



HEALTHCARE RISK MANAGEMENT™

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Vol. 42, No. 5; p. 49-60

➔ INSIDE

CMS issues blanket
waivers 53

Telehealth rules eased,
but use caution..... 54

EMTALA will allow offsite
assessments 56

Some HIPAA
requirements waived
for now 57

Workplace violence
garnering increased
attention..... 58

Think about record
retention now, not at the
end 59

**Legal Review &
Commentary:** Appellate
court affirms \$5.1 million
award for patient's
death after hernia repair
surgery; state supreme
court orders new trial in
childbirth death suit



RELIAS
MEDIA

COVID-19 Creates Multiple Risk Exposures as Hospitals Respond

The COVID-19 pandemic is creating potential liability and compliance risks, even as government regulators and accreditors move to ease some impediments to providing care. Risk managers should monitor several areas of exposure and take steps to avoid adding more burdens to hospitals and health systems responding to the pandemic.

Many potential risks have emerged, related to issues such as telemedicine, relaxed state credentialing requirements, and failures to meet standard of care because of overcrowding and understaffing.

Risk managers must be vigilant for potential problems, even though the Centers for Medicare & Medicaid

Services (CMS), other federal entities, and states are making allowances for the unusual demands placed on the U.S. healthcare system by the pandemic.

“It’s really an extraordinary time. Most physicians, hospitals, and other healthcare organizations are focused

first and foremost on treating the patients that come in and responding to the shortages of equipment and personnel,” says **Richard J. Zall, JD**, partner with Proskauer in New York City.

“The government is responding with some regulatory flexibility, which bears on risk management, by easing many of the rules that apply in

terms of whether you are specifically approved for this many beds or this type of services, whether

“IN THIS TIME OF NATIONAL EMERGENCY, I EXPECT THERE WILL BE A LOT OF ROOM GIVEN TO THOSE WHO ACT IN GOOD FAITH, AND I THINK THAT’S APPROPRIATE.”

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EDITORIAL QUESTIONS
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people are credentialed properly, the ability to render telehealth services in ways that were not previously permitted. I think that's been very helpful, but nonetheless there will be mistakes made and people who make judgment calls that prove to be wrong."

That means the liability risk for providers, hospitals, and other healthcare organizations does not disappear just because regulators and the nation as a whole are making a good faith effort to remove barriers to care, Zall says.

Claims Likely After Pandemic

Despite best intentions, there likely will be claims that patients were misdiagnosed or provided the wrong treatment, particularly with uncertainty about using hydroxychloroquine to treat some COVID-19 patients, Zall explains.

"Some will try it and it will work for some, and some will have bad results. Whether or not mistakes were made, there will be finger-pointing and second-guessing, because we are a litigious society," Zall says. "We are advising that hospitals develop a protocol for making these judgments on the use of medications so they are not just made ad hoc by individual practitioners but by the institution.

Most hospitals are doing that, consulting with hospitals at other institutions, following the CDC guidelines, doing the best they can in a very tense, crisis atmosphere."

Zall expects that in the aftermath of the pandemic, if claims of negligence come weeks or months later, they will be met with some acknowledgment they occurred in extraordinary circumstances and should not be judged in the same way as errors that occur in the normal course of healthcare.

"In this time of national emergency, I expect there will be a lot of room given to those who act in good faith, and I think that's appropriate," Zall says.

Some organizations will try to take unfair advantage of relief programs, such as the Coronavirus Aid, Relief, and Economic Security Act, known as the CARES Act, offered by the federal government, Zall says. Some will falsely certify that they are eligible or try to claim more money than they are entitled to, he says.

"I think there will be false claim investigations after the fact about whether people operated in good faith," Zall says. "Most people will act in a responsible manner, but for those who try to push it too far and commit unscrupulous acts, I think there will be consequences down the road. That becomes a financial risk management issue when you

EXECUTIVE SUMMARY

Risk managers should recognize several types of potential liabilities and exposures related to the COVID-19 pandemic response. Some compliance and regulatory burdens have been eased but risks remain.

- Telehealth rules were relaxed, but there still are requirements to meet.
- Questions remain about malpractice exposure.
- Federal legislation may offer some relief from potential liability exposures.

are aware of someone in your organization taking that approach.”

Credentialing Changes Raise Questions

Physician credentialing became an issue when many states lifted some restrictions on clinician licensing to allow hospitals to more quickly and easily call up clinicians to assist with the increased patient load. The Federation of State Medical Boards (FSMB) reports that it typically can take hospitals weeks to verify training and licensing for a physician, acknowledging that such a delay threatens the COVID-19 response.

The relaxed state rules were welcomed by many hospitals seeking to bring in physicians from out of state, but risk managers should ensure the remaining rules are followed, says **Kyle A. Vasquez**, JD, shareholder with Polsinelli in Chicago. States have changed their licensing requirements in a patchwork of different rules and orders, and there is no overarching allowance to bring in physicians out of state without concerns, he notes.

“You have to look at the state in which your patient is sitting and determine if the existing medical board rules, practice acts, any governor-declared emergencies, or any supplemental documents to those declared emergencies indicate that out-of-state physicians require a license, some sort of interim license, or a notice to the state that they’re going to practice medicine in your state,” Vasquez says. “Even in the states that have said they welcome out-of-state physicians, there may still be a requirement that they file notice with the state that they’re going to be practicing there.”

Each hospital has a responsibility to meet its own credentialing and

licensing requirements, Vasquez says, although most will use a temporary or emergency process in which physicians can be brought on board quickly.

In addition, some states already had provisions allowing physicians from other states to continue caring for their existing patients who travel into the state, Vasquez notes. That can help, but it is not a perfect solution.

“The flip side of that is there are many states who are behind from a practice act standpoint. If there is a new patient or new condition, they restrict that to an in-state doctor only,” Vasquez explains. “CMS issued a waiver for telehealth saying that they don’t care if it’s a new patient or an existing patient — they’ll pay you either way — but we still have states with licensing requirements that won’t allow that to happen if the doctor is out of state. Just because CMS says they’ll pay for it — unfortunately, you can’t just go with that without looking at your state licensing requirements.”

