

- SUBJECT:** Acquisition of non-prescription automated external defibrillators.
- COMMITTEE:** Public Health —favorable, without amendment
- VOTE:** 8 ayes — Delisi, Laubenberg, Cohen, Coleman, Gonzales, S. King, Olivo, Truitt
- 0 nays
- 1 absent — Jackson
- WITNESSES:** For — Stephen Brown, American Heart Association; Constance Snell; Gary Terry
- Against — None
- On — Tom Brink, Texas Department of State Health Services
- BACKGROUND:** An automated external defibrillator (AED) is an electronic device that administers an electrical shock at a preset voltage to the heart during a cardiac arrest in an attempt to restore normal heart rhythm. The voltage for over-the-counter AEDs cannot be changed by the owner.
- Currently, a doctor's prescription is required to purchase an over-the-counter AED in Texas. Under Health and Safety Code, sec. 779.007, a person or entity may acquire an AED only if it has been delivered or prescribed by a licensed physician. In 2004, the Food and Drug Administration approved some AEDs for over-the-counter sale without a doctor's prescription.
- DIGEST:** HB 92 would amend Health and Safety Code, sec. 779.007 to allow FDA-approved, over-the-counter AEDs to be sold in Texas to the general public without a prescription. Only AEDs that were not FDA-approved would require a prescription.
- The bill would take immediate effect if finally passed by a two-thirds record vote of the membership of each house. Otherwise, it would take effect September 1, 2007.

SUPPORTERS  
SAY:

HB 92 would bring Texas in line with the federal policy of allowing sale to the general public of non-prescription, over-the-counter AEDs, as long as the AED was FDA-approved. It also would eliminate some of the costs of acquiring an AED because a person who wanted to purchase an AED no longer would have to visit a physician to get a prescription and pay the co-pays and doctors visit fees. Although AEDs are comparatively expensive, their benefit far outweighs the detriment of loss of life.

AEDs have the potential to save lives. Medical studies have demonstrated that intervention in a cardiac arrest with AEDs improves survival rates. These studies also have demonstrated that most cardiac events occur in the home or the office, where medical personnel are not always immediately available. If AEDs were available in these locations, the survival rate from cardiac arrest could be increased drastically.

AEDs are relatively easy to use and the potential for misuse has been minimized. An AED will operate only if it detects that there is no heart rhythm. AEDs come with a training DVD that guides users through the steps of use and teaches owners CPR. Many AEDs offer written or audio prompts that direct the user through the appropriate steps. The AED, once it has been used, gives a repeated audio prompt to contact 911 for additional medical assistance. The Health and Safety Code still directs owners of AEDs to perform routine maintenance and to register their AEDs with EMS, and these requirements would be unchanged by HB 92.

All AEDs come with registration cards that owners are free to fill out and return to the company for monitoring. Further, any potential problems or defects with an AED would be tracked by the FDA and if they became dangerous, the FDA would issue a recall for the device. The FDA has issued recalls for prescriptive AEDs in the past, but not for over-the-counter AEDs.

OPPONENTS  
SAY:

Acquisition of AEDs should remain under medical supervision through the prescription process. The general public may be unwilling or unaware of the need to get the skills and training they need to make their AEDs as effective as possible. Any person who operates an AED must know CPR to use the device effectively. It could be dangerous and potentially fatal if people purchased an AED without realizing that CPR was a necessary skill for operation of this device. Further, a person should have training with the AED in order to use it effectively. If a person was unfamiliar with the audio or written prompts, they could waste valuable time trying to

understand the next step in the AED procedure. Also, people who used an AED could fail to contact medical personnel after a cardiac event because they believed the problem had been alleviated.

The high cost of and periodic maintenance required by an AED make it an impractical option for the general public. AEDs generally cost about \$1,500, and health insurance rarely covers the cost. Untrained owners could be unwilling to perform the periodic recalibration and upkeep that AEDs need, causing the AED to malfunction and become useless or even harmful.

It would be difficult for the average citizen to remain informed about potential problems with AEDs because the information sources for these problems are read mostly within the medical community. A study recently published in the Journal of the American Medical Association found that 10 percent of AEDs had the potential to cause serious adverse health consequences. This study also found that FDA and manufacturer post-sale tracking of the performance and defects of AEDs was inadequate. It is unlikely that an average citizen would read these studies to learn about these problems.

**NOTES:**

A related bill, SB 7 by Hinojosa, which would require public schools and school athletic activities to have an AED present as well as someone who knew how to use the AED and was trained in CPR, passed the Senate by 29-0 on March 19.