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INSIDE

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Vaccine Rollout Brings Legal, Labor Concerns for Employers

As the rollout of the COVID-19 vaccines continues, healthcare employers face complicated questions about what they can require of employees, how to handle employees who refuse the vaccine, and other potential legal consequences that may result in the coming months.

In December 2020, the Food and Drug Administration (FDA) granted emergency use authorizations (EUAs) for COVID-19 vaccines from Pfizer/BioNTech and Moderna. Distribution of the vaccines began throughout the country with the first doses going to frontline healthcare workers and long-term care residents at skilled nursing and assisted living facilities.

A survey by the American Nurses Foundation revealed only 34% of those surveyed said they would voluntarily take a vaccine if it were not required by the employer. Another 36% said they would not take it, and 31% were unsure. The main reason cited for not taking the vaccine was concern that it was developed too quickly.[1]

> "ALTHOUGH EMPLOYERS WILL LIKELY BE PERMITTED TO MANDATE THE VACCINE, THAT DOES NOT NECESSARILY MEAN AN EMPLOYER SHOULD."

Employers should be prepared for the issues that will arise relative to their employees and the COVID-19 vaccine, says **Timothy J. Ford**, JD, a partner with Einhorn, Barbarito, Frost & Botwinick in Denville, NJ.

"A common question is whether a healthcare employer can require employees to be vaccinated. The answer is generally yes, but with caveats," says Ford.

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The Equal Employment Opportunity Commission (EEOC) recently issued guidance indicating employers may mandate the vaccine, subject to some exceptions. The EEOC emphasizes employers should remember that "guidance from public health authorities is likely to change as the COVID-19 pandemic evolves. Therefore, employers should continue to follow the most current information on maintaining workplace safety."[2] *(See the story in this issue for more information on the EEOC guidance.)*

Throughout the pandemic, EEOC has characterized COVID-19 as a "direct threat," which is defined as "a significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation."[2]

"If an individual with a disability poses a direct threat despite reasonable accommodation, he or she is not protected by the nondiscrimination provisions of the ADA [Americans with Disabilities Act]. With the vaccine in distribution, it is possible for employers to require employees to be vaccinated in order to work or to return to work if the failure to vaccinate will result in a direct threat to other employees," Ford says.

However, as the Pfizer and Moderna vaccines have only received EUAs and not full approval, Ford advises employers to wait until the FDA expands authorization to its standard approval before requiring vaccination.

"Although employers will likely be permitted to mandate the vaccine, that does not necessarily mean an employer should," Ford notes. "The vaccine is in its early stages. Until the vaccine is more widely accepted by the FDA and by society at large, employers that try to mandate the vaccine for their employees may potentially face legal challenges. Another significant aspect of this issue involves the employment agreements and/or policies, as those will need to be reviewed and amended to account for the vaccination so that enforcement is uniform."

ADA Exemptions Apply

The EEOC has stated employees may be exempt from a mandatory vaccine if the employee has a covered disability under the ADA that prevents him or her from taking the vaccine, Ford notes. Under the ADA, employers must provide a reasonable accommodation to any employee with a covered disability that prevents them from receiving the vaccine.

Employers are not required to provide a reasonable accommodation if none is available, if the reasonable accommodation would present an undue hardship to the employer, or

EXECUTIVE SUMMARY

The COVID-19 vaccine raises several legal concerns for healthcare employers. It might not be wise to mandate vaccination for employees yet.

- Many healthcare employees have expressed skepticism about the vaccine.
- The emergency use authorization provides employees with a right of refusal.
- Labor unions should be involved with planning for vaccine programs.

if the employee would pose a direct threat to the health or safety of others, Ford explains.

In addition, an employee may be excused from the vaccine requirement under the religious accommodation provision of Title VII of the Civil Rights Act of 1964, Ford says. Employees must notify employers of sincerely held religious beliefs that prevent them from receiving the vaccine.

"By not requiring a vaccination, some might believe that the employer is failing to provide a safe working environment under the Occupational Safety and Health Act," Ford says. "However, there is no precedent for such a result. If your business is in healthcare or senior housing, there may be liability if the vaccination is not mandated."

The cost of the vaccines is covered by the federal government, Ford notes. However, there may be administrative fees or other costs. If there are costs that are not covered by insurance, employers should strongly consider covering any costs, Ford says, particularly if mandated under the company's employment policies. Employers also are strongly advised to pay employees for the time to travel to and from the vaccination location.

If an employee refuses the vaccine, the employer may have options that include termination, Ford says. In at-will employment states, employees can be terminated for any nondiscriminatory and nonretaliatory reason. Employers may terminate an employee for refusal to fulfill the requirements of his or her position and/or failure to be present at work. Refusing to take the vaccine could qualify for those reasons, Ford says.

However, if an employee has a recognized disability that would affect his or her ability to return to work in an environment with unvaccinated co-workers, state laws may require reasonable accommodation, Ford says. One of these accommodations may include remote work.

"The COVID-19 vaccination is a starting point in stopping the pandemic, but it is unchartered territory for employers," Ford says. "Employers can expect further guidance from their states and the EEOC. This is an evolving area of the law with many variables, and as such, prior to implementing any COVID-19 vaccination policies, employers should consult with counsel."

EUA Makes a Difference

Healthcare employers already have experience dealing with employees who refuse to take flu vaccines, notes **Jennifer L. Curry**, JD, shareholder with Baker Donelson in Baltimore. Many of the same issues will arise with the COVID-19 vaccine, she says.

The EUA aspect makes a difference. FDA regulations suggest an EUA vaccine or treatment cannot be mandated, Curry says. Employees must have the right to refuse the vaccination. *(For more on EUA, see the story in this issue.)*

"There is not necessarily a consensus on this, but my reading of the FDA regulations is that an individual cannot be required to receive a vaccine approved under the EUA," she says. "Once the vaccine is fully approved by the FDA, which I expect to happen, it is possible to mandate it. My recommendation would be strongly encouraging people to get it, but mandating it is not a good idea at this point and is not supported by law."

