FDA Proposes New Rules for Heart Defibrillators

The Associated Press

The Food and Drug Administration will require makers of heart-zapping defibrillators to submit more data on their safety and effectiveness following years of recalls of the emergency devices.

Defibrillators use electric shocks to jolt the heart back to normal after patients collapse from cardiac arrest. Once used exclusively in emergency rooms, they are now found in schools, office buildings and other public places.

The devices have been plagued by design and manufacturing flaws for years. The FDA says it has received 45,000 reports of problems with defibrillators between 2005 and 2012.

Currently the FDA approves defibrillators through a fast-track process reserved for devices similar to ones already on the market.

The FDA proposal, when finalized, will require manufacturers to submit more extensive testing documentation before new defibrillators can be marketed.