There has been some discussion about the federal government overriding state laws on licensing or issuing some type of national license, but it is unclear whether that can be done at a national level, says **Matthew R. Fisher**, JD, partner with Mirick O’Connell in Worcester, MA.

“Licensing is determined under state laws, and Medicare requires that the doctor be licensed in the state in which the care is provided. Medicare might waive that requirement for a temporary period in order to have more physicians providing care where the virus is hitting the hardest, but that probably would not be enough,” Fisher explains. “You would need some action on the state level because that’s where the licensing requirements lie. It is not clear that the federal government has

any authority or any mechanism to override those state laws and just take over the licensing of physicians, even for a short time in an emergency.”

Consider Liability Coverage

Some of the same concerns apply when allowing midlevel practitioners to take on more responsibility, Vasquez says. For instance, even though some requirements may be eased to allow nurse practitioners to act more independently, risk managers must check the different state and federal regulations that may apply. *(For more on risk management concerns and regulation modifications, see the story on page 53.)*

Liability coverage should be considered for these physicians credentialed through an expedited process, Vasquez says. This applies especially to any hospital or health system considering sending its physicians to another state that is hard hit by the pandemic.

“There’s a big emphasis on whether the physician is authorized to practice in a certain bordering state, but there is less thought given to whether your practitioners are covered for liability when they practice in those states,” Vasquez notes. “Assuring there is appropriate medical liability coverage that extends beyond state lines is another key thing for people to think about, and that also applies to institutions that accept physicians from other states.”

PPE Shortage Creates Risk

A lack of personal protective equipment (PPE) also can lead to potential liability, Zall says.

“This is an area where I expect we will see some legal activity. In this crisis time, we’re seeing workers complain of not having adequate equipment, trying to reuse single-use items. As a result I think employers may see claims from workers who fell ill,” Zall says. “Employers have to do the best they can within their capacity, but in some cases it is not enough and there will be contact with people getting the virus. Where there are instances in which employees don’t have the right equipment and they are simply told they must work anyway, I think you will see some legal issues later.”

Some healthcare employees have complained publicly, as well as to regulators and employee unions, about the lack of PPE. Risk managers should work to ensure there is no whistleblower retaliation, says **Benjamin J. Fenton**, JD, partner with Fenton Law Group in Los Angeles.

“There are some stories about hospitals retaliating, so there is potential liability there. If hospitals terminate medical professionals for complaining about safety issues, they will face potential liability in the form of whistleblower lawsuits,” Fenton explains. “The hospital may not be sued or held accountable immediately while everyone is dealing with the crisis, but they could find themselves served with whistleblower lawsuits months down the road. Avoid that kind of knee-jerk reaction to employees complaining about their working conditions.”

There also have been unofficial reports of hospitals declaring universal do not resuscitate (DNR) orders for all COVID-19 patients to conserve staff and physician resources, PPE, and other supplies that can be used in large volume on a resuscitation. Zall says such orders, even if never written or approved by the hospital, could prompt claims after the pandemic.

Similarly, some physicians and hospitals are forced to make difficult decisions about the use of ventilators, he notes.

“There are tremendous ethical and legal issues around who to triage when you don’t have enough resources. I have been part of a number of discussions around how to properly triage. And in this current environment, patients are often kept separate from their loved ones, so

“THIS IS A SITUATION WE HAVE NOT HAD TO DEAL WITH IN THE UNITED STATES VERY MUCH, AND IT IS A STRANGE NEW WORLD, VERY TROUBLING.”

there is not the same opportunity to consult family members about their wishes,” Zall says. “There is risk, but we have never been in a situation like this where decisions are being made for two patients who both have conditions warranting use of the resource but there is not enough to go around. This is a situation we have not had to deal with in the United States very much, and it is a strange new world, very troubling.”

As with other difficult decisions during the pandemic, Zall says he expects physicians and hospitals will be given the benefit of the doubt as long as they were acting in good faith. Fisher agrees, adding that he does not expect federal or state regulators to go searching for technical or minor violations that may have occurred during the pandemic response.

“The enforcement discretion that we’re seeing from a lot of different regulatory bodies suggests that they are taking a practical approach to the challenges that everyone is facing now, and not looking at it as an opportunity to catch someone in a mistake,” Fisher says. “I expect they will continue that approach when things settle down and they have a chance to look back on what you did during the emergency.”

Vasquez says that during a crisis like the COVID-19 pandemic that stretches healthcare resources, including the abilities of risk managers and compliance officers, it can be reasonable to choose battles and focus on the most important issues. In some cases, he says, that might mean risking relatively minor enforcement actions or lower reimbursement.

“There are some states, for instance, that have not fully taken down those barriers to licensure, and people are thinking they can’t sit and wait around. They’re going to do their advocacy work to get the rules changes, but they’re deciding to just treat the patients and if they don’t get paid, they don’t get paid,” he says.

Risk managers also have expressed concern about the potential malpractice liability from calling up retired clinicians, expanding the abilities of nonlicensed personnel, and using medical students for some tasks normally performed by employees. For instance, New York Gov. Andrew Cuomo issued an executive order stating that medical students near graduation could be called to assist in hospitals. (*More information is available at: <https://on.ny.gov/3elhT7Q>.)*

Hospitals may need to take advantage of such tactics, Zall says, but they should monitor and limit those activities carefully. With rules and regulations modified at a rapid pace, Zall says risk managers should

use a mechanism for monitoring and staying abreast of exactly what is entailed in the modifications, as well as when those modifications expire.

“The main risk is assuming that anything goes, which is not the case. Federal agencies, state agencies, and other regulatory bodies have loosened the requirements, but there are still rules,” Zall says. “The primary goal is to be informed about what those rules are and what they allow, without making assumptions. If you

had decided on your own before the governor’s order to enlist medical students to help with the surge in virus patients, you would not have had the protection afforded by that executive order, and even now you could still go beyond the scope of that order.” ■

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CMS Issues Stark Waivers, Makes Other Allowances for Pandemic

The Centers for Medicare & Medicaid Services (CMS) issued waivers and allowances that will affect risk management programs:

- CMS issued 18 blanket waivers of sanctions under the physician self-referral law, known as the Stark Law. CMS refers to the waivers as the Patients Over Paperwork initiative. These waivers allow hospitals and other healthcare providers more flexibility to respond to the pandemic. The Stark Law waivers are retroactive to March 1, 2020, and do not yet have an expiration date. *(The full text of the waivers is available online at: <https://go.cms.gov/2yQ5qcd>.)*

CMS explained the waivers apply only to financial relationships and referrals that are solely related to COVID-19. They allow non-fair market value (FMV) compensation, in which hospitals can pay above or below FMV for equipment, office space, or physician services.