Curry notes healthcare employers should continue COVID-19 precautions, such as personal protective equipment (PPE) use and social distancing, even as employees receive the vaccine. If the vaccines are fully approved and the employer mandates vaccination, the program should include plans for accommodating those employees who cannot take the vaccine for health or religious reasons protected by the ADA, Curry says. That may include additional PPE, changing shifts, or reassignment to other tasks.

"If these accommodations are not enough, the employer may have to allow the employee to take leave, for example, until it is safe to go back to work unvaccinated," Curry says. "The same would apply to someone with religious claims, though employers are not required to do anything that would create an undue hardship for them. If you have a nurse who doesn't want the vaccine but doesn't have a health or religious exemption, there may not be many positions that person could fill at the same pay rate, so it might be an undue burden to allow them stay on even though they can't perform their nursing duties."

Curry points out the protected health or religious exemptions do not extend to general skepticism of the vaccine, or political beliefs. "If someone is generally antivaccination, whether as a social or political belief, that is not protected under the law. Once it is possible to mandate vaccination, the employer can choose what to do with that person based on his or her refusal."

Discuss Claims of Exemption

Religious objections also require proof, says **Jill M. Lashay**, JD,

shareholder with Buchanan Ingersoll & Rooney in Harrisburg, PA. Simply saying the words "religious objection" may not be enough. A physical disability also requires proof.

"Once the employee says he or she has a religious objection or a physical condition that prevents taking the vaccine, the employer has the right under the law to determine if it would be an undue hardship to accommodate this person," Lashay explains. "They have to engage in a dialogue about this so the employer understands the basis of the objections and can make an informed decision about accommodation."

Lashay says she is hearing considerable concern from employees about whether they can be forced to take the COVID-19 vaccine, consistent with the American Nurses Foundation survey results.

"We are hearing about pushback. I would anticipate that a lot of people who are uncertain about it will go to their physician and say they have some chronic pre-existing condition and it's not safe to get the vaccine," she says. "The religious objection could be part of an established, well-known religious faith, or the law says it also can simply be a sincerely held belief that constitutes a religion for the individual."

Avoid Discrimination Claims

If a healthcare employer decides to mandate the COVID-19 vaccine, it must have "evenhanded, across-the-board requirements and repercussions" to avoid discrimination claims, says **Jill K. Luft**, JD, officer with Greensfelder, Hemker & Gale in St. Louis. Risk managers also must work to avoid any violation of the National Labor Relations Act, which prohibits employers from taking disciplinary action against employees who engage in protected, concerted activity regarding conditions in the workplace.

If a person is harmed by a required vaccination, that would result in a workers' compensation claim, Luft notes.

"There are other practical considerations, such as the fact that it's a two-shot series and many people report feeling fatigued afterward. You may have to consider the possibility of having multiple employees out of work if you are doing a mass vaccination program," she says. "If a lot of your top performers or a big group of employees refuse to take it, what are you going to do? Are you going to lose a big chunk of your workforce?"

The flip side is that some employees may expect the employer to mandate the vaccine, she notes. Some hospitals are adopting plans to incentivize COVID-19 vaccination with paid days off after each of the two shots, gift cards, and other rewards in the vein of existing wellness programs, she says.

Union leaders should be involved in any plan for providing or mandating vaccines, notes **Devjani H. Mishra**, JD, shareholder with Littler in New York City.

"If union representation is not on board with something that can represent a fairly significant change, that can really affect the uptake and success of the program," she says. "We also are hearing questions about pay because there is some down time associated with getting the vaccine. Especially for hourly employees, there are questions about how that should be handled."

If the employer requires the vaccination, there will be more expectation that any time away from work for the actual injection and down time from side effects will be compensated by the employer, Mishra says.

An employee who cannot receive or refuses to take the vaccine might still be able to work in his or her usual role, Mishra says. The same PPE and infection control processes that were in place before the vaccine likely will continue for some time and will be just as valid. If a risk assessment determines the employee can perform duties with relative safety with the use of those precautions, that might be a reasonable compromise, she says.

"There are some positions in which the employee's work is 100% patient-facing, creating concerns for both the patient and employee. But in other roles, it might be that continuing with PPE is a sufficient mitigation to the employee not being vaccinated," Mishra says. "The key will be for employers to consider each situation in a detailed way, because the EEOC is taking the position that terminating someone is the option of last resort. Employers should be looking at what other options exist."

Mishra also notes that if the healthcare employer is providing the vaccine to employees or others, there are substantial recordkeeping and reporting requirements for an EUA vaccine. Risk managers and compliance officers should ensure those requirements are met.

Employers are in a difficult position if employees refuse vaccination for a documented medical reason or a sincerely held religious objection, says **David T. Azrin**, JD, partner with Gallet Dreyer & Berkey in New York City. In either case, the employer is obligated to make a reasonable accommodation that would allow the employee to continue working without taking the vaccine, while minimizing contact with others, Azrin says. That may include working

from home or separating from other employees or patients, if such an accommodation is feasible.

"If no accommodation is possible without causing undue hardship or burden on the employer because, for example, the employee cannot work from home and must have direct contact with patients or co-workers, then the employer can terminate the employee for not taking the vaccine despite the objections," Azrin says.

If an employer enacts a mandatory vaccine policy and does not allow an exception for medical or religious objections, the employer could be held liable for terminating employees with those objections, Azrin says. Employers who are found to have violated antidiscrimination laws can be held liable for the employee's lost wages for the period it reasonably takes the employee to find a new position, damages for mental distress, and attorney's fees, he explains.

