



STEPHEN FRINK

Emergency Oxygen Cylinder Refills

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THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) classifies oxygen as a drug when provided to an injured or ill person. It requires specific labeling and product controls and must be individually prescribed to someone suffering from an ailment. When used incorrectly, oxygen can cause damage to someone's health.

Oxygen administration, however, is the emergency standard of care for any in-water incident, including decompression sickness, arterial gas embolism, and near-drowning. The FDA recognizes a delay is not in the injured person's best interest in situations of oxygen deficiency, so

there is an exemption to the requirements for labeling and control of oxygen that allows administration without a prescription. The exemption requires that oxygen may be used only for *emergency resuscitation* when administered by *properly trained personnel*.

Once a provider has been trained in emergency oxygen, the next step is to get access to oxygen equipment, but having cylinders filled is often a challenge. Commercial gas companies that supply medical gas products must follow FDA drug classification requirements and are often unaware of the FDA prescription exemption, so they may be

reluctant to provide fills without that individual prescription.

To help commercial gas companies, filling stations, and first aid providers, DAN prepared a document titled “FDA Prescription Exemption: Oxygen Fills for Emergency Use” and made it freely available. The DAN legal team reviewed it to ensure the exemption is correctly applied. The document explains how the exemption applies to diving first aid and ensures oxygen supply companies that they are not infringing on the FDA’s strict regulatory requirements.

The following requirements are needed to fill an oxygen cylinder without a prescription:

- **The provider shall demonstrate they are properly trained to administer oxygen during an oxygen-deficient emergency.** Completing courses such as

DAN’s comprehensive Diving First Aid for Professional Divers or Emergency Oxygen for Scuba Diving Injuries constitutes proper training. The certification is usually considered current for two years. Be ready to present your valid training certification card.

- **The oxygen equipment shall have a minimum capacity of 180 liters (6.4 cubic feet) of gas, the ability to deliver a minimum flow rate of 6 liters per minute for 15 minutes, a contents indicator (pressure gauge), and a means to administer oxygen to the patient (a suitable breathing device).** DAN’s oxygen kits, among others, meet these requirements.
- **The oxygen equipment and/or container shall be labeled “for emergency use by properly trained persons only.”**

All DAN oxygen equipment now contains these labels on the cylinders, regulators, valves, and the case.

Another common misconception is that nonmedical-grade breathing oxygen from a filling station is not suitable for emergency use. Any breathing-grade oxygen is acceptable for emergencies.

Industrial gas-filling companies may maintain a policy to fill only with an appropriate prescription — and no regulation prevents them from doing so — but we hope this information about the exemption will help filling companies and providers maintain the availability of emergency oxygen.

If you or an oxygen-filling company have questions or need an appropriate label for a DAN oxygen kit, email us at oxygen@dan.org. **AD**

