DEPARTMENT OF HEALTH SERVICES
PUBLIC HEALTH SERVICES
BUREAU OF EMERGENCY MEDICAL SERVICES
#SP-073-PHS-EMS

APPROVAL OF MEDICAL DEVICES

This substantive policy statement is advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona Administrative Procedure Act. If you believe that this substantive policy statement does impose additional requirements or penalties on regulated parties, you may petition the agency under Arizona Revised Statutes § 41-1033 for a review of the statement.

The purpose of this substantive policy statement is to notify the public of the policy of the Arizona Department of Health Services (Department) regarding the Department's approving medical devices for use by an emergency medical care technician (EMCT) in the prehospital emergency medical services (EMS) setting.

Arizona Revised Statutes (A.R.S.) § 36-2205(A) requires the Department, "in consultation with the medical director of the emergency medical services and trauma system, the emergency medical services council and the medical direction commission," to establish "protocols, which may include training criteria, governing the medical treatments, procedures, medications and techniques which may be administered or performed by each classification of emergency medical care technician."

A.R.S. § 36-2205(A) does not require the Department to establish protocols governing the medical devices that may be used by EMCTs in the prehospital EMS setting. Therefore, the Department believes that it is unnecessary for the Department to approve a specific medical device for use by EMCTs in the prehospital EMS setting if the device has approval from the U.S. Food and Drug Administration and is used to accomplish or facilitate a treatment, procedure, or technique that is within the scope of practice of the classification of EMCTs that will be using the device.

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Arizona Department of Health Services
Division of Public Health Services
Bureau of Emergency Medical Services and Trauma System
150 North 18th Avenue, Suite 540
Phoenix, AZ 85007