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LAWYER'S WEEKLY USA FEATURE STORY

Over-The-Counter Defibrillators May Increase Duty For Businesses

By Reni Gertner

The FDA has given clearance for the first time for over-the-counter sales of defibrillators - which might make it easier for plaintiffs' attorneys to prove that businesses have a duty to have a defibrillator on the premises, and breach that duty if they fail to buy one.

Automatic external defibrillators (AEDs) are used to treat an individual suffering sudden cardiac arrest whose heart is beating irregularly. Several legal battles have already been fought against health clubs that didn't have the devices, and some experts have argued that they should be required in many more business establishments.

[Ronald C. Kidd](#), a Springfield, Mass., attorney who has represented plaintiffs in defibrillator cases, said "there's no doubt" that the FDA's action "raises the bar."

"As [defibrillators] become more available, clearly I think it becomes easier for a jury to find that [a business] is negligent not having one," Kidd said.

He said this would especially be true for establishments such as health clubs, where sudden cardiac arrest is more common, as well as places where large numbers of people frequently attend, such as banquet halls, hotels and churches.

Howard Pomerantz, a Sunrise, Fla., attorney who has handled AED cases, said the FDA's decision "is additional evidence that AEDs are safe to use and will counter the traditional argument that these are devices that are not yet the standard of care."

The change is likely to increase not only the use but also the public awareness of defibrillators - which is likely to boost the number of cases and slowly shift the focus of litigation from the question of whether a business had a device to whether it used it and used it properly.

"This is going to be a fight in the courts for the next decade," said Richard A. Lazar, the chief executive officer of the Early Defibrillation Law and Policy Center in Portland, Ore. "As more and more devices are deployed in the private sector, the suits are not going to be about whether it was bought, but how it was deployed."

Business lawyers said the decision raises concerns for their clients.

It puts businesses "between a rock and a hard place," said Boston attorney Kurt B. Gerstner, who represents plaintiffs and businesses. "Once the use becomes so ubiquitous that it becomes the standard of care, if you don't have them, then you are challenged, and if you do, then you have to make sure they are used."

Edward P. Richards, a professor of law, biotechnology and public health at Louisiana State University, said that "people will die having had a defibrillator used on them, and there will be an industry that develops in suing afterwards."

The FDA approved one particular device for home use, the HeartStart Home Defibrillator, manufactured by Philips Medical Systems in Andover, Mass. The agency based its decision on proof from the company that the device could be used without medical supervision, and the recommendation of an advisory panel that met in July to evaluate the product. The device sells for \$2,000.

Duty For Businesses?

Some experts say that the FDA's approval of over-the-counter defibrillators could substantiate plaintiffs' arguments that businesses have a duty to have them on the premises.

"A plaintiff could make the case that it raises the duty. Like any other situation, the standard of care represents the community's expectation for a particular behavior. But it takes a long time to come into existence," said Lazar.

Gerstner noted that "as you get more usage of these devices, it creates a greater incentive for plaintiffs' lawyers to say that there is a new standard of care that exists."

Kidd said this would lessen the effectiveness of defense arguments that "relied on the notion that this was a sophisticated piece of equipment that needed specialized training and as a result, there was essentially no legal duty to have one."

But Lars Noah, a professor of torts and medical technology at the University of Florida, said that the availability of over-the-counter defibrillators doesn't change the question of whether a business has a duty to have one.

"This just provides some evidence this agency thinks anyone can use these [devices]," he said. "To imagine every facility that has people coming through it has to have these devices on hand, that's an enormous burden."

Richards agreed that the existence of a duty isn't clear.

"You have to protect people from risks inherent in your business and undiscovered hazards but beyond that, it's hard to say a business has any special relationship," that would create a duty to have a defibrillator, he said. "The notion you have to buy a fairly expensive medical device to protect someone who might have a heart attack is hard to justify."

Determining whether the standard of care requires a business to have defibrillators on its premises will depend on the relevant state law and what industry the business is in, Lazar said.

John O. Spengler, a professor in the department of recreation, parks and tourism management at the University of Florida, said, "You have to look among industries to determine if the bar is raised. [For example,] if more golf courses started using defibrillators, it would raise the bar for others."

Lazar suggested that it would likely be easier to prove a duty to have a defibrillator in a health club setting, than in a small restaurant.