The waivers also allow physician-owned hospital capacity expansion. This means physician-owned hospitals can increase their number of licensed beds, operating rooms, and procedure rooms temporarily.

CMS also said physician-owned ambulatory surgical centers can convert to hospitals to help address a surge in patients during the pandemic.

Hospitals may provide medical staff benefits such as daily meals, laundry service, or childcare services during the pandemic without running afoul of kickback prohibitions. CMS also will allow nonmonetary compensation such as continuing medical education on COVID-19 protocols, shelter when the physician must isolate, or meals for the family of a physician exposed to the virus. This compensation must not exceed the annual nonmonetary compensation cap.

CMS waived the writing requirement, allowing compensation for physicians without first obtaining all required documentation. CMS explained this could apply, for instance, when a physician provides personal protective equipment from his or her own office or surgical suite to use in the hospital.

- The Department of Health and Human Services Office of Inspector General (OIG) also issued

a policy saying it will not impose administrative sanctions under the federal Anti-Kickback Statute (AKS) for remuneration related to COVID-19. OIG previously issued voluntary safe harbors for activities that pose little risk of fraud, but then went further to state that it will exempt arrangements that do not satisfy the safe harbor requirements. However, they must meet one of the permissible forms of remuneration allowed under the Stark Law blanket waivers.

- CMS issued rule changes and temporary regulatory waivers applying to an expansion of the Medicare home health benefit to COVID-19 patients. It also issued waivers to the Medicare home health and hospice regulations.

- CMS announced temporary measures that will allow ambulatory surgery centers that have postponed elective and nonessential procedures during the pandemic to temporarily contract with a local healthcare system to provide hospital services. They also may bill as a hospital during the federal government’s emergency declaration. ■

Telehealth Rules Eased, but Oversight Still Needed

The federal government acted quickly to make telehealth services more accessible in the COVID-19 pandemic, but risk managers must fully understand the changes to avoid creating liability risks.

Some telehealth changes are aimed at making the service reimbursable, and therefore available to more patients. But there also are compliance issues, says **Matthew R. Fisher**, JD, partner with Mirick O'Connell in Worcester, MA. The Department of Health and Human Services (HHS) announced several regulation changes and new approaches to compliance that are designed to increase access to telehealth services during the pandemic. The Centers for Medicare & Medicaid Services (CMS) explained telehealth falls into the categories of telehealth visits, virtual check-ins, and e-visits.

The categories include their own requirements for billing. Medicare considers a telehealth visit to be an encounter between a patient and a clinician that uses interactive audio and video, Fisher explains. These are visits that usually could occur in person and are used as a replacement for an office visit. In this encounter, the telecommunication platform must provide real-time communication

between the patient and the clinician, Fisher says.

“An important concession by CMS involves the established patient requirement for telehealth visits. This service previously was permissible only when the patient and physician had an established relationship, which would not be as useful in helping respond to the COVID-19 increase in patient volume,” Fisher says. “Under the new conditions, CMS will turn a blind eye to the established patient requirement so you can use it for new patients as well. They're also saying that telehealth services can be used to interact with a patient in their own home rather than having them go to an approved healthcare site.”

Virtual check-ins are brief discussions between a clinician and an established patient, unlike the more thorough telehealth visit. A check-in can be audio-only, but it cannot be related to an office visit from the previous seven days, and it is not reimbursable if it is followed by a full office visit within 24 hours. Additionally, the patient must verbally agree to the check-in. An e-visit is similar to a virtual check-in, but must be initiated by the patient.

A significant change from CMS is the decision to reimburse the telehealth visits at the same level as

in-person visits, which, under normal circumstances, could lead to fraud or compliance failures.

“The HHS OIG [Office of Inspector General] issued a policy statement saying that because patients may not be able to afford cost-sharing amounts for telehealth services, it will not pursue fraud-based enforcement actions when the healthcare organization waives cost-sharing amounts, or if it waives the cost-sharing for the duration of the emergency,” Fisher explains. “This is important for compliance reasons because in normal circumstances waiving or reducing cost-sharing, even if done with best intentions, can result in fraud allegations. Waiving or reducing the costs can be seen as inducement to patients.”

Eliminating or reducing those costs can encourage patients to seek or accept telehealth services from the physician, which provides more Medicare reimbursement, Fisher explains. For that reason, CMS normally prohibits waiving or reducing the costs. (*Complete guidance on telehealth services during the pandemic is available on the CMS website at: <https://go.cms.gov/2JgIg0x>.*)

Embrace Telehealth

Healthcare organizations should embrace the wider use of telehealth during the pandemic, says **Georgia Reiner**, risk specialist for the Nurses Service Organization (NSO) in the Healthcare Division of Aon's Affinity Insurance Services in Philadelphia. Any concerns about compliance and reimbursement issues are outweighed by the significant benefits of making

EXECUTIVE SUMMARY

The easing of telehealth requirements improves access to care but involves risk management concerns. Understand the types of telehealth and the requirements for each.

- Telehealth will be reimbursed as an in-person visit.
- A patient's telehealth costs may be reduced or waived.
- Exercise caution when using technology that is not HIPAA-compliant.

healthcare services available to more patients, reducing exposure to the virus, and minimizing the use of personal protective equipment, she says.

When expanding telehealth services, Reiner says risk managers should remember the key requirements that always apply regardless of any regulatory modifications. Providers must practice in accordance with the standard of care and within the limits of their licenses, she says.

“It’s essential to verify with the state and the medical licensing board which practitioners can legally provide telehealth services,” she explains. “Some states limit the type of providers that can provide telehealth services, but most states allow physicians, clinical nurse specialists, nurse practitioners, physician assistants, licensed counselors, and other types of practitioners.”

