regulated entities and the public' but did nothing of the sort," he says. "If anything, the update further muddied the waters by failing to provide practical guidance."

The examples shared require a healthcare system to discern an individual's motivations for visiting a web page, and that's just not realistic, he says. "If a student is visiting your website to inform research, you can track. If a patient is visiting your website for a second opinion on a procedure, you can't track," Mathis says. "The trouble is, it's the same website for both visitors. And creating that truly individual and tailored, visitor-specific experience would require systems to invest resources that, frankly, are better allocated to delivering patient care."

Mathis recommends the most conservative approach: HIPAA-covered entities should not use tracking on their websites unless they've signed a BAA with the platform. That's been his firm's recommendation to clients since 2022, and that will continue to be their recommendation until court cases are settled and actual clarity is available, he says. "This, of course, limits the toolset health systems have available to reach, engage, and measure. No Google Analytics 4 tracking, no Meta pixel. They won't sign a BAA," Mathis says. "There is a host of tools that just aren't available for this specific group right now. As a result, systems and their partners have invested a significant amount of time and resources to pivot strategies and ensure the needs of their communities continue to be met." ■

SOURCES

- Erin Dunlap, JD, Coppersmith Brockelman, Phoenix. Telephone: (314) 255-5988. Email: edunlap@cblawyers.com.
- Angela Matney, JD, Reed Smith, Washington, DC. Telephone: (202) 414-9343. Email: amatney@reedsmith.com.
- Jeremy Mathis, Vice President of Client Success, Fathom, Cleveland, OH. Telephone: (216) 369-2220.
- Kristen Rosati, JD, Coppersmith Brockelman, Phoenix. Telephone: (602) 381-5464. Email: krosati@cblawyers.com.

Steps to Take in Response to OCR Guidance on Online Tracking

The Office of Civil Rights' (OCR's) updated guidance on HIPAA and online tracking technologies leaves many questions, but covered entities should take certain steps now. **Kristen Rosati**, JD, and **Erin Dunlap**, JD, attorneys with the law firm of Coppersmith Brockelman in Phoenix jointly offer these recommendations for HIPAA-covered entities:

• Take a deep breath. Most HIPAA-regulated entities and other organizations that handle health information are dealing with this issue. Your challenges are shared by many others, so solutions will be found.

• Initiate an internal investigation — under attorney-client privilege — to determine what online tracking your organization uses on its websites and apps. The investigation should determine precisely what data are being sent to what online tracking vendor.

• Get HIPAA business associate agreements in place with any online tracking vendors that are obtaining protected health information (PHI).

• If your organization is (or was) sending PHI to online tracking vendors without a HIPAA business associate agreement in place, conduct a HIPAA breach reporting risk analysis and document whether there is a reporting obligation under HIPAA.

• If your organization is subject to the Federal Trade Commission's (FTC's) Health Breach Notification Rule at 16 C.F.R. Part 318, determine whether there is a reporting obligation under that rule.

• If your organization is subject to a state breach notification law, evaluate whether there is a reporting obligation under that law.

• If the current use of online tracking is not consistent with the law, develop a detailed work plan to remediate such use. Consider the use of a customer data platform vendor that de-identifies data before sending it to online tracking vendors, but do a close examination of the services to make sure it is the right fit before engaging the vendor.

• Develop an internal policy on the use of online tracking. It will help in an OCR, FTC, or state attorney general investigation to demonstrate that your organization is taking steps to address the use of online tracking systematically.

• Make sure you understand the current privacy law landscape, including what laws apply to your organization, in responding to questions from your cyber liability insurer. Cybersecurity insurers also may want to know if you have had the use of online tracking technology reviewed by an attorney. In responding, do not explain the actual advice provided, or you may waive attorney-client privilege.

• Keep an eye out for developments, particularly what happens in response to the American Hospital Association lawsuit in the next few months. The courts may eventually require OCR to undertake a formal rule-making process to conform to the Administrative Procedures Act. ■

OCR Investigates Change Healthcare After Major Cyber Incident

In an unusual move signifying the severity of the huge cyberattack on Change Healthcare, a unit of UnitedHealth Group breach, the Office of Civil Rights (OCR) is formally investigating the incident. The cyberattack is one of the largest ever against the U.S. healthcare system, disrupting healthcare services and billing across the country.

(OCR's "Dear Colleague" letter announcing the investigation is available online at https://bit.ly/3WAcXV0. United Health Group's update on the attack is available online at https://bit.ly/3JPCkuM.)

