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Nursing Homes Face Serious Liability Risks from COVID-19

Nursing homes and affiliated health systems may face an onslaught of lawsuits alleging they failed to properly care for residents during the COVID-19 pandemic. Limited resources and the vulnerability of nursing home residents led to many deaths in nursing homes, and families will question whether those deaths could have been prevented.

Nursing homes are especially susceptible to COVID-19 lawsuits because their residents are particularly vulnerable to the virus, says **Kelli L. Sullivan**, JD, shareholder with Turner Padget in Columbia, SC. More virus-related deaths means more potential for lawsuits, regardless of how the nursing home performed, she says.

> NURSING HOMES ARE PARTICULARLY VULNERABLE TO COVID-19 LAWSUITS BECAUSE THEIR RESIDENTS ARE ESPECIALLY SUSCEPTIBLE TO THE VIRUS.

Families will allege the nursing home did not adequately care for the resident once he or she contracted COVID-19. They also will claim the nursing home did not prevent the spread of the virus in the facility, Sullivan says. But she has seen a lawsuit in which the family claims the nursing home did not adequately communicate with families about the presence of the virus.

"They're saying the nursing home didn't communicate and give them the opportunity to bring grandma home. That's a little bit of a twist on the regular negligence case you might see," Sullivan says. "I think you also may see some negligence suits in which they claim the facility was short-staffed because of the coronavirus. They will say 'You had staff out because of the virus, and so you short-staffed

Financial Disclosure: Author **Greg Freeman**, Editor **Jill Drachenberg**, Editor **Jonathan Springston**, Editorial Group Manager **Leslie Coplin**, Accreditations Director **Amy Johnson, MSN, RN, CPN**, and Nurse Planner **Maureen Archambault** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. Consulting Editor **Arnold Mackles**, MD, MBA, LHRM, discloses that he is an author and advisory board member for The Sullivan Group and that he is owner, stockholder, presenter, author, and consultant for Innovative Healthcare Compliance Group.

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EDITORIAL QUESTIONS
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and I fell,' or 'I wasn't turned often enough and I got bedsores,' or 'My medication wasn't given to me in a timely fashion.'"

Sullivan also anticipates workers' compensation lawsuits from employees who were exposed to the virus in nursing homes, and lawsuits from families for refunds of services not provided during the pandemic, such as outings or hair and cosmetic treatments, she says.

An uphill battle is ahead if plaintiffs simply allege the nursing home is responsible for the resident contracting COVID-19 and dying, Sullivan says.

"The standard is what a reasonable facility would do in the same or similar circumstances. We're going to look at the CDC guidelines and show that we did everything suggested there or show why it was not possible to do that," she says. "It's going to be a tough nut for them to crack if they're saying the resident got the virus and died; therefore it's your fault."

Sullivan cautions there is continued danger as states loosen stay-at-home orders and nursing homes are encouraged to allow more visitation. Acting too quickly could prompt lawsuits alleging a resident contracted the virus because the facility exposed residents more than necessary, she says.

"That's where facilities are going to have to be very careful and err on the side of caution. When it comes to visitors or letting ancillary services back into the facility, I'd urge nursing homes to be very cautious over the next several months as other things start to open up," Sullivan says. "Juries are going to be much more sympathetic to a facility that had something bad happen in the beginning of all this, when we were in thick of it and everyone was still trying to figure it out and cope, vs. a grandma who gets coronavirus in June or July, when you should have known better."

It will be critical for nursing homes to show they followed guidelines specific to their industry from the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS), says **Samuel D. Hodge, Jr.**, JD, professor of legal studies in business at Temple University in Philadelphia. Guidelines include assessing the supply of personal protective equipment (PPE) and initiating measures to optimize that supply. Hodge says there is a risk of liability there for nursing homes.

"Because of the shortage of PPE, not all nursing homes had enough equipment, and that is going to be an area of liability based on the CDC saying you have to have that," Hodge says. "Similarly, the CDC says nursing homes must implement

EXECUTIVE SUMMARY

Nursing homes are at risk for liability related to the COVID-19 pandemic. The high number of deaths in nursing homes may prompt lawsuits.

- Some states are immunizing nursing homes against such lawsuits.
- The standard of care during the pandemic will be a key issue.
- Documentation of a nursing home's response and limited resources may determine the outcome of lawsuits.

controls for anyone entering a healthcare facility, regardless of symptoms. If I file a lawsuit, one of the first things I'm going to ask for is rules and regulations a nursing home put in place to minimize transmission of coronavirus. If you don't have those, that is going to be a degree of negligence."

Some States Offer Protection

One of the most hotly disputed issues is whether states should immunize nursing homes and their employees against COVID-19-related claims, says **Erin M. Eiselein**, JD, shareholder with Brownstein Hyatt Farber Schreck in Denver.

"There is a balance between immunizing nursing homes and their employees who are providing the best care they can under awful circumstances, such as not having PPE or access to tests, against removing the risk of liability to ensure the organizations caring for this fragile population remain accountable," she says. "So far, more than a dozen states have laws or orders providing some type of liability for nursing homes and their employees."

Nursing homes should expect increased state public health oversight especially around infection control issues, Eiselein says. In terms of civil liability, she expects to see employees suing employers for creating an unsafe work environment when employees were working without PPE, with colleagues and residents who had not been tested, and in some circumstances with severe staffing shortages.

Workers' compensation laws often provide the sole remedy to employees regarding injuries occurring on the job, she notes. Whether the dire working conditions created by COVID-19 rise to the level of creating an exception to the exclusivity rule remains to be seen, she says.

"Plaintiffs' lawyers undoubtedly are busy preparing lawsuits on behalf of residents and their family members against nursing homes for abusive and neglectful practices during COVID-19. To succeed on such a claim, the plaintiff will have to demonstrate the nursing home fell below the applicable standard of care," she says. "We do not yet know what standard of care will be applied to care given during this pandemic, but you can be sure that attorneys for the nursing homes will be arguing that the standard of care should be significantly lower than it would have been pre-pandemic."

Eiselein also anticipates an increase in whistleblower cases under the federal False Claims Act. Amid the chaos of the pandemic and the rapidly changing laws, nursing homes that have failed to ensure accurate oversight of eligibility and billing practices could find themselves facing significant liability for fraudulent behavior, she says.

"Beware of disgruntled or terminated employees with an axe to grind against the company," she says. "Even if they ultimately do not succeed on liability, these cases are time-consuming and expensive to defend."

Understand Changing Laws

Nursing homes should be vigilant about staying abreast of the ever-changing law and guidance surrounding caring for their residents and protecting their employees, Eiselein says. Many industry trade organizations are leading the efforts to compile the overwhelming amount of information and share the relevant portions with their members, she notes.

Real-time documentation of challenges and solutions will help demonstrate the organization acted in good faith to do the best it could under the circumstances, she says. If the organization could not obtain PPE, document the steps taken to secure PPE and precautions taken in the interim. If the organization was forced by the state to accept a resident who had not been tested for COVID-19 and did not have access to tests, make detailed notes of everything done to isolate the patient and keep the other residents and staff safe, Eiselein explains.

"Make sure there are robust policies and procedures in place regarding residents, family members, and employees," she says. "Think about health questionnaires, temperature screening, testing, continued use of telehealth, protective equipment, physical separation, continued limits on group activities, and the like."

CMS Rules Apply

Although most nursing homes already put CMS-mandated infection control protocols in place before the nationwide spread of COVID-19, nursing homes remain under constant pressure to implement the rapidly evolving and increasingly detailed protocols issued by the CDC and CMS, notes **Barbara R. Schabert**, JD, attorney with Kaufman Dolowich Voluck in Fort Lauderdale, FL.

Recently, CMS issued updated rules and standards for health

inspectors who are inspecting thousands of CMS-participating facilities. CMS directives focus on monitoring a nursing home's pandemic plan with an emphasis on the effectiveness of the facility's infection control policies and procedures.