The healthcare organization also must protect patient information during telehealth services, which usually means using HIPAA-compliant technology. But Reiner notes the HHS Office for Civil Rights recently stated that everyday communication technologies are acceptable during the health emergency. However, using those technologies, such as FaceTime, is not without risk.

“It is incumbent on providers to notify patients that if they do choose to use these third-party applications like FaceTime, Google Hangout, or Skype, there are privacy risks with those applications. They are certainly easier and quicker to implement when you’re trying to get telehealth services up and running quickly, but they do not offer the optimal protection,” Reiner says. “Whatever platform you’re using, providers should make sure they are implementing all the privacy and protection modes or options available on that application.”

Reiner cautions against any tendency to let one’s guard down too much with the expansion of telehealth. The relaxed rules do not mean telehealth can be used casually or without concern for the usual risks that come with electronic communications, she says.

“There is going to be an increased usage of telehealth services, so it is more important to follow best

ANY CONCERNS ABOUT COMPLIANCE AND REIMBURSEMENT ISSUES ARE OUTWEIGHED BY THE SIGNIFICANT BENEFITS OF MAKING HEALTHCARE SERVICES AVAILABLE TO MORE PATIENTS.

practices to maintain the security and privacy of patient health information. That includes threats like ransomware and other malware threats,” she says. “We know that cybercriminals are trying to take advantage of the coronavirus situation and trying to dupe people into downloading malware on their systems. It is important for everyone to inspect email and links carefully before downloading anything and to be sure systems are updated.” (*NSO guidance for nurses using telemedicine is available online at: <https://bit.ly/2Rkj4L4>.*)

The Drug Enforcement Administration also said it will allow physicians using telehealth

to prescribe controlled substances without a prior in-person exam. This telehealth exception had been approved previously but was lacking rules to implement it, says **Kyle A. Vasquez, JD**, shareholder with Polsinelli in Chicago.

“They’re saying you can go ahead and use telehealth for prescribing controlled substances, but then the issue we still run into is how state laws may apply. A lot of states have laws that say they don’t allow pharmacies to fill prescriptions for controlled substances from out-of-state physicians,” Vasquez says. “It’s unfortunate how you still have conflicts from all these rules.”

Malpractice coverage also may be problematic with interstate use of telehealth, Vasquez notes. Not all professional liability policies will cover care provided by telehealth to a patient in another state, so physicians and risk managers overseeing physician groups should check before agreeing to the service.

“There may be exclusions that specifically state the policy only covers the in-state practice of medicine,” he explains. “Employed physicians may be covered under a hospital or health system’s policy. That may provide more coverage, but it’s something to think about if you have not traditionally had an active telehealth program.”

Polsinelli created an interactive map that explains the regulatory issues pertaining to telemedicine during the pandemic. That map is available online at: <https://bit.ly/2WVkoHC>. ■

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EMTALA 1135 Waivers Allow Flexibility

The Centers for Medicare & Medicaid Services (CMS) Hospitals Without Walls initiative uses section 1135 of the Social Security Act to create waivers for the Emergency Medical Treatment & Labor Act (EMTALA) to address the pandemic.

CMS waived enforcement of some sections of EMTALA to permit hospitals, psychiatric hospitals, and critical access hospitals to perform medical screening exams at offsite locations to reduce contagion and cope with a surge in patient volume. The offsite screening must be consistent with the state emergency preparedness or pandemic plan.

The waiver and previous CMS announcements provide hospitals more flexibility and acknowledge that some typical EMTALA requirements are difficult to achieve during the pandemic response, explains **Shanti M. Katona**, JD, shareholder with Polsinelli in Wilmington, NC.

The waiver of EMTALA sanctions only is applicable to actions that do not discriminate based on a patient's source of payment or ability to pay, CMS stated. The waiver also is effective while the COVID-19 declaration of emergency is in effect. (*More explanation of the waivers is available online at: <https://bit.ly/3a2RE2R>.*)

"The waivers do not mean that EMTALA no longer applies. They are simply saying that they understand resources and staff are potentially going to be very stressed, and they don't want you to be motivated by sanctions that can be very severe," Katona says. "They allow you to direct patients with flu symptoms to another site where they will be examined, or you can create another area at your facility, such as something attached to your ED but a separate space for COVID-19 screening."

Isolate in Cars

CMS also noted that it is permissible for patients to self-isolate in their own vehicles to avoid waiting in a crowded area, as long as that is acceptable to the patient, she explains.

"You have to stay in contact with them so that if they have symptoms that require immediate care you can act on that," Katona says. "That is a really interesting option that we haven't seen before."

Isolation of suspected COVID-19 patients, whether in a separate tent or in their own cars, will require more attention to monitoring and communication, Katona says.

"As EDs [emergency departments]

get filled up and you have lots of people waiting in their cars or in your designated area, it's going to be difficult to maintain contact with them all," she explains. "Someone may have been waiting in their car for a couple hours and the cough is getting worse, but that is going to be hard to evaluate if they are not within your line of sight. If you are going to use these available avenues of isolation, you have to find ways to stay in touch through texting or telehealth, some way to treat them if they take a bad turn, because you have initiated the screening and they are under your care at that moment."

CMS also will overlook transfers of patients who have not been stabilized. EMTALA generally requires that a patient be stabilized before transfer but is recognizing that overstressed EDs may not always be able to meet that requirement, Katona notes.

"If they determine that they need to transfer an individual before stabilizing, based on a realistic view of capacity, staffing, and other factors, the violation will be waived," she says. "CMS is acknowledging the fact that some hospitals may not be able to meet this standard when they are struggling to treat an influx of patients, and they don't want the caregivers to be distracted by the idea of EMTALA sanctions when they need to be providing care."

Protective Equipment Shortage No Excuse

CMS also addressed the use of personal protective equipment and the shortage at some hospitals. A shortage of masks, gowns, gloves, or other equipment is not an acceptable reason

EXECUTIVE SUMMARY

The Centers for Medicare & Medicaid Services issued waivers for some Emergency Medical Treatment & Labor Act (EMTALA) requirements, acknowledging certain expectations are not reasonable to achieve during a pandemic. However, EMTALA still applies.

- Hospitals can separate screening sites for COVID-19 patients.
- Self-isolation in patient cars is acceptable.
- Lack of personal protective equipment does not obviate the need for assessment.

for declining a transfer or for not providing proper assessment, CMS stated.