To have a strong defense in case a suit arises - and to avoid suits in the first place - businesses that do have defibrillators should focus on deployment, assessing carefully how many devices they need and where to place them.

"When you design a program you have to make sure you design it to achieve your response time goals," said Lazar.

That means having enough defibrillators and enough people trained to work them such that if someone collapsed anywhere in the building, the response time "from collapse to shock" would be no more than three to four minutes, Lazar said. The devices are 90 percent effective for ventricular fibrillation if used within one minute, but that success rate declines by seven to ten percent for every minute that goes by after that.

He recommends that businesses document their programs carefully, so in the event of a suit, "you can point to the appropriate policies and procedures used."

More AEDs, More Suits

Experts said the more defibrillators are utilized, the more lawsuits there will be over the use of them - and the lack thereof.

Gerstner said he is currently representing the family of an individual who died of sudden cardiac arrest in a hotel that had AEDs but failed to use them.

Lazar expects suits will start to focus on whether the business had a well-functioning program for the use of defibrillators.

As a result, lawyers will have to answer several questions in evaluating cases, including:

- How many devices did the business have?
- Where were they placed?

- How many employees were aware of them?
- How many were trained in using them?
- Was the device used quickly enough? And if not, why not?

Lazar described a lawsuit over a situation where a man "collapses on tennis court, they call 911 and it takes 12-14 minutes for the ambulance to get there, and it's too late. The health club has an AED at the desk but the person on duty didn't know about it and wasn't trained in using it. That's a program flaw."

He cited another example: An 18-year-old girl collapses at a shopping mall. Someone calls mall security, but no one answers. Then they call 911, and the ambulance gets there too late, so she dies.

"The mall had five AEDs controlled by security, but no one answered the phone," Lazar said. "There you've lost your [no] duty defense because you have assumed a duty to design a program that is reasonable."

A business should also have a system in place to maintain the devices and make certain the batteries don't run out, said Kidd.

That includes "making sure all the parts of the device are present at all times," said Gerstner.

Cases might arise if an entity had defibrillators but didn't have an employee trained in their use present at the time of the cardiac arrest.

However, given that the HeartStart device has been approved for use by laypeople, lawyers could argue that users don't need training.

"At Chicago O'Hare airport, which is equipped with defibrillators, 60 percent of the saves were performed by people who had never used" the devices before, according to one study, said Lazar.

"Sixth graders can work [the devices] almost as quickly as trained paramedics," he claimed. "Businesses can't credibly say they have no duty because these things are hard to use."

However, Gerstner suggested that a child or someone who has never used the device might not be able to do so quickly enough in a pressure situation.

"In an emergency, there is a heightened level of tension when there is a concern you could do harm," he said. "Would you want some third grader using an AED in a real cardiac emergency situation?"

Several states have Good Samaritan laws intended to shield people who unsuccessfully use a defibrillator on someone from liability. Some states require that users go through training in order to be insulated from liability.

But Kidd said he believes the device is very "user-friendly" and not likely to be used improperly. "I am not aware of any situations where there has been bystander liability for failing to use the device properly," he said.

Pomerantz agreed.

"If someone is unconscious, and you put a defibrillator on him and [his heart] is not in a shockable rhythm, the computer is sophisticated enough" not to apply a shock, he said.

No Guarantee

Pomerantz said that in 20 percent of sudden cardiac arrest cases, the individual will have a heart rhythm that defibrillation cannot help. Thus, there will be situations in which someone dies, yet it is not the fault of the person administering the shock.

"In the cases we investigate, we get the paramedics' records," which include an EKG stream and other data, said Pomerantz. "In discovery, I ask questions to establish whether the signs and symptoms are such that the person was probably in one of those treatable heart rhythms, such as whether they were respirating, unconscious or pulseless."

These issues might make proving cases difficult across the board.

Alan G. Minsk, a partner and leader of the Food and Drug Practice Group at Arnall Golden Gregory LLP in Atlanta, said, "if someone obviously needed a defibrillator, they were not in a good state to begin with. How do you prove it was the machine or the person using it [improperly] and not that the person would have died even without the machine?"

Richards agreed that the issues could make risk management complicated for businesses.

"What if your business uses [the defibrillator] and the person dies anyway? Is the business going to be fighting a negligence suit every time [it] uses one?" he asked. "This is something that will make a thoughtful business very nervous."

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