These stricter inspection standards already have led to civil monetary penalties for nursing homes' failure to comply with infection control protocols, she says. Additionally, certain nursing homes have faced losing their Medicaid certification based on a lack of pandemic control efforts.

"First and foremost, nursing homes should maintain complete documentation as to all infection control policies and procedures, staff training on such procedures, efforts to adhere to such procedures, and records as to the necessary updates to such procedures," Schabert says. "In addition, nursing homes should document their implementation of, and efforts to comply with, all updated CDC and CMS guidelines and regulations. Overall, the nursing home should maintain sufficient documentation demonstrating the nursing homes' efforts in protecting staff and residents from COVID-19."

Such documentation should include:

- Policies and procedures followed for investigating, controlling, and preventing the spread of COVID-19;
- Infection control precautions such as hand hygiene, disinfection, and isolation of sick residents;
- Staff education on infection control protocols;
- Monitoring staff compliance with infection control protocols;
- Identifying signs of infection in residents and staff and related isolation protocols;
- Notifying state and local health departments, as well as CMS, of the extent of COVID-19 cases within the facilities.

States Offer Immunity

The high potential for COVID-19-related lawsuits has led numerous states to call for executive orders or legislation to provide immunity for healthcare facilities, including nursing homes, Schabert says. Currently, 15 states have enacted laws or issued executive orders providing nursing homes protections from lawsuits arising from the crisis.

In Florida, the governor is reviewing a request for immunity from liability under certain conditions for nursing homes submitted by the Florida Healthcare Association, Schabert says.

"In response to such immunity orders, resident advocates have voiced concerns and raised challenges as to the effectiveness such orders will have in eliminating causes of action. However, movants for the immunity orders illustrate the ways in which such orders acknowledge the conditions nursing homes have been forced to navigate during COVID-19, including staff shortages and a lack of personal protective equipment," she explains. "Generally, the currently issued immunity orders grant immunity to nursing homes providing care during the COVID-19 pandemic, in good faith, during the COVID-19 state of emergency. The immunity orders also do not appear to provide immunity to nursing homes for acts or omissions occurring prior to the COVID-19 pandemic."

The immunity orders would apply to negligence actions but would not provide immunity for cases of gross negligence, extreme neglect, or willful misconduct, Schabert says.

"Ultimately, the COVID-19 pandemic has created a unique setting for an inevitable increase in civil lawsuits related to deaths and alleged healthcare failures of nursing homes during the pandemic despite any such immunity orders. Nursing homes will likely see COVID-19-related lawsuits that involve wrongful death and negligence," she says. "However, given the unprecedented and extraordinary nature of these expected pandemic-related lawsuits, it should be expected that the debated issues will involve the standard of care and what establishes negligence during a pandemic."

The courts likely will examine the updated guidelines, protocols, and regulations of nursing homes issued by federal, state, and local agencies in response to COVID-19. In anticipation of the forthcoming pandemic lawsuits the nursing home industry is facing, Schabert says it is imperative that facilities apply all feasible precautions — and document them well — to limit any potential liability exposure. ■

SOURCES

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Limited Protection from COVID-19 Liability Available in Some States

Healthcare organizations facing potential liability related to COVID-19 may have some protection available on state and federal levels.

State protections vary, but one example is New York, which recently passed legislation that provides healthcare providers and facilities with immunity against potential lawsuits related to COVID-19, says **Kara White**, senior claims consultant with the Graham Company in Philadelphia.

Such legislation likely will apply to civil cases, in which patients or their families sue hospitals or other healthcare facilities that provided care for COVID-19, she says. Other states have enacted or are considering similar measures, but risk managers should confer with general counsel in their particular state to confirm how this type of legislation may apply, White suggests.

The state-specific immunity legislation passed in New York offers protection against both civil and criminal liability but does not apply to willful or intentional conduct or gross negligence. These types of allegations often are raised in professional liability claims. However, in New York, the statute makes clear these immunity exceptions do not apply to decisions resulting from a shortage of resources or staffing.

"As a result of the immunity granted to healthcare providers, I anticipate that any potential lawsuits brought against them as it relates to COVID-19 care will attempt to circumvent the legislation by alleging conduct that does not fall within the purview of the immunity," she says.

IN NEW YORK, THE STATUTE MAKES CLEAR THESE IMMUNITY EXCEPTIONS DO NOT APPLY TO DECISIONS RESULTING FROM A SHORTAGE OF RESOURCES OR STAFFING.

While this type of legislation will not prevent anyone from filing a claim against a provider, it has been proposed or enacted in many states to assist organizations while they focus on other challenges, such as navigating extreme staffing and personal protective equipment (PPE) needs to handle critical patients.

"In this unprecedented situation, immunity is especially valuable because it gives providers the freedom to do what is best for patients while limiting fear of exposure to liability," she says. "This immunity can be triggered as a potential defense from professional liability claims, questioning decisions that healthcare providers are making as they treat patients amid the pandemic."

To best prepare and protect their organizations, White says risk managers should adhere to their established policies and procedures for executing tasks and keeping all parties safe. As long as the protocols implemented to handle the COVID-19 pandemic are applied consistently and risk managers continue to act in the best interest of patients or residents, this type of immunity legislation should help protect the organization, she says.

"Risk managers should also keep in mind the vital nature of documentation during this type of crisis. Even though the provider may have immunity for certain types of lawsuits, they may still be put in a position where they need to defend the decisions that were made under certain circumstances," she says. "Risk managers can streamline this process by keeping a thorough risk management log outlining actions like transferring staff from one unit to another and the thought process behind doing so. It also is key to note any training given to ensure those staff members are prepared for their new role is also key in this situation." ■

EXECUTIVE SUMMARY

Some states are limiting the liability of healthcare organizations related to COVID-19. The immunity is limited.

- Documentation is critical.
- Claims are possible but may be easier to defend.
- Immunity will not apply to gross negligence.

SOURCE

- **Kara White**, Senior Claims Consultant, Graham Company, Philadelphia. Email: kwhite@grahamco.com.

Review Insurance Policies for Benefits to Help with COVID-19 Costs

Professional liability insurance can help mitigate costs and shore up funding gaps for the cost of operating during the current crisis, says **Margaret Karnick**, senior underwriter with Burns & Wilcox in Chicago.

Professional liability insurance is designed to pay for damages and legal defense, up to the policy limit, should a named insured be found liable for a covered claim. But healthcare facilities should review their professional and general liability policies for a communicable disease exclusion, Karnick says.

Many carriers are adding communicable disease- or COVID-19-specific exclusion endorsements. Sometimes, this exclusion language is baked into their policy form, she says.

An evacuation expense endorsement can help mitigate costs of transportation, lodging, and food associated with evacuating community members, Karnick notes. If a professional liability insurance policy includes an evacuation expense endorsement, it may provide reimbursement for a covered evacuation.

Incurring expenses associated with fleeing a disaster can be considered reasonable and necessary. These expenses could include lodging, transportation, housing, food, and providing general care to patients and residents during an emergency or at an alternative location, she says.

"Healthcare residential facilities should review their professional liability and general liability policies to see if they have evacuation expense coverage," Karnick says. "The coverage trigger is often subject to a certain percentage of the named insured's patients and residents needing to be evacuated. Reimbursement is often a sublimit in addition to and outside the standard policy limits of liability."

Another option is a crisis management expense endorsement, which can assist with the expense of crisis-related communications and developing crisis procedures. Similar to the evacuation expense, crisis management expense reimbursement often is a sublimit in addition to and outside the standard policy limits of liability, Karnick explains.

A crisis often is defined as a public announcement that an incident has occurred on the named insured's premises or at an event sponsored by the insured. Crisis management emergency response expenses are incurred by the insured for services provided by a firm to respond to such a crisis.