“I know that’s heartbreaking because we want all our frontliners

protected as much as possible, but CMS says you can’t use that as the reason for not providing care in the ED as required by EMTALA,” she says. ■

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Do Not Forgo HIPAA Requirements in Pandemic Response

The HHS Office for Civil Rights (OCR) is waiving some HIPAA sanctions and penalties, but hospital risk managers should study the modifications to understand exactly what is and is not allowed.

OCR issued a statement saying it would not pursue sanctions and penalties for healthcare organizations that do not comply with these HIPAA Privacy Rules:

- 45 CFR 164.510(b): Obtain a patient’s agreement to speak with family members or friends involved in the patient’s care;
- 45 CFR 164.510(a): Honor a request to opt out of the facility directory;
- 45 CFR 164.520: Distribute a notice of privacy practices;
- 45 CFR 164.522(a): The patient’s right to request privacy restrictions;
- 45 CFR 164.522(b): The patient’s right to request confidential communications.

The changes are intended to

reduce the compliance burden on overworked hospital staff, says **Matthew R. Fisher**, JD, partner with Mirick O’Connell in Worcester, MA.

“It’s about not having to worry about getting some documents signed. They were already talking about eliminating the signing document anyway,” Fisher says. “They’re giving some wiggle room in terms of how to share information, trying to get people who might have secondary contact info in their hands, or just to allow concerned family members to know what’s going on.”

To qualify for the waiver, the covered entity must be in the emergency area identified in the public health emergency declaration, and the hospital must have instituted a disaster protocol. The waiver is valid for up to 72 hours from the time the hospital implements its disaster protocol.

OCR pointed out that when the

public health emergency declaration terminates, a hospital must then comply with all the HIPAA requirements for any patient still under its care. That is true even if it has been 72 hours since the hospital implemented its disaster protocol, OCR explained. (*The OCR statement is available online at: <https://bit.ly/2RIWH7O>.*)

OCR may make further allowances regarding HIPAA compliance, Fisher says.

“It’s been demonstrated that as the need arises, action will be taken,” he says. “The goal of all this action is to promote access to care and hopefully protect the health and well-being of as many people as possible. Healthcare leaders just need to stay abreast of the changes so you understand the limitations and opportunities that are presented to you.”

Telehealth Raises HIPAA Issues

HIPAA requirements can be difficult to meet when using telehealth services, which many hospitals are using more to deal with the surge of patients, says **Kyle A. Vasquez**, JD, shareholder with Polsinelli in Chicago. The easing of federal and state requirements for telehealth has some clinicians and organizations making greater use of the technology, but

EXECUTIVE SUMMARY

The Department of Health and Human Services Office for Civil Rights will disregard some HIPAA violations during the pandemic response. Risk managers should understand which parts of the privacy rule are affected.

- The signing requirement to speak to a patient’s family is waived.
- Patients do not have to be offered confidential communications.
- Telehealth service changes will raise potential HIPAA issues.

HIPAA should be considered, he says.

The good news is that OCR said they will allow the use of some telehealth technology that usually is not considered HIPAA-compliant. OCR indicated that providers can use “non-public-facing remote technologies” including Skype, Apple FaceTime, or Facebook Messenger video chat. “Public-facing” technology that can be accessed by more than the two individuals, like Facebook Live or TikTok, cannot be used.

“They’ve said they’re going to use their enforcement discretion to allow certain modalities that previously could not be used because

they know that more people have access to them,” Vasquez says. “There still may be state privacy issues to consider because some states are still saying no, that they want a HIPAA-compliant methodology like Zoom for Healthcare. Privacy is an area to think through before you widely implement telehealth services during the pandemic.”

OCR will exercise enforcement discretion by not imposing penalties for noncompliance with HIPAA for the good faith provision of telehealth. The enforcement discretion will apply to any use of telehealth services during the pandemic period, not just related to COVID-19.

OCR does still prefer the use of HIPAA-compliant services, Fisher notes. The announcement stating that other technology will be acceptable includes a final statement that OCR would be happier if providers stick with the usual approved modalities, he says.

“They are acknowledging that the current situation requires some flexibility, and more people will have access if they allow the use of the commonly available technologies,” Fisher says. “But if you have a choice and if you want to maintain your HIPAA compliance efforts even in these difficult times, OCR would rather you stick with a fully compliant, secure service even now.” ■

More Attention Now to Workplace Violence; Employers More Receptive

Workplace violence is receiving more attention from hospital and health system leaders. Now may be the time to push for worker safety initiatives that previously could not gain traction.

Healthcare workplace violence is increasingly seen as a legitimate issue needing attention, not just a part of life that nurses and other employees must tolerate, says **Jennifer Flynn**, CPHRM, manager in healthcare risk management with Aon in Fort Washington, PA.

“Workplace violence is getting a light shown on it at this time. I’ve not seen in my career more interest from governments and facilities alike to put into place measures to decrease workplace violence in healthcare settings,” she says. “I would say, however, that it is still hugely underreported. There are data showing that workplace violence is not only a common occurrence for

healthcare workers, including nurses, but it also has been on the rise lately.”

Data from the Bureau of Labor Statistics show a 70% increase in reported violence against healthcare workers from 2012 to 2018, Flynn notes. It is an area of concern for nurses, but the good news is that the problem is no longer hidden, no longer a dirty secret that hospital administrators will not acknowledge, she says.

More Resources Available

Although there is a long way to go in improving the safety of workers, Flynn says the increased attention is bringing more resources to bear.

“We have an increase in overall knowledge, identifying for nurses what we mean by workplace violence and a safe workplace, and facilities

establishing a zero-tolerance policy for workplace violence. We’re seeing much more recognition that it’s not OK to tell a nurse ‘This is part of the job and to get over it, get back to work,’” Flynn says. “There is still work to do there so that nurses don’t see it as part of the job, but we’re seeing progress.”

Risk Managers Push for Change

Reporting workplace violence is key to improvement, Flynn notes. The most progress is made at facilities where nurses have clear processes for reporting incidents without retribution. Hospitals must create a culture in which violence of any kind, from anyone, is not accepted and can be reported without fear of reprisal, she says.