"On the flip side, if an employer does not adopt a mandatory vaccination policy, and an employee who contracts the virus brings a claim against the employer on the theory that the employee was infected by a co-worker and that the employer failed to take adequate measures to prevent infection, such as mandatory vaccination policies, such a claim would likely be covered by the employer's workers' compensation insurance policy, which would provide a defense to the employer against the claim," Azrin says. "The employee will have difficulty in prevailing on such a claim unless the employee can prove with some reasonable degree of certainty that he or she contracted the disease at work."

If the employee does not demonstrate a valid medical or religious reason for not taking the vaccine, the employer can terminate an employee who refuses the vaccine, Azrin says. If the employee demonstrates a valid medical or religious reason, the employer must try to keep the employee by making reasonable accommodations to prevent the employee's exposure to other colleagues or patients. If this is not feasible without causing undue hardship, the employer can terminate the employee despite the medical or religious objections, he says.

"If the employee is a member of a union, the collective bargaining agreement negotiated by the union with the employer may limit the circumstances under which the employer can terminate employees and might prevent the employer from terminating the employee

HIPAA Issues Can Arise with COVID-19 Vaccinations

HIPAA can become an issue if healthcare employers require proof that employees have received a COVID-19 vaccine, says **Abbye Alexander**, JD, partner with Kaufman Dolowich Voluck in Orlando.

Under HIPAA, immunization records are protected health information, Alexander notes. Therefore, whether an employee has received a COVID-19 vaccine may be disclosed only by a healthcare provider if the employee has furnished the provider with their written authorization.

"Employers may ask their employees whether they have received the vaccine, but they may only seek information from the employee's medical provider with written authorization from the employee," Alexander explains. "Once this information is obtained, it may not be disclosed by the employer without the employee's consent."

Alexander notes that Equal Employment Opportunity Commission (EEOC) guidance states employers may require employees to provide proof that he or she received a COVID-19 vaccine. However, disclosure of information reflecting a disability could implicate the Americans with Disabilities Act, she says.

The EEOC seeks to prevent this by recommending employers' requests for proof of a COVID-19 vaccine also include a request that no medical information be disclosed along with proof of the vaccination, she says.

"HIPAA concerns are particularly noteworthy in healthcare employment settings where employees may be more likely to be offered vaccinations at their place of employment," Alexander says. "Healthcare employers should be mindful to ensure proper, HIPAA-compliant employee authorizations are obtained and retained in the same manner as patient authorizations." ■

SOURCE

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for not taking the vaccine," Azrin says. "If the collective bargaining agreement does not address the issue, such a policy would likely be considered an issue which the employer is legally obligated to negotiate with the union before implementing such a policy."

Because the situation is fluid, healthcare employers should monitor any new legislation or regulations, Azrin advises. If the pandemic worsens, and if vaccinations become more widely available and accepted, it is possible the legislature or government agencies might mandate vaccinations.

Some Vaccines Required

New York Public Health Law, and the laws of 15 other states, require all healthcare workers receive the measles, mumps, and rubella vaccine as a condition for their employment, and for public school students, Ford notes. In November 2020, the New York State Bar Association adopted a resolution urging the legislature to consider enacting mandatory COVID-19 vaccine policies if the pandemic cannot be controlled by other means and the vaccine is considered safe.[3]

"It is also possible that the Occupational Safety and Health Administration [OSHA] may issue further guidance on this issue. Currently, the OSHA worker safety regulations do not require employers to mandate vaccinations to protect employee safety, even for healthcare workers," Ford says. "Historically, OSHA has generally not issued vaccination mandates for healthcare workers for other similar diseases, such as the H1N1 influenza. But if the situation worsens and vaccines are proven safe and effective, OSHA could decide to issue regulations mandating vaccinations to protect employee safety, in which case employers would be legally obligated to require vaccinations."

Employers who mandate or administer a COVID-19 vaccine before employees return to work should be afforded liability protection under the Public Readiness and Emergency Preparedness Act (PREP Act), says **Erin S. Whaley**, JD, partner with Troutman Pepper in Richmond, VA. The Department of Health and Human Services amended the PREP Act in December 2020 to include provisions specific to COVID-19.[4]

The PREP Act should provide protection if the employer acts in accordance with its provisions and other appropriate guidance, Whaley says. If the CDC issues guidance recommending the vaccine, an employer's refusal to follow such guidance will not necessarily result in liability.

"Typically, state and local agencies and health departments have authority to enforce more or less restrictive requirements within their jurisdiction, which can result in conflicts between federal, state, local, and city requirements. For example, while the CDC may recommend the vaccine, certain states or localities may prohibit vaccination mandates, or limit such mandates to certain industries," Whaley explains. "Employers also should monitor guidance from relevant government agencies like the EEOC and OSHA."

Richard Gerakitis, JD, partner with Troutman Pepper in Atlanta, notes that although an employer may require employees to receive the COVID-19 vaccine to return to the office, telework or mask-wearing may constitute an appropriate and effective accommodation for certain positions.

Gerakitis cautions against using any EEOC-protected distinctions when determining work arrangements, such as avoiding those with health or religious objections to the COVID-19 vaccine.

"Regardless of whether a vaccine is required, as the EEOC recently confirmed, employers should avoid selecting individuals for return to work in the office or telework based on protected categories," he notes. ■

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EEOC Says Employers Can Mandate Vaccines — with Exceptions

Under certain circumstances, employers are permitted to mandate their employees to receive a COVID-19 vaccination as a condition of their employment, says **Henry Norwood**, JD, attorney with Kaufman Dolowich Voluck in Orlando.

That position was outlined by the Equal Employment Opportunity Commission (EEOC) in guidance published in December 2020. However, this guidance is not without its limits.