"Evacuation expense and crisis management expense reimbursements could be great assets to healthcare insureds," Karnick says. "Any potential coverage will depend on the policy language and specific allegations of a claim when submitted. It would be highly beneficial to review your professional liability policy with your broker."

Best practices in risk mitigation require thorough risk management protocols, Karnick says. These include hiring the right people and completing thorough background checks on all employees, creating formal policies and procedures, and properly training employees. Every healthcare facility should be training its employees on infection prevention, fall prevention, abuse prevention, medication safety, and the Health Insurance Portability and Accountability Act, including device and social media use policies, Karnick advises.

"With the current global COVID-19 pandemic, it has never been more important to make certain that your facility has clear written risk management policies and procedures, and that you are adhering to the CMS [Centers for Medicare & Medicaid Services], CDC [Centers for Disease Control and Prevention], and DPH [department of public health] guidelines and protocols," she says. "Many carriers are requiring COVID-19 supplements to be completed with their professional liability application submission and asking about the insured's infection prevention and infection response policies and procedures." ■

EXECUTIVE SUMMARY

Insurance policies may include features that can produce unexpected costs from COVID-19. But policies may exclude communicable diseases.

- Some policies will cover evacuation costs.
- Crisis management expenses might be reimbursed.
- Carefully review policies for exclusions and benefits.

SOURCE

- Margaret Karnick, Senior Underwriter, Burns & Wilcox, Chicago. Phone: (248) 932-9000.

Handle Whistleblower Complaints with Care

At the height of the healthcare industry's response to COVID-19, some hospital employees gained national attention for their criticism of the lack of personal protective equipment (PPE) and supposed failings by their employers. Some employers appeared to retaliate against those whistleblowers, raising questions about how such complaints should be handled.

Whistleblowers are afforded many legal protections under federal and state laws, says **Tricia Fratto**, JD, co-founder and chief counsel at Ethics Suite, a company in Scottsdale, AZ, that manages misconduct reporting, including whistleblower and misconduct-related investigations.

Most relevant to COVID-19 are the anti-retaliation protections offered to those reporting unsafe working conditions under the Occupational Safety and Health Administration (OSHA) Whistleblower Protection Program, she explains. OSHA's program enforces the provisions of more than 20 federal protection laws and allows employees to submit complaints directly. In some cases, an enforcement action will follow a complaint.

"Every organization should have internal reporting channels and policies, ideally allowing for anonymous reports," Fratto says. "Internal anti-retaliation policies that prohibit retaliation against an employee for submitting a good-faith report of internal misconduct or other concerns, such as failure to follow safety regulations, also are critical."

If a report is received internally, an employer can and should respond to the whistleblower, tell them their concern is taken seriously, and the employer will take any action it determines is necessary, Fratto advises. Then, the employer should plan and conduct a complete and impartial investigation to determine the appropriate and available steps.

"There are many things that an organization should not do as a matter of best practice — for example, fail to respond or investigate — but what it cannot do under any circumstances is retaliate against an employee for making a good-faith report," she says. "Always keep in mind that when we discuss employment action, it is not just terminating employment. This also can include a change to a less desirable role or schedule, negative performance reviews, being verbally abusive, or threatening other negative consequences, for example."

Any affirmative steps an employer takes to silence a whistleblower likely are a violation of state and or federal law, Fratto says. Ignoring a whistleblower also may violate the law, depending on the circumstances, but certainly will have extremely negative consequences to an organization.

It will have a chilling effect on internal reports because employees will not trust the employer to respond to their concerns, she explains. This is extremely perilous in general, but particularly so with OSHA-related reports where life and safety are at risk. With no other options, employees will report directly to regulators, Fratto says. Instead of fixing the problems internally, an employer will be exposed to regulatory action, fines and penalties, and other attendant costs.

"Foster an environment where internal reports are encouraged and valued. If a report is received and the steps to respond are not clear, or the employer cannot respond appropriately because of a lack of resources or equipment, seek guidance from outside counsel or a regulator," Fratto advises. "For the health of an organization and for its ability to continue to focus on providing services instead of the disruption that can come from having to respond to a regulator, this is the best option."

In some cases, regulatory scrutiny is unavoidable despite best efforts and, in those cases, an employer should fully cooperate and seek guidance from counsel, she says. When dealing with regulators relating to PPE and other workplace conditions related to COVID-19, employers should know that OSHA recognizes the unique challenges related to the pandemic, she says. OSHA has provided for more flexibility in enforcement and has

EXECUTIVE SUMMARY

Whistleblowers have complained publicly about the lack of adequate personal protective equipment during the COVID-19 response. These cases show the need for handling whistleblowers properly.

- Whistleblowers are afforded legal protection in several ways.
- The public relations cost of appearing to punish a whistleblower may be severe.
- Employees should have a clear way to report concerns without retaliation.

issued temporary guidance in many areas designed to address these challenges.

Handle Whistleblowers Carefully

Every whistleblower should be handled with kid gloves, regardless of the merit of their complaints, says **Peter Cassat**, JD, partner with Culhane Meadows in Washington, DC.

Employers are entitled to act when an employee's actions are disruptive to the workplace, and when their actions prevent them from fulfilling their duties, Cassat says. But doing so requires a delicate touch, emphasizing that you are responding because of those concerns and not because you disagree with the employee's opinion, he says.

"When it comes to someone speaking out about a lack of PPE during a pandemic, it's easy to look like you are retaliating against the employee for revealing your shortcomings to the public, punishing him or her because they made the organization look bad," Cassat says. "You may actually be on firm grounds for disciplining this person because they are disruptive or in violation of some legitimate policy, but you can be the one who looks bad in the public eye. A lot of this is more about public relations than employment law."

Employees who raise occupational safety or health concerns in good faith, either with OSHA or internally with a representative of the individual's employer, such as a supervisor, human resources representative, or occupational health specialist, enjoy protection from retaliation under Section 11(c) of the Occupational Safety and Health Act of 1970, notes **Robert S. Nichols**, JD, partner with Bracewell in Houston.

An employee who believes he or she has been subject to retaliation must file a complaint with OSHA within 30 days of any adverse action against the employee for raising the safety or health concern. If OSHA finds merit, the government will generally pursue legal action against the employer under Section 11(c) seeking to reverse the wrongful action and to obtain an appropriate damage recovery for the employee, Nichols says.

A second important federal law is the National Labor Relations Act (NLRA). In addition to encouraging and regulating the formation of unions, that law protects most nonsupervisory private sector employees, in both union and nonunion workplaces, who work together to improve terms and conditions of employment. One or more nonsupervisory healthcare employees can engage in this kind of protected, concerted activity under the NLRA by raising, among other issues, concerns about employee health or safety related to PPE or other COVID-19 workplace concerns, he says.

"An employee can file a complaint with the National Labor Relations Board if the employee suffers some adverse action for speaking out about some workplace condition, and the board will investigate. If the board finds merit, it will pursue administrative action against the employer to force corrective action," Nichols says. "Many states, including New York, Texas, and California, have laws that specifically protect hospital and other healthcare workers against retaliation for raising good-faith, healthcare-related health or safety concerns."

Conduct in which employees cannot engage includes acting in bad faith, such as making maliciously false factual claims or improperly disclosing individual patient information. Additionally, employees cannot engage in, or threaten, violent conduct, Nichols says.

All Parties Should Remain Professional

Employees cannot unfairly disparage services or products provided by their employer, he says.

"Employee complaints about PPE or other safety or health concerns should be presented in a professional manner, but those concerns definitely can be raised whether the employer wants to hear those complaints or not," Nichols says.

If an employer is found to have unfairly tried to silence a whistleblower, the employer could be ordered to reverse some adverse action against a whistleblower, like discharge or demotion, and may have to pay damages, Nichols says. Additionally, and sometimes even worse, the healthcare employer can face adverse publicity that damages both the organization's public relations and employee relations, he notes.

