

What Is The Latest FDA Thinking About Emergency Use Of Oxygen?

According to the FDA, any oxygen inhaled by a human or animal is considered a drug as per section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), and is required to be dispensed by prescription. *However*, the agency allows medical oxygen to be dispensed without a prescription to properly trained individuals for oxygen deficiency and resuscitation, as long as the following conditions are met:

- 1) A high-pressure cylinder filled with medical oxygen and used for oxygen deficiency and resuscitation must have the following statement present on the drug label: "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only."
- 2) The equipment intended for such use must deliver a minimum flow rate of 6 liters of oxygen per minute for a minimum of 15 minutes, and include a content gauge and an appropriate mask or administration device, and
- 3) Proper training is documentation that an individual has received training within the past twenty-four months or other appropriate interval, in the use of emergency oxygen including providing oxygen to both breathing and non-breathing patients, and safe use and handing of emergency oxygen equipment. Training may be obtained from any nationally recognized professional organization, such as the National Safety Council, the American Heart Association, the American Red Cross, etc.
- 4) Under no circumstances can emergency oxygen be used to fill high-pressure cylinders or be used in a mixture or blend.

Once all of these conditions are met, an individual may have access to medical oxygen without a prescription.

Keep in mind that this is the Federal FDA position and that some state Boards of Pharmacy may have different rules.

Recommended Practice

AsteRisk recommends that you have a training record or certificate when you distribute medical oxygen for emergency use without a prescription. Consider the attached certificate or one supplied by a national training organization. If you have questions about this, or other FDA issues, please contact Tom Badstubner: tom@asteriskllc.com or 508-883-0927.

Health Care Professional/Emergency Responder Training Certification

I am a health care professional and/or an emergency responder. Administration of emergency oxygen is a normal element of my professional activities. I attest that I am familiar with the use and administration of emergency oxygen and have received relevant training in this subject.

Print Name _____ Date _____

Signature _____

Date of training _____ Valid until (max 2 years) _____