Risk managers who have sought to

address workplace violence in the past but met resistance should consider another attempt, Flynn says. The attitude in the healthcare industry overall is improving, and leaders may respond differently now.

“I believe the tide is turning on management’s commitment to having

a safe, violence-free workplace,” Flynn explains. “When you have top administrators, risk managers, other leaders declaring that violence from patients, visitors, staff, anyone is not acceptable, you create real change. Management is making more resources available and implementing the steps

necessary for a zero-tolerance policy on workplace violence.” ■

SOURCE

- Jennifer Flynn, CPHRM, Manager, Healthcare Risk Management, Aon, Fort Washington, PA. Email: jennifer.flynn@aon.com.

Think About Record Retention Now, Not at End

Physician practices and even hospitals sometimes make the mistake of putting off decisions on record retention until they think it is time to clear out a storage facility or reduce their data storage expenses.

A better approach is to determine how long certain records should be kept and then establish a destruction date, says **Jonna Eimer**, JD, principal with Much in Chicago.

“Rather than looking at documents and asking if you’ve held on to this one long enough and can we throw it now, it is more effective to establish up front how long you are going to keep a document from the time it is generated,” Eimer says. “A lot of physicians don’t think about it until they are retiring or selling their practices, and then they have to look at these records and determine whether they can be destroyed,

maintained in storage, or handed over to the purchaser of the practice.”

Failure to retain records long enough will run the risk of a lawsuit from a patient who needs access to past records that no longer exist, Eimer says. State and federal compliance penalties also are possible.

Retention periods vary according to state law, federal law, and the requirements of liability insurers. Eimer recommends assessing them and determining the longest retention period that applies to the organization. For instance, Illinois requires hospitals to maintain medical records for 10 years, but does not provide guidance for physician practices. Medicare and Medicaid require five years for some documents, HIPAA generally requires six years, and the Centers for Medicare &

Medicaid Services requires 10 years for some managed care programs.

Malpractice insurers also usually have required retention periods, often five years or less, but they vary among insurers and states, she says.

“My thought is that I like to err on the side of caution, and that means for providers in my state I would recommend 10 years,” Eimer says. “I recommend that hospitals and physicians here retain records for 10 years since the last patient encounter, with the caveat that the statute of limitations might be longer in some situations and require a longer retention. The same formula can be applied for any provider in any state.” ■

SOURCE

- Jonna Eimer, JD, Principal, Much, Chicago. Email: jeimer@muchlaw.com.

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CME/CE QUESTIONS

- 1. What does Richard J. Zall, JD, predict regarding malpractice lawsuits following the COVID-19 pandemic?**
 - a. Despite best intentions, there likely will be claims that patients were misdiagnosed or provided the wrong treatment.
 - b. Because caregivers were acting with best intentions, there likely will not be claims that patients were misdiagnosed or provided the wrong treatment.
 - c. The federal government may enact legislation protecting healthcare professionals and hospitals from malpractice claims related to the pandemic.
 - d. States may enact legislation protecting healthcare professionals and hospitals from malpractice claims related to the pandemic.
- 2. Which may be necessary for physicians who travel to another state to provide care during the pandemic under relaxed licensing requirements?**
 - a. It may be necessary to file a notice with the state that the provider intends to practice medicine there.
 - b. It may be necessary to wait 14 days before treating patients.
 - c. It may be necessary to go through the normal licensing requirements that existed before the pandemic.
 - d. It may be necessary to obtain a recommendation from a physician licensed in that state.
- 3. What is allowed by one of the waivers the Centers for Medicare & Medicaid Services issued in response to the pandemic?**
 - a. Full documentation is not necessary for Medicare reimbursement.
 - b. Hospitals may provide medical staff benefits such as daily meals, laundry service, or childcare services during the pandemic without running afoul of kickback prohibitions.
 - c. Hospitals will not be subject to normal reimbursement requirements regarding patient length of stay.
 - d. Physicians do not need to meet the normal requirements for an in-office patient visit when it is related to COVID-19.
- 4. What is one change to the Emergency Medical Treatment & Labor Act allowed during the pandemic?**
 - a. Hospitals do not need to assess all patients presenting to the emergency department.
 - b. Hospitals may direct suspected COVID-19 patients to a separate site for evaluation.
 - c. Hospitals may declare their emergency departments closed to COVID-19 patients.
 - d. Hospitals may include ability to pay when determining whether to accept COVID-19 patients.



LEGAL REVIEW & COMMENTARY

EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

Appellate Court Affirms \$5.1 Million Award for Patient's Death After Hernia Repair Surgery

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News: An appellate court affirmed a \$2.5 million verdict in favor of a husband whose wife passed away days after a routine hernia surgery. The jury found the physician's gross negligence had caused the patient's death and that a nurse's actions contributed to the patient's pain and suffering.

On appeal, the defendants argued the evidence did not support the jury's findings. However, the appellate court rejected these arguments and affirmed the award.

Background: An adult woman was referred to a physician for the treatment of a hiatal hernia, a condition in which the stomach protrudes into the chest through the hiatus, an opening in the diaphragm. The physician determined the patient required surgery to return the stomach to its proper position, but alleged the patient would need to lose weight prior to the surgery. A few months later, the patient underwent laparoscopic surgery to facilitate the required weight loss. Following the laparoscopic surgery, the physician performed the hernia surgery, assisted by a registered nurse.

The hernia repair was performed by attaching a mesh closure to the patient's diaphragm using a device commonly referred to as a "tacker." The device uses absorbable "tacks" to attach prosthetic material to soft tissue. Each tack is approximately 5 millimeters in length. At the time of insertion, the device presses them as far as 6.7 millimeters into soft tissue. Because of these precise measurements, the manufacturer expressly warns against the use of a tacker if the total distance

between the surface of the tissue and any underlying bone, blood vessel, or organ is less than 6.7 millimeters. Additionally, the manufacturer cautions against the use of a tacker during diaphragmatic hernia repair on the diaphragm near the pericardium, aorta, or inferior vena cava.

