WHITE PAPER

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Breaking down USP Good Distribution Practices for EMS

USP Chapter 1079 and EMS Accreditation: What you need to know

Your business is all about saving lives. That includes having the best trained staff and most current technology and equipment to ensure both the fastest response times and the best patient outcomes. But, as you know, there's so much more that goes into maintaining the highest quality of care – even down to the seemingly smallest detail, like keeping medications within their ideal temperature range.

There are a variety of standards that EMS organizations can use to make sure they are up-to-date with industry best practices where safe temperatures are concerned. However, the content is dense and related information may be included in more than one section. That's why we're taking the time in this VUEPOINT to highlight what matters most about temperature monitoring for ambulances and other EMS vehicles as well as storage facilities like station refrigerators.

First...Some Industry Background

The US Pharmacopeia (USP) has had standards in place for many years around the best practices for shipping and storing pharmaceuticals. USP Chapter 659 Packaging and Storage Requirements provides definitions for appropriate and various packing materials as well as storage conditions, specifically temperature definitions – from frozen and refrigerated, to cold and cool, to room temperature and controlled

room temperature. There is also information related to allowable temperature excursions and how best to measure and track temperature, all meant to protect the integrity of drugs as well as ensure patient safety.

More recently, as the industry has been working toward Good Distribution Practices – the USP updated their guidelines to include Chapter 1079 Good Storage and Distribution Practices for Drug Products. This informational chapter builds on the definitions provided in the earlier Chapter 659 and is used as guidance for all organizations and individuals involved in any aspect of the storage and distribution of all drug products, including Emergency Medical Services.

These USP guidelines, and in particular USP Chapter 1079, are the basis for the standards set forth by both the Commission on Accreditation of Medical Transport Systems (CAMTS), which covers air and ground services, and the Commission on Accreditation of Ambulance Services (CAAS), which covers ground transportation specifically. While not required, many EMS providers seek accreditation from one or both CAMTS and CAAS as a point of differentiation and illustration of best practices – and understanding the USP standards is important to meeting the requirements for accreditation. The USP guidelines can be found at http://www.usp.org./

The Commission on Accreditation of Ambulance Services

In Version 3.0 of CAAS standards, released in October of 2009, Section 203.03.04 covers temperature extremes saying:

> *"The agency shall have a policy/procedure for the storage of medications and IV fluids that allows for protection from extreme temperature changes. The policy shall also include a procedure for what to do if medications or IV fluids do get exposed to extreme temperatures."*

The Commission on Accreditation of Medical Transport Systems

As noted, CAMTS includes air transportation in its standards in addition to ambulances, vans and other ground EMS vehicles. In the tenth edition of their accreditation standards, updated in October of 2015, the CAMTS states in Section 03.06.00, Page 3.27 and 3.28:

> *"Storage of medications allows for protection from extreme temperature changes if environment deems it necessary. If there is a refrigerator on the vehicle for medications, a temperature monitoring and tracking policy is required, and the refrigerator is used and labeled 'for med use only.'"*

Then on Page 3.29 regarding blood products:

> *"Determination of when the blood product was released from the Blood Bank. Blood must be maintained at a controlled temperature of 2-8 degrees C during transport and must be infused within 4 hours of removal from thermal control. The temperature of the cooling mechanism is monitored and recorded."*

CAMTS standards also address cabin temperature on Page 3.33:

"The interior of the aircraft must be climate controlled to avoid adverse effects on patients and personnel on board. (RW/FW/S)

a. Cabin temperatures must be measured and documented every 15 minutes during a patient transport until temperatures are maintained within the range of 50-95 degrees F (10-35 degrees C) for aircraft and range of 68-78 degrees F (20-25.5 degrees C) for ground vehicles. Thermometer is to be mounted inside the cabin.

b. The program has written policies that address measures to be taken to avoid adverse effects of temperature extremes on patients and personnel on board.

c. In the event cabin temperatures are less than 50 degrees F or greater than 95 degrees F, the program will require documentation be red flagged for the QM process to evaluate what measures were taken to mitigate adverse effects on the patient and crew and what outcomes resulted.

d. For those flights meeting the definition of "long range," additional policies must be in place to address how adequate cabin temperature will be maintained during fueling and/or technical stops to ensure patient, crew and passenger comfort."

How You Can Ensure Compliance with Accreditation Standards

In general terms, the standards do not specifically define extreme temperatures, which is why it's important to understand the guidelines outlined in USP Chapter 659 and what is considered extreme temperatures.

Temperature Ranges According to USP Chapter 659

Frozen	Between -25° and -10°C (-13 and 14°F)
Refrigerated	Between 2° and 8°C (36 and 46°F)
Controlled Room Temperature	Between 20° and 25°C (68 and 77°F) with allowable excursions [see Good Storage and Distribution Practices for Drug Products (1079)]
Warm	Between 30° and 40°C (86 and 104°F)
Excessive Heat	Any temperature above 40°C (104°F)

Source: USP Chapter 659 Packaging and Storage Requirements

It also means EMS providers need to have processes in place that reliably monitor temperature. An electronic monitoring device that records temperature throughout storage is the preferred method for determining if medications or IV fluids and blood product have been exposed to extreme temperatures.

An electronic monitoring device is also useful in monitoring cabin temperature, as described in the CAMTS standards. In a manual environment, personnel would need to look at the thermometer and write down the temperature in 15-minute increments – a process that's highly prone to human error and uses valuable time, especially in emergency situations. Using an electronic monitoring device, the temperature is recorded continuously, and data can be easily downloaded, stored in the cloud and accessed via a web portal on-demand.

You can access the full set of standards at *http://www.caas.org* and *https://www.camts.org,* and the USP Guidelines at http://www.usp.org/.

Learn more about the EDGE products and EMS medication temperature monitoring at *temptimecorp.com/edge*

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