

FDA Prescription Exemption: Oxygen Fills for Emergency Use

There is a common misconception that oxygen cylinders can be filled only with a prescription. In fact, the U.S. Food and Drug Administration (FDA) allows an exemption from the requirement of a prescription for oxygen fills when the intent is administration in oxygen deficiency emergencies as may be seen in scuba diving incidents. This is documented and described in several places.

FDA CODE of Federal Regulations – Drugs: General – Labeling – Other Exemptions - 21CFR201.161 states that “...in the case of oxygen that may be provided without a prescription for use in the event of ... oxygen deficiency or for use in emergency resuscitation when administered by properly trained personnel, a warning statement providing that oxygen may be used for emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation, and that for all other medical applications a prescription is required.”



FDA Guidance Document – “Review Guidelines for Oxygen Generators and Oxygen Equipment for Emergency Use” – FDA-2020-D-0957 states, “Oxygen generators and oxygen equipment intended for emergency use may be marketed for over-the-counter (OTC) distribution, provided such devices deliver a minimum flow rate of 6 liters of oxygen per minute, maintained for a minimum of 15 minutes... Labeling for the emergency use of oxygen generators and oxygen equipment for OTC use may not contain references to heart attacks, strokes, shock or any other medical condition which only licensed practitioners diagnose or treat.”



CGA G-4.3 – Commodity Specification for Oxygen - 7.3 Oxygen USP states, “Oxygen USP is classified as a drug and shall be labeled in accordance with the appropriate food and drug regulations.” 7.3.1 clarifies, “... For emergency use by properly trained personnel, a prescription is not required. The device shall be labeled in accordance with FDA regulations...” “The device shall consist of pressure-reducing equipment capable of maintaining a constant flow of at least 6L of oxygen per minute for a minimum of 15 minutes, a contents indicator, and a mask or other means of administering oxygen to the patient.”

Oxygen administration is the standard of care during any suspected decompression illness or drowning.

To fill an oxygen cylinder without a prescription, the following is required:

- The provider shall demonstrate they are properly trained to administer oxygen during an emergency.
 - o Completion of DAN Diving First Aid for Professional Divers or DAN Oxygen First Aid for Scuba Diving Injuries, among other courses, within the last two years represents proper training to administer oxygen in a diving or submersion related incident.
- The oxygen equipment shall have the capacity to deliver a minimum flow rate of 6 liters per minute for 15 minutes, a contents indicator and means to administer oxygen to the patient.
 - o Among others, DAN O₂ kits meet this requirement.
- The oxygen equipment and/or container shall be labeled “for emergency use by properly trained persons only.”
- Note: Industrial gas filling companies may have policies that still limit oxygen fills.

If you have questions or need an appropriate label for a DAN O₂ kit, email us at oxygen@dan.org.