STATE OF ARIZONA ● EMERGENCY MEDICAL SERVICES AND TRAUMA SYSTEM

Drug Shortages

Background

In the past few years, emergency medical services (EMS) providers have periodically been unable to comply with minimum supply requirements for certain agents due to national or regional shortages of these agents. In some instances, EMS providers may be able to utilize an agent beyond its expiration date if a specific lot of the agent is authorized for extended use by FDA during a drug shortage. National drug shortage information is available on the Federal Drug Administration (FDA) website, including FDA Drug Shortages (at https://www.accessdata.fda.gov/scripts/drugshortages/) and FDA Extended Use Dates (at https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages).

The intent of this guidance document is to inform EMS providers how the Bureau of Emergency Medical Services and Trauma System (Bureau) will accommodate an EMS provider who, despite efforts to locate and obtain a required agent, formulation, concentration, or delivery vehicle, is unable to meet the minimum supply requirements.

Process

Arizona Administrative Code (A.A.C.) Title 9, Chapter 25, Article 5, and Table 1 (EMCT Drug Box) establish the agents and minimum supplies that an EMS provider or base hospital is required to furnish for use by an emergency medical care technician (EMCT). *See* https://www.azdhs.gov/preparedness/emergency-medical-services-trauma-system/index.php#chapter-25. The Bureau is aware that some of the agents required in Table 1 may periodically be unavailable for purchase due to a national or regional shortage. Although specific lots of some of these may have been approved for extended use according to the FDA, extended use of an agent beyond its expiration date does not apply to all lots or to all agents.

When an EMS provider or, if the EMS provider obtains agents through a base hospital, the base hospital does not have, and is unable to obtain, the minimum supply of a required agent in Table 1, the EMS provider or, if applicable, the base hospital must submit to the Bureau the documentation specified below. This request must be reviewed and approved by the administrative medical director. The Bureau will review the method proposed by the EMS provider to address the shortage to ensure that the health and safety of the public is protected. If the request meets those standards, the Bureau will send the EMS provider notification that the Bureau will not cite the deficiency for 90 days after the Bureau receives the documentation. If a specific lot of the agent is approved for extended use by the FDA, the Bureau will also notify the EMS provider of how to obtain that information. If, after 90 days, the EMS provider remains unable to obtain the minimum supply of the agent, the EMS provider must again submit to the Bureau the documentation specified below, reflecting new efforts to obtain the agent.

During an inspection, an EMS provider must provide the inspector with a copy of the Bureau's response to the submitted documentation specified below if the EMS provider or, if applicable, base hospital does not meet the minimum supply requirements of any agent in Table 1. The documentation specified below will not be accepted retroactively after a citation, but the EMS provider may submit it to the Bureau to prevent further citations if the EMS provider cannot obtain the required minimum supply of the agent.

Documentation of good-faith effort to obtain a required agent:

The documentation must contain the following:

1. The name and contact information for the EMS provider or, if applicable, base hospital making the request.

2. Contact information, including date of contact, for three sources through which the EMS provider or, if applicable, base hospital attempted to obtain the agent. The sources can be distributors, other health care providers, or any other reseller that could reasonably be expected to be able to sell agents to the EMS provider or base hospital.
3. Instructions issued to EMCTs indicating:
    a. An alternative agent also listed in Table 1, including formulation, concentration, or delivery vehicle to be used in place of the listed agent; and
    b. If applicable, that an expiring agent in the possession of the EMS provider may be used until a specific date, according to extended use guidelines by the FDA.
4. A description of training provided to EMCTs about administering the alternative agent, formulation, concentration, or delivery vehicle to avoid medication errors.
5. **Attestation statement**: "I attest that I have made a good-faith effort to obtain [name of agent] from the sources described herein for use by [EMS provider], but was unable to obtain the required minimum supply. I issued the instructions and training described herein to EMCTs on alternative administration methods during the shortage."
6. Printed and dated name and signature of the administrative medical director. The signature may be electronic.
7. Printed and dated name and signature of a representative of the EMS provider or, if applicable, base hospital. The signature may be electronic.

Submit the documentation to the Bureau Chief via email or fax.