"Employers should make it clear to employees that the organization welcomes employees raising any concerns about health and safety. Employers should provide multiple alternative avenues for employees to raise concerns, including hotline numbers, grievance procedures, and open-door policies," Nichols says. "Further, employers should understand if employees raise concerns not using one of these available complaint procedures, their conduct is still likely protected. Employers should never react

negatively to complaints about health or safety, even if the employer regards the complaint as lacking merit."

Show Compliance When Questioned

The majority of employee concerns should be addressed head-on by complying with OSHA requirements and other obligations, says **Todd A. Bromberg**, JD, partner with Wiley in Washington, DC. That goes to the heart of whether an employee shows a good-faith basis for his or her complaints.

"Disciplining an employee for speaking out is generally counterproductive both from a PR perspective and in opening up the possibility of claims against the employer for retaliation," he says. "The better course is to showcase the employer's commitment and efforts to protect the health of its workforce."

There is not a one-size-fits-all approach to understanding what employers can and cannot do in response to whistleblowers, says **Olaoluwaposi O. Oshinowo**, JD, special counsel with Wiley in Washington, DC.

"Even during a pandemic, employers retain the right to make decisions, including disciplinary decisions, they believe are in the best interests of maintaining the orderly operations of their business," he says. "There is a delicate balance between exercising that right and complying with relevant law, and it is best to analyze each situation based on the facts in front of you and your conversations with counsel."

Beyond the publicity concerns inherent to the current climate, employers face significant potential legal liability for violating the anti-retaliation laws, he says.

"For example, employers who violate the Occupational Safety and Health Act must deal with the workplace interruption created by an OSHA investigation, and they may also be liable for back pay and benefits, compensatory and punitive damages, and fees and costs," Oshinowo says. "OSHA also may impose civil penalties — ranging from about $10,000 to $135,000 — against employers who it finds to have willfully or repeatedly failed to comply with OSHA standards or correct violations. Violations that lead to the death of an employee can even be subject to criminal penalties."

THE MAJORITY OF EMPLOYEE CONCERNS SHOULD BE ADDRESSED HEAD-ON BY COMPLYING WITH OSHA REQUIREMENTS AND OTHER OBLIGATIONS.

Bromberg says that although COVID-19 is an unprecedented situation that has created numerous difficult questions and issues for employers and employees alike, it does not mean the best practices for emerging intact are complicated. Employers should listen and take employee concerns seriously, clearly communicate about their decisions and the basis for them, and document their efforts to address issues that arise, he says.

"Open lines of communication and transparency are the keys to limiting the severity of employee dissatisfaction and the legal risks that arise when employees feel they have no resort but to turn to channels outside of the organization to address issues," he says. "To the extent an employee's actions are disruptive and unreasonable, the golden rule is that any discipline must be consistent with the employer's policies, precedent, and a general sense of fairness."

Whistleblowers may proclaim their statements are protected by the First Amendment, but those protections only extend to prevent government retaliation for exercising free speech rights, explains **Autumn L. Moore**, JD, senior attorney with Clark Hill in Los Angeles. However, that does not mean private employers are completely off the hook.

Although employees cannot reveal such things as confidential information or personally identifying information, if employees are making complaints about working conditions possibly violating federal, state, or local laws, then the legality will depend on the content and type of employer, she says.

For example, California employers should proceed with extreme caution before disciplining employees for protesting working conditions, she says. These types of protests and/or public complaints may constitute protected activity under Labor Code section 1102.5, in addition to other similar laws. California's whistleblower laws prohibit an employer from retaliating against employees for refusing to participate in an activity that would result in a violation of or noncompliance with a local, state, or federal rule or regulation.

"The law also prohibits employers from preventing employees from disclosing information to a government or law enforcement

agency, to a person with authority over the employee, or to another employee who has authority to investigate, discover, or correct the violation or noncompliance, or from providing information to, or testifying before, any public body," she says. "The employee must have reasonable cause to believe that the information discloses a violation of state or federal statute, or a violation of or noncompliance with a local, state, or federal law." ■

SOURCES

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Online Privacy Threats Increasing with More Internet Use

Scammers are using the COVID-19 pandemic as cover for increased online threats to patient privacy. Covered entities and business associates should pay more attention to the technological threats that could lead to a Health Insurance Portability and Accountability Act (HIPAA) breach.

There is a higher risk of online threats to privacy while the healthcare industry responds to COVID-19, says **Gonzalo Raposo**, technology manager at Globant, a digital security consulting company in San Diego.

"Due to the nature of this virus, providers and professionals, in general, are relying more on technology in order to keep their businesses running. For many of them, this will be a new experience with an associated learning curve, which can be used as a target for online threats," he says. "Unfortunately, we've already seen popular conferencing applications suffer from online threats and be banned by some companies as a tool for their internal communication, as a way of preventing a security breach."

There is another threat that can be exploited and is related to geolocation information collected from mobile devices, Raposo says. Information about people's location can be shared and distributed without explicit consent to obtain precise information for epidemiological models that could help make better decisions around resources, social distancing, mandatory quarantine, and related concerns.

"In the rush of having solutions implemented in record time, mistakes can be made and security holes can be found that can lead to accessing private information," he says. "An example of that kind of threat may arise from the recent collaboration project that two major mobile companies just announced. Aiming to help to minimize contagions and keep infected or exposed people isolated, they are creating a solution to automatically — without user consent — interchange private information through Bluetooth technology to be notified when the person has been physically exposed to someone who has been tested positive for the virus."

EXECUTIVE SUMMARY

Online threats to patient privacy are increasing as healthcare organizations rely more on technology to interact with patients. Scammers are looking for new opportunities.

- The learning curve for using new technology creates opportunities for hackers.
- Increased use of geolocation services also creates a risk.
- Risk managers should remind employees of best practices for online security.

Alert Employees to Risk

Risk managers should remind employees that malicious actors are using this pandemic as an

opportunity to exploit people and systems, says **Madeline H. Gitomer**, JD, senior associate with Hogan Lovells in Washington, DC. Covered entities should remain vigilant in identifying these types of attacks and educate their workforce to ensure they are aware of the most common types of attacks, she says.

In addition, as covered entities approach the provision of care in new ways, they should continue to evaluate the privacy and security practices of their vendors and appropriately train their employees on how to use new technologies and services.

"Covered entities are facing two related challenges: being strapped for resources and providing care in new ways. We've heard from covered entities that privacy- and security-focused professionals are overextended as they address emerging threats and serve in additional roles during the pandemic," she says. "Other covered entities are conducting business remotely, which introduces new challenges."

Many covered entities are being asked to share information in ways they have not shared before, such as for public health oversight, she says.

"All of these changes can affect how a covered entity approaches HIPAA compliance," she says. "This may mean putting in place new processes to account for these new practices."

Any time the internet is used, the risk of threats to patient privacy is increased, says **Gevik Nalbandian**, vice president of software engineering with NextGate, a technology consulting company in Monrovia, CA. There is no doubt that healthcare organizations are using the internet more.

"These risks can be mitigated and in many cases eliminated if the appropriate tools and procedures are used. In certain cases, covered entities may have to educate their patients on safe internet use practices," he says. "Allowing doctors and physicians to use widely available and often free software to conduct virtual visits reveals just how ill-founded the restrictions are and vastly expands the number of practices that can incorporate telemedicine." ■

SOURCES

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Department of Justice Halts Enforcement and Civil Penalties

The Executive Office for United States Attorneys (EOUSA) recently announced that because of the COVID-19 pandemic, the U.S. Department of Justice (DOJ) has temporarily halted enforcement actions and the collection of civil penalties. The original period ran through May 31 but DOJ said it may extend the period.