When questioned about his use of the tacker, the physician testified he had used the same procedure in several hernia repair surgeries before without incident. The physician also opined that he preferred tacks to sutures because tacks were less likely to tear, thus decreasing the likelihood of hernia recurrence. The physician used the tacker to attach the mesh to the muscular edge of the diaphragm, which he did not

measure but "ballparked" its thickness to be approximately 10 millimeters.

The patient appeared stable after surgery. However, after two days she began complaining that her heart was racing and she was experiencing abdominal pain. An ECG revealed a fast, irregular heart rate, as well as excess fluid in the patient's pericardium near the tacks. She received blood-thinning medication and morphine, but about one hour later she went into cardiac arrest. Resuscitation was unsuccessful.

THE JURY FOUND
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An autopsy revealed the patient's pericardial sac contained blood, likely caused by prolonged heart compressions. Furthermore, the autopsy revealed puncture marks on the patient's heart, and acute and chronic inflammation of the pericardium. The acute pericarditis most likely occurred at the time of the surgery. It concluded that unequivocal evidence of surgical trauma could not be demonstrated.

The patient's husband filed a medical malpractice lawsuit against the physician, the registered nurse who assisted with the surgery, and the corporate employer of the physician and nurse. The defendant care providers denied liability, claiming the use of the tacker did not constitute malpractice. Expert witnesses for both sides offered conflicting opinions about the propriety of the tacker, although experts agreed that alternative methods were available.

After a six-day trial, the jury found the physician's use of a tacker was negligent and awarded the plaintiffs \$5.1 million: \$2.6 million in compensatory damages for pain, suffering, and loss of consortium, and \$2.5 million in punitive damages. The defendants appealed, arguing the evidence was insufficient to support the jury's finding. The appellate court rejected those arguments and affirmed the award.

What this means to you: This case raises important considerations about making appropriate choices in the selection of equipment and methods for treatment, as well as the importance of retaining a qualified and persuasive expert witness in the event of litigation. Liability for the care providers in this case arose as the result of the tacker, which likely pierced the patient's pericardium and punctured her heart, causing cardiac arrest and death. As to the suitability of the tacker, that is when expert testimony becomes relevant as experts

for the patient and care providers presented conflicting opinions about whether the tacker was appropriate to use in these circumstances. When a medical malpractice action becomes a battle of the experts, as frequently occurs, it is of the utmost importance to critically evaluate prospective experts and choose the right expert for you — an expert who is knowledgeable and persuasive.

In this case, the battle of the experts determined the outcome of the litigation, as the jury agreed with the patient's expert and theory of the case. Although the final autopsy identified puncture marks on the deceased's heart, the defendants argued those injuries likely resulted from the chest compressions performed during attempts to resuscitate the patient after she went into cardiac arrest. Additionally, the defendants noted that the autopsy report indicated no evidence of surgical trauma could be demonstrated.

The defendant physicians retained an expert physician witness — a general and gastrointestinal surgeon — whose theory was the patient died of longstanding damage to her heart caused by the hiatal hernia, injury caused by blood-thinning medication, and prolonged resuscitation efforts. The expert witness provided insight as to the choice of using tacks on the diaphragm as well as an interpretation of the patient's postsurgical condition. The expert opined that despite the manufacturer's warning regarding a tacker for diaphragmatic hernia repair, it was common practice to use this device to fasten material to the muscular wall of the diaphragm, which was certainly thick enough to withstand the 5 millimeter tacks. The expert added that the manufacturer's warning likely was placed to prevent their own liability, rather than an express preclusion for using the

tacker in this manner. As additional evidence to the positive outcome of the surgery, the expert noted that the patient's vitals were stable and she felt fine immediately after the surgery. Had the physician punctured the pericardium when inserting the tacks, the patient would have not felt well after the procedure, according to the defendants' expert.

Unsurprisingly, as is the case with innumerable medical malpractice actions, the plaintiffs retained and presented testimony from an expert whose opinion conflicted with the defendants' expert. This expert was a general surgeon who had performed nearly 1,000 hiatal hernia surgeries, and expressly opined to a "reasonable degree of medical certainty" the treatment of this patient was below the standard of care expected from the average qualified surgeon and registered nurse assistant. The plaintiffs' expert believed the punctures on the patient's heart as well as the choice to go against the manufacturer's recommendations demonstrated the tacks had injured the patient and caused her death, and the defendant physician acted negligently in using the tacker.

With an inconclusive autopsy report and two expert witnesses clearly presenting opposing conclusions based on the known facts, the jury looked to a source of less biased information: the manufacturer's specific warning, which recommended against use on the diaphragm during diaphragmatic hernia repair procedures.

The jury agreed with the patient's expert and supporting manufacturer's warning, concluding the punctures on the patient's heart were sufficient evidence that the physician's conduct had caused the patient's injuries and subsequent death. Accordingly, the care providers' actions fell below the applicable standard of care. On appeal, the appellate court confirmed

the jury had a “substantial basis on which to reject the defense theory of the case” given the expert testimony and manufacturer’s warning.

This case demonstrates how the choice of not following a manufacturer’s warnings can be extremely detrimental to care providers even if an expert witness presents a plausible argument and opines the injuries were the result of other causes. Relying on a manufacturer’s recommendations and

warnings are valuable tools that should never be overlooked, disregarded, or ignored. Although these may be partially intended for manufacturers to protect themselves from litigation, these also are developed after extensive research during pre-market testing phases of new products. Proceeding in total disregard of manufacturers’ warnings, especially when alternative methods or equipment may provide similar, safer treatments, could constitute malpractice. Physicians and

care providers who are unsure about manufacturers’ warnings can contact the manufacturer and request specific details about a warning or recommendation to shed valuable insight as to the rationale behind the warning. ■

REFERENCE

Decided on Feb. 28, 2020, in the Appeals Court of the State of Massachusetts, Case Number 18-P-1373.

State Supreme Court Orders New Trial in Childbirth Death Suit

News: A patient contracted an *Escherichia coli* infection following an emergency cesarean section delivery, and ultimately died as the result of the infection. During trial, the plaintiff introduced expert testimony of two different physicians. The defendants moved to strike the plaintiff’s evidence, arguing the expert witnesses failed to prove causation. The trial judge granted the motion.

The patient appealed to an intermediate court, which found the trial court erred. The defendants appealed to the state’s supreme court. It affirmed that the trial court erred, ordering a new trial to be held.