Title VII Requirements

Employers are limited by certain provisions of Title VII of the Civil Rights Act of 1964 and the Americans with Disabilities Act (ADA), Norwood says. Even a blanket requirement that all employees receive the vaccine must include exceptions.

Title VII requires employers to provide exemptions from any vaccine requirement to employees with sincerely held religious beliefs preventing them from receiving the vaccine, Norwood explains. Further, the ADA requires employers to provide exemptions from any vaccine requirement to employees with a disability that prevents them from receiving the vaccine. Employees with either a religious belief or disability exemption still can be required to receive the vaccine or be "excluded" from the workplace if their presence is a direct threat and no reasonable accommodation could reasonably mitigate the threat.

Four Elements to Consider

Norwood explains the EEOC put forth four elements to consider in determining the existence of a direct threat: the duration of time the risk will exist, the potential harm posed by the risk, the probability that any potential harm will occur, and the imminent nature of the potential harm.

"An accommodation is not reasonable if it would pose an undue burden on the employer. The EEOC delineates between 'excluding' employees and 'terminating' employees," Norwood explains. "While terminated employees will no longer be employed by the employer, 'excluded' employees may still be entitled to an accommodation that allows them to work away from the workplace if such an accommodation would be reasonable."

Other reasonable accommodations might include requiring additional use of personal protective equipment, isolated/relocated workstations, or removing employees from positions of public exposure, he says.

The EEOC guidelines are consistent with its prior guidance regarding mandatory vaccination requirements in the wake of widespread health crises, such as previous EEOC guidance in response to the H1N1 epidemic, Norwood says.

"It also should be noted that, in the healthcare context specifically, several state statutes currently require healthcare workers in certain settings to receive various vaccinations including, for example, influenza and pneumococcal vaccinations," he explains. "Employers seeking to implement mandatory vaccination requirements in their workplaces should provide their employees with clear procedures, providing them the option to claim either the religious or disability-based exemptions, while also conducting a threat analysis to determine whether certain employees may or may not be reasonably accommodated based on their position."

The EEOC guidance is available online at: https://bit.ly/35vxoau. ■

SOURCE

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Understanding Emergency Use Authorization Issues with COVID-19 Vaccine

Current COVID-19 vaccines have not undergone the process for full FDA approval, but have been authorized under a streamlined process known as an emergency use authorization (EUA), notes **Christopher Tellner**, JD, partner with Kaufman Dolowich Voluck in Blue Bell, PA.

Because the vaccines have only received an EUA, they are technically considered experimental and are subject to regulations that may affect whether employers are permitted to mandate their use by employees, he says.

Section 360bbb-3(e)(1)(A)(ii)(III) of the Food, Drug, and Cosmetics Act – 21 U.S.C. § 564 provides that people be informed of "the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."[1]

Because COVID-19 vaccines are authorized through EUA, as opposed to having been authorized via FDA approval, this section of the Food, Drug, and Cosmetics Act applies to the current vaccines, Tellner says. This section appears to require the Department of Health and Human Services to ensure people are informed of their right to refuse the vaccine, he says, but the EUA is silent on this topic.

"While this section may serve as grounds for employees to challenge mandatory vaccination requirements imposed by employers, it is too early at this time to determine the likelihood of success of such a challenge," Tellner says. "Should the current vaccinations eventually achieve full FDA approval, this section would no longer serve as grounds for a potential challenge to mandatory vaccination requirements." ■

REFERENCE

1. Federal Food, Drug, and Cosmetics Act 21 U.S. Code § 360bbb–3 - Authorization for medical products for use in emergencies. https://bit.ly/2XzD3rG

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- **Christopher Tellner**, JD, Partner, Kaufman Dolowich Voluck, Blue Bell, PA. Phone: (215) 461-1100. Email: ctellner@kdvlaw.com.

Nurse in Jeopardy for Refusing Hospital's COVID-19 Policy on Scrubs

A nurse in Minnesota claims he was fired for refusing to follow hospital policy regarding the use of scrubs during the pandemic, and the state nursing board is investigating his license. The nurse is suing the health system for whistleblower retaliation.

The case began when, during the early months of the pandemic, hospital managers instructed nurses to use and reuse their own scrubs instead of using garments provided by the hospital. Nurses countered they did not want to risk spreading the coronavirus by taking their scrubs home. The nurse in question was vocal in resisting the policy.

A pertinent question is whether the hospital used this policy before the pandemic or enacted it as a response, says **Svetlana Ros**, JD, partner with Pashman Stein Walder Hayden in Hackensack, NJ. Scrubs can be considered personal protective equipment (PPE), she says, and employers are responsible for providing and cleaning PPE.

"If they changed it because we were in the midst of a pandemic, I think that weakens their case," Ros says. "The question becomes whether they are considered PPE. OSHA generally says you can make your employees launder their scrubs, but there is a caveat that says 'unless the uniform or scrub has not been properly protected or become contaminated.'"

Ros says the nurse could reasonably argue the scrubs are contaminated and the employer is responsible for laundering. She wonders if the hospital provides disposable gowns to wear over the scrubs, or any other mitigating factor that would work in the hospital's favor to say the scrubs were not contaminated.

"In general, you can't leave [the facility] in your scrubs. Unless there's a way to claim they are not contaminated, the hospital has more exposure because they are shifting

their own responsibility to the employee," Ros explains. "The nurse is facing a difficult situation because even if he may have been in the right, the licensing board may focus more on his character and whether his behavior was appropriate, not necessarily whether he was right or wrong."

The whistleblower retaliation is a serious allegation for the hospital, but it could defend itself by showing the firing was the result of multiple documented instances of refusal to follow hospital policy, Ros says.

"I would imagine a good labor and employment attorney might be successful and will definitely test the bounds of the whistleblowing statute," Ros says.