This includes the collection of civil penalties incurred in suits under the False Claims Act (FCA), notes **David J. Pivnick**, JD, partner with McGuireWoods in Chicago.

The EOUSA notices explained that U.S. attorney's offices will temporarily suspend enforcement activity on civil debt levied against healthcare providers for FCA violations, which can include billing for services not rendered or services not medically necessary.

U.S. attorneys were instructed not to pursue new enforcement actions, Pivnick explains. Healthcare organizations not making payments on civil penalties would not be considered in default. Interest may still accrue on civil debt, he says.

"There has been a little more flexibility from DOJ because of the COVID-19 pandemic to work with healthcare organizations on the timing of payments and settlements, in recognition of the fact that a lot of these hospitals and health systems are under tremendous strain right now financially, in addition to the rest of the challenges they're facing," Pivnick says. "We would not advise anyone to ignore their payment obligations because the obligation is not going to go away. It's a good opportunity to have some frank discussions with your contacts at the DOJ to see what arrangements might be worked out for extended payments." ■

SOURCE

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CME/CE QUESTIONS

1. **What is one type of COVID-19-related nursing home lawsuit that Kelli L. Sullivan, JD, anticipates?**

   a. Allegations related to short staffing caused by the virus
   b. Claims against individual staff members for transmitting the virus
   c. Allegations that the nursing home provided false information to public health authorities
   d. Claims that the presence of the virus in the nursing home automatically proves negligence

2. **What is one type of coverage that hospitals and other facilities might find available in their existing policies for use with COVID-19 expenses, according to Margaret Karnick?**

   a. Evacuation
   b. Public communication
   c. Public health data reporting
   d. Emergency staffing

3. **What does Tricia Fratto, JD, say likely is a violation of state and/or federal law?**

   a. Responding to a whistleblower by making a public statement
   b. Any affirmative steps an employer takes to silence a whistleblower
   c. Asking management to speak to the whistleblower about his or her concerns
   d. Documenting the whistleblower's complaint

4. **Why does Gonzalo Raposo say the online threat to patient privacy is increasing?**

   a. More patient records are digitized.
   b. The value of patient information on the black market is increasing.
   c. Some key technological safeguards have been bypassed recently.
   d. COVID-19 is prompting much more use of technology such as online conferencing and telemedicine.

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

Brain Damage Lawsuit Settles for $5 Million

*By **Damian D. Capozzola**, Esq.*
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***Elena N. Sandell**, JD*
UCLA School of Law, 2018

News: A child was born severely premature and suffered several medical conditions throughout her infancy, including severe respiratory problems. The child subsequently suffered a heart attack that led to significant loss of oxygen to her brain. The child lost the ability to walk, crawl, and carry out many normal life activities. A settlement of $5 million was reached in a medical malpractice suit.

Background: The patient, a child, was born premature at 23 weeks, weighing only approximately 1 pound. Her twin brother suffered extreme complications from premature childbirth and died three days after birth. The patient immediately required intensive neonatal care, and showed symptoms of morbidity consistent with those of a fetus born so prematurely. Specifically, the patient exhibited apnea and bradycardia, which were treated through caffeine medication; jaundice, which required phototherapy; and breathing difficulties, which required a ventilator to assist respiration for 52 days followed by 19 days on a continuous positive airway pressure machine. The patient was diagnosed with bronchopulmonary dysplasia.

BECAUSE OF THE PATIENT'S COMPOUNDING INJURIES AND SIGNIFICANT BRAIN INJURY, SHE COULD NOT WALK, CRAWL, OR CARRY OUT MANY NORMAL LIFE ACTIVITIES.

After five months of treatment, including a prolonged stay in the neonatal intensive care unit, the patient was discharged in December 2013. However, the patient was to remain on oxygen therapy for her chronic lung disease, including a pulse oximeter and apnea monitor. The patient was prescribed multiple medications, and her parents received assistance from a nurse and education on how to use the medical devices. The patient visited a pediatrician several times after discharge.

The patient's pediatrician visits included scheduled check-ups and emergency visits due to deteriorating health. During the first several months, the patient was successfully but slowly weaned off her supplemental oxygen requirement, but there were several events that indicated a deteriorating respiratory condition. The patient also developed frequent vomiting and difficulty feeding. In February 2014, the patient visited a pediatrician after an episode of increased coughing and wheezing. The patient was treated with inhaled albuterol and oral steroids. During subsequent visits, the patient's pulse oximetry seemed stable.

In April 2014, the patient developed a urinary tract infection that required antibiotics. Around the same time, the mother brought the child to the pediatrician for an illness visit due to coughing and wheezing that, according to the mother, had been ongoing for two days. The pediatrician noted abnormal lung sounds that improved following treatment with inhaled albuterol and suctioning. Her oxygen saturation was reportedly greater than 96%. No further testing was performed.

A few days after the visit, the patient was found choking and suffered a cardiopulmonary arrest, and was rushed to the hospital. During resuscitation, the patient suffered

a skull fracture that caused a brain bleed. This injury, combined with a hypoxic episode, worsened the patient's frail health. Because of the patient's compounding injuries and significant brain injury, she could not walk, crawl, or carry out many normal life activities.

The patient's mother filed a medical malpractice action against multiple individual physicians and the hospital where the patient was born. The complaint alleged the physicians, including the patient's pediatrician, failed to adequately and appropriately investigate the cause of the patient's coughing, particularly during the patient's most recent visit. Additionally, the plaintiff alleged that the physicians and hospital failed to insert a gastrostomy tube and perform a laparoscopic procedure, commonly known as a Nissen fundoplication.

The physician and hospital defendants initially denied liability. However, the parties eventually reached a settlement, and the defendants agreed to pay the plaintiff $5 million.

What this means to you: This case exemplifies the benefits of resolving medical malpractice litigation through negotiation and prior to an adverse verdict. There are many factors that can affect a mutual agreement between the parties and a settlement, but such efforts can be extremely beneficial to physicians and care providers to better control payment amounts in the event of liability and to reduce negative exposure and publicity.

In this case, the settlement was $5 million. While this is a substantial amount, a jury award could have been a lot worse. According to the physician expert reports, the six-year-old patient will never be able to walk, sit, talk, or eat by herself, and the injuries shortened her life expectancy. In addition, the patient will require continuous assistance throughout her life, as well as physical therapy and medical monitoring.

One likely reason for the reasonable settlement value in this case involved issues pertaining to causation, which is a necessary element for medical malpractice cases. Based on the patient's extremely premature birth, experts offered conflicting opinions as to the connection between the patient's injuries and the care provider's actions related to the patient's resuscitation and gastrointestinal issues. The defendants' experts opined that the extremely premature birth was the primary reason for her developmental delays. While the brain injury certainly created an additional setback, most of the conditions the child suffered were common among infants born before week 28 of gestation. Additionally, the defendants' pediatrician expert argued that after a careful review of all medical records, the patient's pediatrician acted within the accepted standard of care.

The patient argued that the defendant pediatrician breached the standard of care by failing to further investigate the child's cough and wheezing, as he only treated that with albuterol. Specifically, the plaintiff alleged the physician should have ordered X-rays, a repeat swallow test, and investigated the possibility of aspiration pneumonia, a complication of pulmonary aspiration that occurs when one inhales food or saliva into the lungs. The plaintiff also indicated that after the reports of continuous vomiting, the physician should have performed a Nissen fundoplication, a procedure that wraps the stomach around the lower part of the esophagus, and should have also inserted a gastrostomy tube. The plaintiff alleged these procedures would have prevented the patient from suffering the severe cardiopulmonary arrest and the brain injury that occurred during resuscitation.