The wide impact of the attack and the seemingly slow response of Change Healthcare apparently prompted the OCR investigation, says **John F. Howard**, JD, senior attorney with the Clark Hill law firm in Scottsdale, AZ.

"What I think is pretty telling is how long it took them to respond and recover, which is essentially, I think, what also got OCR's attention. This is shutting everybody down, and it took them two weeks to get fixes in place that would allow the health system in which they are a huge player to start to function again," he says. "So that's a huge red flag."

Being able to recover from any known vulnerability or potential attack is required under the rule, Howard says, which means having plans in place and testing them to make sure that you are able to implement them effectively.

"Everything we're seeing coming from Change Healthcare screams that didn't occur," he says. "It really comes to call the need for everyone to take a good look at their third-party risk management programs and make sure that they're actually doing due diligence, not just kind of checking the box."

Wake-up Call for Covered Entities

OCR investigating Change Healthcare compliance with HIPAA should be a wake-up call to healthcare companies of all sizes, says **Nicholas Kathmann**, chief information security officer at LogicGate, a governance, risk, and compliance solutions provider based in Chicago. Due to complex systems and interdependencies, whether you work in a regional health center or at a national chain, healthcare entities are a juicy target for bad actors, he says.

"Security within healthcare is a complicated problem. You have to balance speed and ease of use with security, as forcing an anesthesiologist to log in with a hardware token when a patient is redlining would be the exact antithesis of the mission of providing expert medical care," he says. "The focus should be on how to limit cybersecurity incidents' impact as much as possible."

OCR's "Dear Colleague" letter and the impending investigation hopefully will bring awareness to the importance of cybersecurity practices, specifically the ramifications of not having a mature and thorough program, he says.

Kathmann offers these tips for healthcare cybersecurity:

• Focus on resilience. Map out all critical functions, such as payment cycle management in the Change

Healthcare example, and perform risk assessments on each component, process, and dependency.

• Do not just assess the risk of the third party, but of the operational risk if/when there is an incident with that component (be it third-party or internally managed).

• Build out separately distinct and segregated solutions to have options and redundancy for critical processes and assess their ability to scale rapidly should you have to switch 100% to one due to another being down.

• Build a strong security architecture team and enable them. Everyone builds trust boundaries to protect the inside from the internet, but cybersecurity professionals also should focus heavily on protecting internal systems from users (and vice versa), as well as internal systems from each other. For example, a compromise of the application delivery subsystem for Epic should not be able to talk to or even network to the Cerner system in another facility.

"There's no reason your ITSM (information technology service management) system and end node management solution need to talk to the Epic cache systems," he says. "Build multiple boundaries a malicious actor needs to traverse to limit the 'blast radius' of an incident to the smallest form factor possible."

• Focus on the basics. "All too often in security, we're distracted by the new shiny vendor object or feature and let the basics fall to the wayside. Vulnerability management, application security, supply chain, incident response, security operations center detection, threat hunting, risk management, controls management, identity management: these are all things that aren't the most exciting areas of cybersecurity, but are easily the most important," Kathmann says.

• Foster a culture of security within your organization. Build a culture where people feel safe to bring up security weaknesses and have safety in fessing up to infractions. If the culture is always to pin the remediation on the reporter or chastise a staff member for reporting an incident they may have allowed to happen, employees hide their mistakes. The longer they lie in the shadows, the longer bad actors have to find and exploit them or maintain a foothold.

• Understand that governance, risk, and compliance — especially security — is a team sport. Build a great team and clearly define roles and responsibilities across teams and departments. All too often, there is a tendency for operations teams to look at all security initiatives as "that's the security team's responsibility."

"Good operations is good security, and the security team is a tiny fraction of the larger operations/applications team," Kathmann says. "Just like the neighborhood watch doesn't show up to your house to lock your door when you leave for work, security isn't going to show up to make sure you configured that server with the proper hardening protocols or didn't forget to add the authorization decorator on that new function you just wrote. Clear lines of communication reduce disagreements and missed steps — which all too often lead to security incidents." ■

SOURCES

- John F. Howard, JD, Senior Attorney, Clark Hill, Scottsdale, AZ. Telephone: (480) 684-1133. Email: jfhoward@clarkhill.com.
- Nicholas Kathmann, Chief Information Security Officer, LogicGate, Chicaco. Telephone: (312) 279-2775.