Unless state law says otherwise, it should be possible for a hospital to require employees to wash their own scrubs, says **William H. Chamblee**, JD, managing partner with Chamblee Ryan in Dallas. With or without resource scarcity related to COVID-19, Chamblee says a hospital can establish that rule as a condition of employment and discharge employees who refuse to follow it.

"As long as you don't violate federal or state law, you can just walk in and terminate them. They can scream and holler and be mad, but they have no cause of action against you," Chamblee says. "People forget that both sides can end the relationship and you can end it any time you want, as long as you don't violate federal or state law. The hospital can follow lots of employee handbook procedures, but the bottom line is that the employer can establish conditions of employment and require employees to comply."

Employee handbooks do change the nature of the employer/employee relationship, Chamblee says. Once an employer establishes a procedure for handling employee behavior and termination, they must follow it.

"I've had many conversations about similar situations with risk managers and human resources people, and I tell them that you have far more rights with regard to employees than you give yourself credit for. Risk managers and human resources directors have far more rights in dealing with troublesome employees than they believe," Chamblee says. "This hospital in Minnesota apparently knew that they could go ahead and fire their employee, and they did. If there is a lawsuit against the hospital or health system, they absolutely will win." ■

EXECUTIVE SUMMARY

A Minnesota nurse refused to follow his hospital's policy on taking scrubs home and laundering them, rather than using hospital-provided scrubs. The hospital fired the nurse, who is alleging whistleblower retaliation.

- Nurses at the hospital resisted the policy because they did not want to take COVID-19 home to their families.
- The hospital may have been within its rights to enact the policy.
- Risk managers often do not realize how much authority they have to dismiss employees.

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New and Proposed HIPAA Rules May Offer More Protection

New legislation and proposed changes to HIPAA are aimed at resolving issues that created difficulties for both patients and covered entities.

On Jan. 5, President Trump signed HR 7898 into law, requiring the Department of Health and Human Services (HHS) to give covered entities credit for using best-practice security systems and processes for meeting HIPAA requirements.

The law amends the HITECH Act so HHS must consider whether a covered entity or business associate met recognized security practices when making enforcement decisions. *(The text of the bill can be found online at: https://bit.ly/2LeyZL6.)*

The law incentivizes covered entities and business associates for making their best effort at ensuring HIPAA compliance, says **Brad Rostolsky**, JD, an associate with Reed Smith in Philadelphia.

"This provides [reassurance to] covered entities that if they take certain meaningful steps for HIPAA

security, there is going to be meaningful consideration given to it," he says. "On the ground when you're dealing with OCR [HHS Office for Civil Rights], these are the conversations you have with the investigators. They want to know what your approach has been to compliance historically, whether you've been ignoring it and have policies in place just for saying you have them, or have you been doing the things you can do to keep everything secure."

The revision codifies and standardizes what was practice among some investigators. "It reinforces what we always tell clients, which is that the breach or other reason you're investigated can result in a back-door audit," Rostolsky says. "The best way to protect yourself is to show that you have historically been doing things the right way, and this legislation means [investigators] will consider that."

Also, OCR recently announced proposed additions to HIPAA intended to "support individuals' engagement in their care, remove barriers to coordinated care, and reduce regulatory burdens on the healthcare industry." The Notice of Proposed Rulemaking (NPRM) is part of HHS' effort to promote value-based healthcare by examining "federal regulations that impede efforts among healthcare providers and health plans to better coordinate care for patients."

OCR says the proposed changes would reduce administrative burdens on HIPAA-covered healthcare providers and health plans while strengthening individuals' rights to access their own health information, including electronic information, among other improvements. The proposed rule changes are available online at: https://bit.ly/3hUnS5C.

The regulatory change proposed by HHS in the recent HIPAA NPRM is another step in the HHS objective to encourage a patient-centric healthcare environment and reduce regulatory burdens on providers, says **Beth Pitman**, JD, partner with Waller Lansden Dortch & Davis in Birmingham, AL.

"The HIPAA NPRM tilts the balance of protecting privacy and facilitating availability of information toward loosening restrictions on disclosures of patient information. The big winner in the government's regulatory reformation race is the patient," she says. "In combination with the 21st Century Cures Act Information Blocking and Interoperability Rules, the proposed HIPAA regulations are intended to empower patients with greater access to information, remove barriers to care coordination by facilitating greater flow of information among healthcare providers and others participating in a patient's care, and make information readily available in the event of emergencies and as related to mental health and substance use disorder treatment."

HHS made serious efforts to align HIPAA regulations with Cures Act regulations, Pitman says. Many of the defined HIPAA terms were updated to reflect terms used in the Cures Act, and regulations were updated to account for anticipated increased use of personal health records and the availability of standards-based application programming interfaces (APIs) for transmission of electronic records, she says.

However, there remain some discrepancies in the two related sets of regulations, Pitman says. The period during which a provider must make information accessible to a patient in compliance with both regulations is uncertain. Under the proposed HIPAA Rule, the deadline is 15 days. The Cures Act Information Blocking Rule implies that electronically available information should be made accessible by patients in near real-time but refers to the HIPAA regulation, she notes.

The HIPAA proposed rule will also require that providers who have a standards-based API make patient records available in the form and format permitted through the API, Pitman says.

"While transition in the federal administration will certainly slow adoption of final HIPAA regulatory revisions and may result in curtailing the proposed loosening of disclosure restrictions, compliance with the Cures Act regulatory prohibition on information blocking is imminent," she says. "This impending compliance deadline may drive a more prompt but piecemeal finalization of Cures Act-related sections of the proposed HIPAA regulations."

It is premature for providers to

EXECUTIVE SUMMARY

New legislation and proposed rules will affect HIPAA compliance. Both actions are good news for covered entities and business associates.