Following the incident, the patient had to spend several months in the hospital and developed seizures for which she continues to take medication. However, according to the defendants, the medical records do not indicate the patient lost any of the milestones she had reached following the incident. According to the defendants' expert, the results of the developmental tests that were performed shortly after birth demonstrated that her state of development remains consistent with standards for individuals born so prematurely. The expert also testified specifically about the patient's birth weight and time spent on a respirator. The expert argued the respiratory and developmental injuries were expected. The expert said between 75% and 93% of babies born before week 28 of gestation and who have to spend at least 30 days on a ventilator sustain such injuries.

Although it may seem unpalatable, payment of $5 million by the defendants in this action was far more manageable compared to the patient's initial demand of $40 million. Physicians and care providers are not infallible, mistakes happen, and the specter of liability looms whenever a patient suffers an injury, particularly a significant injury as in this case. Settlement provides a vehicle for care providers to prevent runaway jury verdicts. An additional benefit of settlement is that, in most cases, the results of settlement can be maintained as confidential — thus shielding care providers from negative headlines following multimillion-dollar jury verdicts. While this settlement became public (likely due to the involvement of a minor or other unique circumstances), such a case is the exception, not the rule.

Thus, even if the settlement amount is ultimately the same — which is unlikely as settlement provides an opportunity to mitigate payment, too — the confidentiality aspect may be valuable to physicians and care providers who are interested in maintaining positive public opinion. It is almost always worth exploring such alternative resolutions, through informal settlement discussions and mediations, while simultaneously pursuing an aggressive defense in litigation. Working closely with experts and counsel will better help physicians and care providers understand their case to pursue such resolutions. ■

REFERENCE

Decided on March 26, 2020, in the United States District Court for the Southern District of New York, Case Number 7:16-cv-08038.

Insufficient Expert Report Leads to Partial Defense Dismissal in Botched Hysterectomy Suit

News: A patient who underwent a hysterectomy allegedly suffered multiple bowel and bladder lacerations, and a severed left ureter. The patient filed a medical malpractice action against the hospital and the physician who performed the hysterectomy. However, the court ruled in favor of the hospital defendant based on a plaintiff's deficient expert report, which improperly required assumptions and did not sufficiently link the expert's conclusion to the plaintiff's injuries. While the hospital defendant was successfully dismissed from the action, the litigation continued against the physician defendant.

Background: An adult woman had been a patient of a licensed obstetrician/gynecologist (OB/GYN) since 2016. The patient first contacted the OB/GYN complaining about an irregular menstrual cycle. From May-August 2016, the OB/GYN collected the patient's medical history and performed several tests to evaluate the patient's condition. The patient's medical history included multiple procedures: three cesarean sections in 1989, 1994, and 1999; a bilateral tubal ligation; and a splenectomy. A sonogram revealed multiple cysts on the lower part of her uterus. The patient also reported that she was taking hydroxychloroquine and prednisone to treat lupus.

The OB/GYN's notes indicated the patient requested a hysterectomy, partially based on her fear of endometrial cancer. According to the physician, robotic-assisted laparoscopic hysterectomy and bilateral salpingo-oophorectomy was discussed with and recommended to the patient, who decided to continue with the hysterectomy. At the preoperative visit, the OB/GYN documented the patient was informed of robotic hysterectomy, abnormal uterine bleeding, and endometrial hyperplasia without atypia and still wished to proceed with the surgery. The physician performed a total hysterectomy to treat the endometrial hyperplasia without atypia. The patient alleged this constituted malpractice and argued she was not totally informed about the total hysterectomy procedure. Furthermore, during the operation, the physician allegedly perforated the patient's left ureter, perforated the plaintiff's rectum, and the patient allegedly suffered several lacerations to her bladder.

The injuries necessitated more surgeries for the patient. Shortly after the incident, the patient filed a medical malpractice action against the OB/GYN only. However, the patient amended the complaint to include the hospital that employed the OB/GYN as an additional defendant. The amended complaint alleged the patient's injuries would not have occurred but for the hospital's negligence in selecting and hiring the physician.

Pursuant to state law applicable to this case, a medical malpractice plaintiff is required to submit a report from an expert identifying the applicable standard of care, how the physician or healthcare provider failed to meet that standard, and the causal relationship between the care provider's conduct and the patient's injury. In this case, the patient initially submitted an expert report regarding only the physician's alleged negligence. The patient eventually submitted a second expert report that detailed the reasons for the hospital's alleged liability.

The defendants challenged the second report. They argued the plaintiff's expert failed to provide any explanation as to how the hospital's conduct caused the plaintiff's injuries. The trial court ruled in favor of the hospital. The patient appealed, but the appellate court affirmed the trial court's decision. As for the hospital's dismissal, the physician defendant remained in the case.

What this means to you: A major lesson from this case is a successful avenue for physicians and care providers to challenge a patient's inadequate

claim: by undermining a patient's expert. While the patient's case against the physician defendant has yet to be decided, this ruling in favor of the hospital defendant provides an opportunity for defendants generally. In its analysis, the court focused on how the plaintiff's expert's report lacked essential elements specifically required by state law applicable in this case to qualify as a "good faith" effort to "inform the defendant of the specific conduct the plaintiff questions, and provide a basis for the trial court to conclude the plaintiff's claims have merit." While different states may have different requirements for experts, it is universal that there always is some standard applicable for an expert to qualify, and some minimal guidelines that must be satisfied. If an expert fails to meet those standards or to provide the state's required documentation, it is imperative for defendant care providers to challenge an opposing expert of that basis. Such a challenge may, as in this case, provide a complete defense.

Here, the court explained the expert report must indicate how the negligent conduct caused the alleged injuries to establish the necessary element of causation. The defendants challenged this last point, arguing the patient's expert failed to provide any such explanation, and therefore the entire report was deficient. The court first noted the expert report consisted of questions and answers, which was atypical. Injured patients claiming liability of a hospital in a medical malpractice case typically provide a history of the physician's malpractice as well as evidence that their employer, the hospital or practice group, failed to take any remedial measures following such incidents.

However, in this case, the expert challenged the hospital's hiring of the physician on the sole basis of the hospital's low insurance requirements, which the expert argued constituted negligence. The state's appellate court recognized negligent hiring is a viable claim, but the trial court identified multiple issues with the expert's report. First, the main argument contained in the expert's opinion required the assumption that only an unqualified physician would have such low insurance coverage.

The court noted the evidence did not support this assumption. The claim the hospital's low insurance requirement constituted negligence in the selection of physicians who were allowed to practice at the facility was not supported by any factual basis, and thus was rejected by the court. Furthermore, the court identified how the expert's report failed to explain how a higher insurance requirement would have changed the outcome of the procedure for the plaintiff and questioned what the minimum reasonable threshold for insurance requirement should have been. By failing to sufficiently support these allegations, the expert's report did not satisfy the state's requirements; it did not constitute a good faith effort to meet the definition of an "expert report." By contrast, it required the court to infer, assume, and draw conclusions that were not based in fact.

This case exemplifies the importance of retaining an appropriate and qualified expert and providing the necessary supporting expert reports and documentation, particularly when required by state law. The appellate court recognized the negligent hiring of a physician was a viable claim in malpractice actions. Hospitals and employers should create policies, procedures, and mechanisms for evaluating a physician or care provider's qualifications. Investigation into an applicant's background, education, past employment, and any previous medical malpractice claims — and, critically, the result of such claims — are appropriate steps to take when considering whether to hire the applicant. Beyond these policies and procedures, thorough documentation is equally necessary. If a patient subsequently attempts to include the hospital or employer as a malpractice defendant, documentation of an existing policy and adherence to the policy will help defeat a claim that a hospital hired an unqualified physician.