Background: In 2011, during her first pregnancy, a patient was diagnosed with an incompetent cervix. To prevent a premature birth, a physician placed a cervical cerclage, a procedure that uses a stitch or tape to reinforce the cervix. The patient later successfully delivered her first child. After the delivery, the cerclage was left in place.

In December 2013, the patient was five months into her second pregnancy. The physician performed an ultrasound to locate the original

cerclage, but he could not locate it. The physician placed a new cerclage on Dec. 12, 2013. A week later, during a follow-up visit, the patient reported discomfort and pain in her legs, abdomen, and lower back. The patient did not experience these symptoms after the first cerclage in 2011. Her husband inquired as to whether she may have been suffering from an infection. According to the patient, the physician ruled out the possibility of an infection without any further investigation.

Two days after the visit, the patient called the physician and reported continuing pain and fever. The physician prescribed nifedipine over the phone and instructed the patient to take Advil. The physician did not perform any physical examination. Four days after the phone call, on Dec. 26, the patient called again and spoke with a different physician who was on call that night. The patient reported continued pain and fever. The on-call physician instructed the patient to continue taking Advil, Tylenol, and nifedipine. Shortly thereafter, the patient called yet again, at which point the physician instructed her to go to the hospital. Upon arrival, a nurse recorded that

the patient experienced tachycardia, dizziness, lightheadedness, contractions, and discomfort. The patient indicated she had experienced fever and a change in vaginal discharge. The on-call physician was informed about the patient’s status over phone, but he did not go to the hospital to see the patient or to perform a physical examination.

An hour later, the patient’s membranes ruptured and released a yellow pus-like fluid followed by a green-brown discharge. The physician was immediately informed, but he still did not go to the hospital. An hour and a half after her admission, the patient’s temperature reached 100.8°F, and she was transferred to a nearby hospital that was better equipped with neonatal intensive care units (ICUs) as delivery appeared inevitable. The patient presented with severe bleeding, fever, ruptured membranes, pus discharge, and multiple organ dysfunction. Physicians immediately treated her for sepsis and chorioamnionitis by administering three complementary antibiotics and a blood transfusion. A blood test later confirmed the patient suffered from an *E. coli* infection.

The patient underwent an emergency cesarean section and was subsequently transferred to the ICU. She succumbed to the significant infection and resulting sepsis, and died on Dec. 31. The patient's surviving family filed a malpractice lawsuit against her physician and the on-call physician, alleging their actions were negligent and directly caused the patient's death. During the trial, the plaintiffs presented two expert witnesses: a physician who specialized in fetal medicine, and another physician who specialized in infectious diseases. The defendant physicians filed a motion with the court, asking to strike the expert witnesses' statements. The defendants argued the experts' statements failed to prove the physicians' actions caused the patient's death. The trial judge granted the defendants' motion.

Multiple appeals followed the trial court's ruling. The plaintiffs immediately sought an appeal to an intermediate court, arguing the trial court's ruling was erroneous. That intermediate appeal was granted, and the appellate court found the trial court's determination was in error. Next, the defendants appealed this determination, but the state's supreme court affirmed the trial court erred, and ordered that a new trial.

What this means to you: This case reveals the indisputable importance of experts. Important lessons from this case relate to challenging the sufficiency of such experts and whether the experts have offered opinions relevant to the proceedings. Who qualifies as an "expert" may be the proper subject of debate. It is possible for care provider defendants to challenge a patient's "expert," who may be a specialist in a different field or who may not offer an opinion about the specific circumstances applicable to a unique case.

In this matter, the defendants challenged whether the opposing

expert's evidence was legally sufficient to demonstrate causation. The specific legal definition of causation may vary on a state-by-state basis, but often is defined as whether the party's action or inaction played any part, no matter how small, in causing the harm, even if other factors also contributed to the harm. If multiple sources contributed to the harm, liability can be apportioned according to the varying significance levels of the harm. Here, the trial court initially determined the expert testimony did not sufficiently establish causation, as there was no testimony about what the defendants should have done and what the probable outcome would have been if they had done that.

However, the state's supreme court disagreed, ruling the evidence submitted was enough to survive the initial litigation stage and to be presented to the jury. The state supreme court noted that the expert testified that the patient "probably" had an infection based on the progression of symptoms, and that she "would have survived" if the infection was promptly and timely treated.

Challenging the sufficiency of experts and evidence may vary depending on the timing. This is a matter of legal procedure that can significantly affect medical malpractice actions and appeals. Since this case was not presented to a jury, but instead was summarily dismissed by the court during the trial, the legal review process is extremely deferential to the presented evidence. Courts are required to consider the evidence in the "most favorable" light, and to assume that a jury would believe any and all logical inferences. It is difficult to attack evidence prior to a jury's findings, and it may be a more beneficial option to argue this to the jury and attempt to sway the jury directly, rather than a deferential appellate court.

Upon review in this matter, the appellate court reversed the trial court's decision to exclude the experts, and mandated a new trial. In analyzing the testimony of the plaintiff's experts, the court noted that the first physician, a specialist in fetal medicine, clearly identified how the care providers breached their duty. The first negligent act was the treating physician's failure to perform a physical examination, or take the patient's vitals during the follow-up visit after the surgery. At that time, the patient already was experiencing pain in her abdomen. If a more thorough exam was performed and antibiotics prescribed, the patient would have survived. According to the court, this statement sufficed as proof of a causal link between the negligent conduct and the patient's death.

The second witness, a specialist in infectious diseases, claimed the patient suffered an intra-amniotic infection, which pathology confirmed. The expert also opined the infection progressed into the bloodstream, indicating the patient had suffered from it for a prolonged period. Had the patient been treated immediately after exhibiting early symptoms, the spread of the infection could have been prevented, and the patient most likely would have survived. With testimony from two qualified experts, the appellate court found that any remaining factual questions were for the jury to decide. Unfortunately, in this case, the challenge to the patient's experts was unsuccessful. However, each case is unique, as is each expert. Care providers should carefully review the propriety of challenging an opposing expert when faced with the option. ■

REFERENCE

Decided on Feb. 13, 2020, in the Supreme Court of the State of Virginia, Case Number 190019.