- Investigators now must give credit for good-faith attempts to adopt recognized security practices.
- The Department of Health and Human Services is trying to align HIPAA regulations with Cures Act regulations.
- The proposed rule changes provide clarity around a covered entity's obligations and the fees that may be charged.

consider making policy revisions based on the proposed HIPAA rules, Pitman says. But considering the relationship between HIPAA and the Cures Act, providers should begin reviewing HIPAA policies for compliance gaps that relate to the Cures Act Information Blocking Rule.

Providers who use an electronic medical record (EMR) system (which is the large majority at this point) should begin discussions with their EMR vendors to determine the technology's ability to meet the Cures Act requirements as well as any of the HIPAA NPRM API-related provisions, Pitman says.

"Notably, the NPRM requests a comment on whether, if available through an EMR or at little cost, providers should be required to adopt an API for transmission of electronic records to patients and others. Under the Cures Act, only certified healthcare technologies are required to offer a standards-based API," she says. "Not all healthcare providers, such as many dental providers and speech therapists, use a certified technology."

Related to the patient's right of access, HHS tried to correct an administrative error highlighted in a case that implicated HHS guidance regarding patient's right to direct access or copies of records to third parties and the fees that may be charged, Pitman says. The proposed regulations codify much of the guidance and provide clarity around a covered entity's obligations and fees, she says.

Pitman notes these highlights of the proposed changes to HIPAA:

- Expands patient rights of access and aligns with 21st Century Cures Act Information Blocking provisions;
- Shortens deadline for providing access to 15 days;
- Right of access to electronic health record can be met by transmission to patient's personal health app;
- Requires access in form and format available through a standards-based API (to the same extent as required by the Cures Act) if the covered entity has adopted an API;
- Seeks comment on requiring use of an API by the covered entity if the cost is minimal;
- Fees can vary based on the type of access or copy, electronic vs. paper;
- Codifies guidance (which had been removed) related to a patient's right to direct delivery of records to a third party;
- Reduces paperwork and burden on patients and providers by no longer requiring patients to acknowledge receipt of the notice of privacy practices;
- Expands disclosures permitted for care coordination and case management and permitting disclosures to community-based, home care and others providing health-related services to individuals.

It is unclear how long it will take HHS to move from the comment period to the final regulations stage, says **Nathan A. Kottkamp**, JD, partner with Waller Lansden Dortch & Davis in Nashville, TN. Given the demands for public health communication in the era of COVID-19 and with HHS' recent emphasis on a patient's right to access their health information, it appears likely the timeline will be shorter than the roughly four years it took for the most recent revisions to be issued, he says. The Omnibus Final Rule was issued in 2013 in response to the 2009 HITECH Act.

The core concept of the current NPRM is increasing access rights for patients and facilitating information exchange for public health and health crisis purposes, Kottkamp says.

"From a public health perspective, the NPRM would facilitate information exchanges for public health matters such as a pandemic, responses to drug overdoses, and other situations in which health information may need to be shared with someone other than the patient," he says. "Significantly, the NPRM leaves the HIPAA Security Rule untouched. However, this does not mean that security practices will not be affected by revisions to the Privacy Rule."

From a cybersecurity perspective, it is almost certain that covered entities and business associates will need to revise their technology, vendors, and internal policies to implement any changes to the Privacy Rule, Kottkamp says. Of course, any operational modifications would call for reconsideration of security issues and updating of Security Rule Risk assessments.

"As we await next steps from HHS, providers should pay special attention to their patient access practices. Indeed, the OCR has recently issued its 13th Right of Access enforcement settlement," Kottkamp says. "Between the settlements and the NPRM, the OCR is very clearly signaling that patient access is a major priority, and providers should not wait until new rules are issued to be sure their current practices are consistent with the HIPAA regulations as they exist today." ■

SOURCES

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HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **According to Timothy J. Ford, JD, which is true if an individual with a disability poses a direct threat despite reasonable accommodation?**

   a. He or she is not protected by the nondiscrimination provisions of the Americans with Disabilities Act (ADA).
   b. He or she can be terminated without cause.
   c. He or she must be restricted from any form of patient care.
   d. He or she must be among the first to be vaccinated.

2. **The Equal Employment Opportunity Commission has stated employees may be exempt from a mandatory vaccine if:**

   a. the employee has a covered disability under the ADA that prevents him or her from taking the vaccine.
   b. the person has been employed for six months or less.
   c. the employee works in a position that involves no direct patient contact.
   d. the employee has not been exposed knowingly to a COVID-19-positive person.

3. **According to Svetlana Ros, JD, what does OSHA say is one reason a healthcare employer may be unable to require employees to launder their own scrubs?**

   a. The hospital owns a sufficient supply of scrubs and can launder them.
   b. The scrubs are contaminated.
   c. The hospital has not previously required employees to launder their own scrubs.
   d. Employees cannot launder their own scrubs.

4. **What does Brad Rostolsky, JD, say is the benefit of HR 7898?**

   a. Office of Civil Rights (OCR) investigators cannot consider a history of compliance with HIPAA.
   b. OCR investigators must consider good-faith efforts to comply with best security practices related to HIPAA.
   c. OCR investigators must inform covered entities of expected HIPAA violations before filing a final report.
   d. OCR investigators may ask about compliance with best security practices but cannot factor them into a final evaluation.

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

Hospital to Stand Trial for Botched Brain Surgery Performed with Recalled Laser

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News: A Texas appeals court ruled a trial court did not err in allowing the plaintiffs' expert to amend his report to address certain deficiencies, and that, consequently, the hospital would have to face trial for the permanent injuries a patient sustained following brain surgery performed with a laser device recalled by the FDA. The device was recalled because it could unexpectedly heat and cause brain tissue damage. The patient was dismissed from the hospital a few days after surgery, but began experiencing dizziness, vomiting, and loss of consciousness. A few days later, she was admitted to a different hospital, where she was diagnosed with a ruptured pseudoaneurysm. The injury caused permanent brain damage. On appeal, the hospital challenged the plaintiff's expert report, arguing it failed to provide sufficient facts regarding the connection between the alleged breach of proper care and the injury sustained. This appeal was rejected, and the court affirmed the trial court's decision.