While physicians' and hospitals' interests are most often aligned and overlapping in the context of a single patient, there may be nuanced differences between applicable defenses for one or the other, depending on the specific facts and circumstances of the case. Where state law allows, a hospital may attempt to distance itself from a physician by arguing the physician was an independent contractor rather than employee, when the physician's negligence is definite. Generally, physicians and care provider defendants are likely to present a united front against a medical malpractice claimant. This permits the parties and attorneys to coordinate and better challenge a malpractice action, rather than fighting among themselves as to who bears liability. Such a determination is likely to happen eventually regardless, as juries are tasked with attributing percentages of liability in the event of an adverse verdict. Absent such an adverse verdict, physicians and care providers should attempt to collaborate in joint defense, circumstances permitting. ■

REFERENCE

Decided on March 5, 2020, in the Court of Appeals for the State of Texas, Case Number 13-18-00638-CV.

HIPAA REGULATORY ALERT

CUTTING-EDGE INFORMATION ON PRIVACY REGULATIONS

COVID-19 Changes HIPAA Compliance, But Caution Necessary

The Department of Health and Human Services Office for Civil Rights (OCR) has issued waivers and notices of enforcement discretion for several issues related to Health Insurance Portability and Accountability Act (HIPAA) compliance, but healthcare organizations still must be careful to comply with the privacy law even during the pandemic.

As the COVID-19 impact begins to wane and healthcare operations return to normal, it will be important to reframe HIPAA expectations, experts say. Remember that even with waivers and relaxed requirements, OCR still expects HIPAA compliance, says **Lucie F. Huger**, JD, an officer with Greensfelder in St. Louis.

"OCR is taking this pandemic very seriously and trying to be helpful in providing guidance and clarification on enforcement. But make no mistake — HIPAA is still here," Huger says. "Compliance is still very important. Even though we have a pandemic, HIPAA still should be a significant concern."

Covered entities must tread carefully, says **Mark R. Ustin**, JD, partner with Farrell Fritz in Albany, NY. OCR has emphasized the concepts of "minimum necessary" and "good faith," he says.

"We have fewer rules than we used to have in this period. But you still want to ensure that you're breaking the usual rules only to the extent that you need to break them so you can provide good patient care, and no further. That's the minimum necessary concept," he says. "OCR is also saying it won't enforce where there's a good faith breach, but they're still reserving the ability to enforce where there has been some bad faith. This is not the opportunity for you to gather up someone's healthcare data and sell it to someone."

Some waivers did not apply to all hospitals and do not last for the duration of the pandemic response, says **Melissa A. Borrelli**, JD, LLM, CHC, CHPC, director of healthcare consulting with Mazars USA, a consulting firm in Sacramento, CA.

"OCR's COVID-19 blanket 1135 waiver issued on March 13 was in fact very surgical. It only applied to hospitals for 72 hours after the hospital implemented its disaster protocols, and it did not waive all HIPAA requirements," Borrelli explains.

Instead, the 1135 waiver concerns requirements to secure a patient's agreement to speak with friends or family involved in his or her care. The waiver also allows the patient to request confidential communication and privacy restrictions, to opt out of the facility directory, and receive a notice of privacy practices.

More broadly, OCR eased its stance on communications technology, specifically in telehealth, Borrelli notes. This guidance allows flexibility in the tools providers use to communicate with their patients, permitting providers to use technology that does not currently comply with the HIPAA Security Rule but are not "public facing." For instance, FaceTime and Skype are allowed.

"Also, OCR provided business associates the freedom to share certain data for public health purposes only," Borrelli says. "That is, a business associate may previously, by contract, not have been allowed to disclose data to the CDC [Centers for Disease Control and Prevention], but under this guidance, they can."

Laura Peth, CHC, CFE, principal in healthcare consulting with Mazars USA, recommends two major focus areas to help covered entities be sure they are complying with HIPAA in extraordinary times. First, she says, stay the course as much as possible. Maintain and follow the organization's existing privacy structure, policies, and procedures to maintain compliance with HIPAA, and only deviate from those standards when absolutely necessary.

Before operating outside normal privacy-related procedures, ensure the existing blanket waiver and enforcement discretion is applicable to the organization by reviewing source materials and guidance from the Centers for Medicare & Medicaid

Services, OCR, and state regulators, Peth advises.

"When it is absolutely necessary to operate within the new limits of the waiver and/or enforcement discretion environment, documentation of the reasoning for operating outside your existing policy is paramount. Even a quick memo-to-file noting the temporary change in procedure, the time period during which that change will be effective, the criteria considered for that change, how protected health information is continuing to be safeguarded, how staff are informed and monitored of the new process, and including review approval by authority figures within your organization will aid you in the future," Peth says. "Documenting this type of information, including the reasoning and criteria behind such decisions, will assist your organization in showing good faith per the OCR announcement guidance."

Regardless of any changes to processes, waivers, or discretion in enforcement, adherence to the minimum necessary standard always is the best course, Peth says. The minimum necessary standard calls on healthcare professionals to make reasonable efforts to ensure any protected health information disclosed is restricted to the minimum necessary information to achieve the purpose for which the information is being disclosed. Be sure to include in any documentation how the organization is continuing to use the minimum necessary standard.

"Now is not the time to let any of your proactive controls or monitoring processes fall by the wayside. Preventive controls, detective monitoring, and auditing activities are more important than ever," Peth says. "For example, given the likely increase in public figures in medical facilities, ensure any proactive medical record lockdown of high-profile patients is working well, and continue to monitor audit logs for inappropriate access of medical records. It is vitally important to maintain these processes as they can be your first indicator that a recent change to your privacy processes is creating issues."

Continuing to perform these tasks also allows the organization to show good faith, Peth adds.

The second focus area involves educating staff and communicating well. Remind both remote and on site staff about existing privacy-related policies, especially those most important given the current situation, Peth advises. However, now is not the time to drone through every single small procedure. Focus on what will affect staff right now on a daily basis. For example, Peth suggests addressing these issues:

- Review the overall privacy and security rules, any state-level laws and regulations, and contract requirements at a high level as they relate to the organization.
- Review the employee conduct code.
- Review how employees can contact the chief compliance officer and/or privacy officer directly.
- Review how employees can use any anonymous reporting mechanism, such as a hotline.
- Provide examples of issues staff may see right now that would be of concern and should be reported.

By using relatable examples that are unique to staff, this education will not only help prevent staff from inadvertently making these mistakes, but alert them to report any incidences they observe, too. Use current and real-life examples to make sure the message hits home.

Those examples might include pictures on social media of remote workspaces, pictures on social media of the facility environment, unsecured remote meetings with discussion of protected health information (PHI), frustrated remote workers going around existing information technology controls to access files and information they need to do their job if there are technology issues, and record snooping. "Keep records of this additional training and communication, including attendance, and save them with the memo-to-file," Peth says. "This will assist you in evidencing good faith per the OCR announcement guidance."

Employees should be trained on the temporary exceptions so that they can apply them during the emergency, says **Cori R. Haper**, JD, partner with Thompson Hine in Dayton, OH. "Employees should also be reminded that protecting patient privacy, even the privacy of public figures who may be patients, is still required," she says. "In the midst of a pandemic, it is easy for employees to become distracted and inadvertently disclose PHI."

Healthcare organizations should make a point of educating their employees about HIPAA waivers and changes in compliance expectations, says **W. Reece Hirsch**, JD, partner with Morgan Lewis in San Francisco. "There is misunderstanding, and it can be a lot for people to try to digest as they're trying do their jobs in these conditions. It's important to be very clear about whether the waiver provisions have been triggered for your organization, and what is considered the minimum necessary deviation for your organization," Hirsch explains. "It should not be left to the rank and file personnel to assume there are certain waivers."

Even though hackers still are trying to break through security protocols, the biggest threat to privacy and security remains human error, Borrelli notes. "For example, healthcare administrative staff working remotely sharing a picture of their new home office set-up on social media with protected information visible on their computer monitor or within paperwork on their desk," she says. "Or, clinical staff sharing photos of a facility setting to show the world what

their day-to-day work is like or ... they may accidentally include the face of a patient in the background."