Background: The patient, a minor, had epilepsy, which required treatment by a minimally invasive brain surgery. In July 2018, a physician employed by the defendant hospital performed the surgery using a NeuroBlate system. The system, an MRI-guided laser device, had been recalled by the Food and Drug Administration (FDA) in October 2017 because the temperature measuring system in the device was potentially inaccurate and could cause unexpected heating and probe damage. This unanticipated heating could warm the surrounding brain tissue, leading to damage to the tip of the probe, causing CO_2 cooling gas to leak into the brain. The FDA placed the system under a Class I recall, meaning device malfunction can cause death or serious injury. The physician who performed the surgery failed to disclose the device recall to the patient's parents.

THE PHYSICIAN WHO PERFORMED THE SURGERY FAILED TO DISCLOSE THE DEVICE RECALL TO THE PATIENT'S PARENTS.

Two days after the procedure, the patient was discharged; however, shortly thereafter, she started experiencing symptoms, including dizziness, vomiting, and loss of consciousness. The patient was admitted to another hospital for further treatment, where CT imaging revealed a large acute right temporal intracerebral hematoma, intraventricular hemorrhage, and acute hydrocephalus. Another procedure was performed to reduce swelling in the patient's brain. Additional scans revealed a pseudoaneurysm, which was treated at the hospital. Subsequently, the patient was transferred to a hospital in Tel Aviv for additional rehabilitation. According to the complaint, the patient suffered permanent brain damage.

The patient's parents filed a lawsuit individually and on behalf of their daughter, alleging the hospital and the surgeon who performed the procedure were negligent in using the recalled device, and had failed to disclose material information to the parents, consequently depriving them of their right to make an informed

decision on surgery. Defendants filed a motion to dismiss, arguing the plaintiffs' expert failed to establish a causal nexus between the procedure and the injury sustained. The trial court ruled in favor of plaintiffs. On appeal, defendants argued the trial court erred in allowing the amended expert report. However, the court of appeals concluded the trial court had not abused its discretion and the plaintiffs' expert report was sufficient.

What this means to you: As often is the case in medical malpractice cases, defendants made a concerted effort to dismiss the case based on the insufficiency of the plaintiff's expert report. Here, however, the court of appeals began its analysis by specifying that based on the applicable standard of review, the purpose of the plaintiffs' expert report is to demonstrate the plaintiff is not filing a frivolous lawsuit (i.e., that based on the opinion of a qualified medical expert, defendant's conduct breached the standard of care).

State laws vary concerning whether and to what extent an expert must validate a malpractice case before they are even commenced. This is called the "certificate of merit" process, requiring a plaintiff to obtain a medical expert's opinion that the facts give rise to medical malpractice before the case is even filed. Relatedly, states also vary as to what an expert must say to make the case stand up in court once it begins

Based on the applicable statute here, an expert report is sufficient when it identifies the applicable standard of care, identifies the manner(s) in which the physician's care fell short of the standard, and establishes a relationship between the substandard care and the injury the plaintiff sustained. The report need not be indisputable; it must merely show the plaintiff made a good-faith effort in complying with the statutory requirements.

In this case, plaintiffs' expert was a pediatric and adult neurosurgeon. The defendants noted the initial report submitted by the plaintiffs lacked certain information. The court allowed the expert to amend the report to address the deficiencies, which primarily related to why the FDA had recalled the NeuroBlate laser probe. The amended report explained the FDA's recall strongly advised physicians to treat patients using alternative methods whenever available.

ALTHOUGH THE OUTCOME OF A TRIAL IS NEVER CERTAIN, IN THIS CASE THERE ARE COMPELLING ARGUMENTS FOR DEFENDANTS' NEGLIGENCE.

The expert also analyzed the physician's report and noted the doctor had noticed an abnormal heating pattern during the surgery and later discovered a bleed in the patient's brain. The bleed was located in the same region of the brain where the patient suffered a massive bleed 16 days after the surgery. Based on the FDA's warnings, when the recalled laser probe excessively heated, the blood vessels in contact with the probe likely would be damaged, which could cause a pseudoaneurysm. A pseudoaneurysm occurs when the walls of a blood vessel are damaged, leading to blood leaking and collecting in the surrounding tissue. Based on the tests performed on the patient after the surgery, it was clear she had suffered from a pseudoaneurysm, which was one of the main risks the FDA indicated in its recall notice. Based on these facts, the court opined the expert's report satisfied the necessary statutory requirements and the trial court did not abuse its discretion in denying defendant's motion to dismiss.

It also should be noted that responsible healthcare facilities, including hospitals, surgery centers, and other settings where medical equipment is used, employ people responsible for monitoring the functionality of the biomedical equipment. Part of that responsibility includes monitoring for recalls of medical devices and reporting those recalls to areas in their facility that use the devices. Those departments are then required to remove the device or equipment from the shelves and return them to the manufacturer. These actions prevent the inadvertent use by a provider or staff member, and thus, the possibility of harm to the patient or the device user. Such arguments also could potentially bolster the plaintiff's case, depending on what the facts reveal about these issues.

Although the outcome of a trial is never certain, in this case there are compelling arguments for defendants' negligence. Given the detailed recall notice issued by the FDA eight months before the surgery, and the physician's operative notes indicating excessive heating and a brain bleed during the surgery, it is likely that with a strong expert witness, plaintiffs will have a good chance of prevailing during trial. ■

REFERENCE

- Decided Nov. 19, 2020, by the First Court of Appeals of Texas, Case No. 01-20-00146-cv.

Court Orders New Trial Over Hospital's Improper Closing Arguments

News: A court of appeals in Illinois ordered a new trial in a medical malpractice case. In the initial case, the trial court ruled in favor of the defendant hospital due to the hospital's closing arguments. The case involved a patient in the hospital's care while recovering from back surgery. A hospital employee dropped the patient while helping him into a wheelchair. The nurse who dropped the patient was not a party to the suit. However, the court said this did not matter because the nurse was an agent of the hospital; therefore, the hospital could be held liable for her negligence.

According to the complaint, the nurse did not alert the patient as she began lowering him into the chair, nor did she use a walker or other support device. The patient sought nearly $800,000 for present and future pain and suffering and for present and future medical expenses, alleging the fall worsened his leg weakness and caused severe pain. Defendants countered by claiming the nurse did use a walker and did cue the patient when she began to lower him. Further, the leg weakness was a known and documented risk for the surgery the patient received. During closing arguments, the defendant attorney made comments plaintiffs considered improper. Still, the jury ruled for the defense. On appeal, the court ordered a new trial, finding the evidence presented in the case was fairly balanced, and the defense attorney's improper comments might have skewed the jury, entitling the plaintiff to a new trial.

Background: In October 2010, the 57-year-old plaintiff underwent back surgery to remove a cyst. Immediately after the surgery, the patient experienced weakness in his legs. A few days after the surgery, while plaintiff was still in the hospital, a member of the nursing staff was helping the patient lower himself onto a commode when the patient unexpectedly fell. The impact, which caused the patient great pain, also exacerbated the feeling of weakness in his legs, to the point the patient described his legs as feeling "dead."

A few days after the incident, the patient underwent a second surgery to verify whether a screw may have been pressing on his nerves, causing the leg weakness. During the procedure, the physician removed a screw and, over time, the patient started to regain strength in his legs. The patient was sent to a rehabilitation clinic to relearn how to walk. At the clinic, the patient suffered a blood clot and an infection, and underwent a third emergency surgery. The patient was dismissed, and gradually continued to improve.

The patient filed a lawsuit against the hospital alleging the nurse who helped him to the commode had breached the standard of care and, because she was acting as an agent of the hospital, the facility also could be held accountable. The plaintiff alleged the nurse failed to use an assistive device (such as a walker) to help the patient lower himself, failed to involve a second person as an additional aid to help the patient lower himself, and failed to instruct the patient as to when to sit or how to descend. Because of these three alleged breaches, the patient fell onto the commode, which caused him pain, suffering, and additional injuries.

Several pieces of evidence were disputed. Specifically, the nurse testified she had used a walker to assist, while the plaintiff denied this. During closing arguments, defendant's counsel made several comments to which the plaintiff promptly objected. The jury returned a verdict in favor of defendants. The plaintiff filed a post-trial motion arguing the defendant's improper closing arguments warranted a new trial. The trial court rejected the motion and ruled the evidence supported the verdict. However, on appeal, the court ruled the improper closing arguments warranted a new trial.

What this means to you: The appellate court's decision focused on whether the non-party status of the nurse who allegedly dropped plaintiff was determinative in the case at hand. The court of appeals found the trial court failed to exercise its full range of discretion and had not carefully considered the fact that although the nurse was not a party to the case, her conduct was the object of the case, and it was unclear whether the jury fully understood that she was not a party to the matter.

The court of appeals stated that improper comments during closing arguments may taint the outcome of a trial if the comments are aimed at obtaining the jury's sympathy. Here, the defense's counsel repeatedly violated this standard by making improper comments about the plaintiff "mocking" the nurse while she testified, and about how many years a nurse would have to work

to obtain the sum requested by the plaintiff.

The plaintiff promptly objected to the comments. However, the trial court ruled the comments did not alter the outcome because the nurse was not a party to the case. Further, the court found the verdict was supported by the weight of the evidence. However, the appeals court found the comments were improper and likely affected the jury's verdict; therefore, a reversal was in order.

Both the trial court and the appeals court agreed the evidence was closely balanced. In fact, one of the key elements in dispute was whether the nurse used an aid in helping lower plaintiff onto the commode. Each side primarily relied on testimony; however, the plaintiff also demonstrated the nurse's notes did not indicate that any such aid was used. Further, the fact the nurse was not a party to the matter was irrelevant. In fact, the court found the relevant test to apply in this case was to determine whether the improper comments prejudiced the jury. Specifically, the court noted, reaching any different conclusion would essentially open the gate for attorneys to make many improper comments during closing arguments, as long as they do not pertain to a party. Further, the court added, if such improper comments are directed to a non-party, it may be inferred that purpose of such comments is solely to create sympathy in the jury, which is not allowed. Thus, the court concluded a new trial was warranted.

Because the evidence appears to be so balanced in this dispute, it is difficult to predict the outcome. While the plaintiff undeniably suffered injury and had to undergo two additional surgeries, it is not easy to establish the injuries occurred due to the fall. In fact, the weakness the patient experienced is a well-known risk of the surgery he received. Additionally, the nurse and plaintiff provided flawed testimony, with several memory gaps. The question at trial will ultimately turn on witness' credibility.

The first lesson that every nurse learns is that if an action is not documented, it did not happen. This case demonstrates that lesson. Often, electronic records are designed to prompt the nurse to document "by exception," which assumes that orders are followed and procedures and protocols are carried out unless there is documentation otherwise. While this speeds up the documentation process, it can present a nightmare for defense counsel. In other words, if the nurse did not document that a walker was used to assist the patient to transfer to the commode, but the policy for patient transfers states a walker must be used, that would suffice for a licensing or accreditation agency, but could be arguable in front of a jury. Direct and specific documentation is the best approach in court. ■

REFERENCE

- Decided Dec. 12, 2020, in the Appellate Court of Illinois, Second District, Case No. 2-19-0684.