Remember that even with enforcement discretion, OCR requires covered entities to act in good faith to comply. Part of that is maintaining the highest HIPAA compliance when necessary and not unnecessarily taking advantage of OCR's response to the pandemic.

"If you are a small entity that is not seeing patients, is it OK for you to relax your standards? I would argue no, there is no exigent circumstance here that would mean shutting down security systems or not requiring staff to verify the identity of those on the phone that would qualify as acting in good faith," Borrelli says. "If you are a large hospital struggling from the weight of treating multiple COVID-19 patients, the answer may be different."

Also beware of online threats to HIPAA security. Hackers see the COVID-19 crisis as an excellent opportunity to take advantage of people and systems that are occupied dealing with the crisis, Borrelli says. People are distracted and stressed, their critical thinking is not as attuned as it usually is, so they are more susceptible to phishing and other online attacks. "Add to that a large part of the workforce that has not worked remotely before and the lack of time to deal with the security and privacy controls needed in those environments. It's a perfect storm for fraud, breaches, and cybercrime," Borrelli says.

Huger suggests this is a good time to review HIPAA policies and procedures to look for ways they might be improved. "We are seeing situations that we did not even imagine before, and now they are becoming very real," Huger says. "This is an opportunity to reassess what you have on paper in light of what your doctors, nurses, and administrators are actually facing right now." Educating those on the front line about what they can and cannot do regarding HIPAA compliance also is important, Huger says. "There is a very real human element here. Sometimes, people don't have the luxury of referring to the policy and keeping up with how requirements have changed," she explains. "Providing some easy-to-understand education is going to be important through this period. The policy might be there, but you might need to help your people understand how it applies now."

There is a higher risk of some types of HIPAA violations during the pandemic response, says **Kristen Rosati**, JD, an attorney with Coppersmith Brockelman in Phoenix. "One of the HIPAA compliance problems that likely spike during a healthcare crisis is increased incidence of curiosity viewing," she notes. "Healthcare personnel want to know if a patient on the floor has tested positive for COVID-19. It's tempting to look at a patient record, even if the personnel member is not involved in treating the patient. It's also tempting for personnel with access to the electronic health record to look up neighbors, family members, or perhaps ex-spouses interacting with children. But unless there is a valid treatment reason to have access to the patient's record, personnel shouldn't be in the record."

There also may be a desire to share COVID-19 infection information to protect others, such as fellow employees, first responders, or family members, from becoming infected, Haper says. "This can be accomplished under the new exceptions, but healthcare providers should understand the boundaries of the exceptions so that they can properly apply them at the time an issue arises," Haper says. "Another issue is the unique situation where the employer is a covered entity that provides testing for COVID-19 and wishes to use the information that one of its employees tested positive to protect other members of the workforce from contracting the disease. Again, this can be accomplished within the boundaries of the public health emergency exceptions, but it raises interesting issues when a company is both an employer and a covered entity."

Even in the chaos of a pandemic, covered entity providers should try to implement their privacy procedures and adapt those procedures as necessary, says **Thomas E. Jeffry, Jr.**, JD, partner with Arent Fox in Los Angeles. For instance, the minimum necessary rule requires that steps be taken so that persons only have access to the minimum amount of health information necessary based on their role and association with a patient.

"Only key personnel and those directly involved in the treatment and care of COVID-19 patients should have access to the identity of patients and their complete medical record. Because COVID-19 patients are separated from family members upon their admission to the hospital, the hospital should do its best to identify their designated personal representative and health decision surrogate. Communications about the patient should be channeled through that representative."

While it may not be possible to engage in a private conversation with a patient who is in a hallway because there are no other beds, providers should do what they can to minimize others from hearing, Jeffry says.

Covered entities and their business associates should track disclosures; report any unauthorized uses and disclosures; maintain administrative, physical, and technical safeguards to protect the security of electronic PHI; and limit internal uses and disclosures consistent with its minimum necessary policies. Jeffry says covered entities should plan now for recovering from the pandemic.

"Covered entities should think about the transition back to meeting all HIPAA requirements when the public emergency is removed, particularly with respect to telehealth security requirements," Jeffry offers.

Huger agrees, saying it will be important to bring employees back to the "normal" HIPAA compliance expectations once OCR revises its requirements after the pandemic slows or ends.

"If OCR is going back to business as usual, how is that going to impact the guidance we gave our staff members during the pandemic? That was then, and this is now. How are we going to get back to where we were with HIPAA compliance?" Huger asks.

Covered entities should plan for additional HIPAA training as soon as the pandemic subsides enough to allow it, suggests **Stephanie Winer Schreiber**, JD, shareholder with Buchanan Ingersoll & Rooney in Pittsburgh.

All communications about HIPAA compliance during the pandemic, especially any regarding a change in policy or procedures, should emphasize that it applies only "during the period" and "until further notice," she says.

"It would be a very wise endeavor for healthcare providers to engage in some additional HIPAA training post-COVID 19," Schreiber recommends. "Start thinking now about what you will need to tell your employees about rolling back to the way you previously addressed HIPAA compliance, what you learned about your program during the crisis. Maybe people can tell you about how your policies and procedures worked." OCR's response to the COVID-19 pandemic may yield some long-lasting benefits, says **Rose Willis**, JD, with Dickinson Wright in Troy, MI. She expects OCR to consider maintaining some of the telehealth changes even after the pandemic subsides.

"We are going to see ... OCR making the rules a little more flexible for telehealth, with things like allowing the use of Skype to conduct a telemedicine consultation," Willis says. "Before, it may not have been technically compliant from a security perspective, but I think as long as we don't see any huge problems come up as a result of that, I think we're going to see more of the flexibility continuing in the future." ■

Tips for HIPAA Compliance During a Pandemic

Remember that the pandemic response may create unique Health Insurance Portability and Accountability Act (HIPAA) compliance risks, says **Victoria Vance**, JD, partner with Tucker Ellis in Cleveland.

Time, staffing, and focus are at a premium, she says, but staying cognizant of patients' privacy remains important.

Vance offers reminders on how the pandemic response can increase HIPAA compliance risks:

• Use caution when deploying staff from other departments, offices, or facilities within a health system. This includes bringing back retired healthcare workers or volunteers to work in unfamiliar surroundings.

These individuals may need a refresher on the electronic medical record (EMR) systems and the facility's unique HIPAA policies and resources.

• In the press of patient care, remember not to share EMR passwords or forget to close patient encounters.

• Be mindful of the media interest in hospital operations and patient treatment experiences. Designate a point person to serve as the media contact for press statements. Also be careful about the use of photography and videotaping in areas where patients may be identified.

• Likewise, be cautious in phone encounters. Identify the caller, know with whom you are speaking, and share only minimum necessary information with designated individuals with a right to know about a patient's condition and status.

• Remember that compliance with HIPAA may not be enough. Local and state rules could provide additional protections for patient privacy and limitations on disclosure that are more restrictive than HIPAA.

In many instances, treating COVID-19 patients has meant working in conditions that are far from ideal for HIPAA compliance, notes **Raymond Krncevic**, JD, counsel with Tucker Ellis in Cleveland. Care is provided in overcrowded hospital units, drive-through testing sites, and other suboptimal situations where providers cannot communicate with patients in typically private settings.

"It sounds simple, but in these situations, common sense goes a long way," Krncevic says.

He offers these suggestions:

• Talk to patients in hushed voices if there are others standing nearby.

• Log out of a patient's medical chart if you are working in an area where the computer screen could easily be viewed by others.

• Do not share computer passwords.

• If treating a patient via telehealth link, make sure no one else is within earshot on your end.

• Even if you are using or disclosing protected health information where patient consent is not required, such as obtaining a consult or submitting data to a local health board, make sure to use only the minimum amount of information necessary to complete the tasks. ■