



for oxygen deficiency and resuscitation. For all other medical applications, Rx Only.” This provision is unique to the gases industry. While narrowly focused on a specific set of circumstances, it effectively allows the sale of a prescription drug without a prescription.

This special dispensation for emergency oxygen is not codified in any regulation. It comes from the FDA simply exercising its enforcement discretion, and deciding that not enforcing the regulations for this specific, narrowly defined instance was in the public’s best interests. At some point in the future the FDA could decide to change its mind and impose additional requirements on the sale of emergency oxygen, but it would probably take some sort of catastrophic event to energize the agency to take this step.

Meanwhile, at the state level. . .

Additional emergency oxygen regulatory requirements are more likely to come from state regulatory agencies. Many state boards of pharmacy, notably Florida, are currently considering new specific requirements for emergency oxygen. While state regulatory agencies typically adopt medical gas regulations that mirror FDA requirements, Florida has already published a notice of intent that it does intend to promulgate new requirements, and that those requirements may differ from Federal regulations.

One of the potential driving factors behind states adopting additional emergency oxygen regulations are the number of oxygen fires both in ambulances and in other situations where emergency oxygen is used. State regulatory agencies looking to prevent these types of incidents could consider more formal requirements for training/qualification of those who purchase and use this product.

Facts and fictions

Contrary to the urban legends floating around on the World Wide Web, emergency oxygen is **not** an over-the-counter (OTC) drug. OTC drugs are permitted to be sold virtually without restriction, and have gone through an FDA vetting process to gain that status. You can find OTC drugs like aspirin sold in gas stations and vending machines in airports. And while you can buy emergency oxygen online, I do not expect to see emergency oxygen sold in my local pharmacy anytime soon.

Based on the language in the 2003 medical gas guidance document it appears that the FDA would really prefer that emergency oxygen could only be sold to government-affiliated emergency medical service (EMS) providers – which we presume includes volunteer fire and ambulance squads. The selling of emergency oxygen to

Understanding emergency oxygen systems

Today there’s a soaring interest in emergency oxygen systems from medical gas firms to equipment manufacturers throughout the industry. So let’s take a look at current compliance requirements, some prevalent “urban legends,” and the key Do’s and Don’ts.

The recent upsurge in interest related to emergency oxygen systems now reaches across the entire business spectrum — from medical gas firms looking to add emergency oxygen systems to their business portfolio, to equipment manufacturers seeking to introduce new units to the market.

Since Oxygen USP is an RX only drug, yet emergency-use oxygen is permitted to be sold without a prescription, those seeking to enter this market require a solid understanding of its unique compliance requirements. The Food and Drug Administration (FDA) defines an emergency oxygen system as a medical device that can deliver at least six liters per minute of oxygen for a minimum of 15 minutes. There are a plethora of systems available today, some

are basic systems, and others are considerably more sophisticated. However, they are all considered FDA-registered medical devices, and once filled with drug product (Oxygen USP) these systems meet the FDA’s definition of a drug delivery system. This makes emergency oxygen systems regulatory cousins with medical devices, such as the automatic insulin delivery pumps diabetics wear on their belts.

A truly unique situation for the gas industry

In accordance with the requirements published in the FDA’s 2003 medical gas industry guidance document, every medical oxygen cylinder in the U.S. must include the following statement on its label – “For emergency use only when administered by properly trained personnel

▶ private companies, such as sports centers, hotels, golf courses, and private corporations, as well as private individuals is not mentioned in the guidance document.

When selling or re-filling emergency oxygen systems, especially to non-government affiliated entities, firms should ensure they strictly adhere to all relevant label requirements.

Also, based on a number of face-to-face meetings we had with the FDA on this topic, if a non-government entity requests you sell them emergency oxygen, they should provide you with documentation of proper training for the administration of emergency oxygen. A number of sources provide this training. The American Red Cross offers web-based training to anyone with a Red Cross CPR certificate. The training takes about one hour and only costs \$25. Another source of this training is offered by emergency oxygen system manufacturers. We have reviewed a handful of these training programs and all appear to offer acceptable training and documentation programs. Some of these programs are web-based, and some are CD-ROM based. They are often packaged with the unit itself. When selling new or re-filled units to private entities we strongly recommend medical gas firms keep a copy of their customer's training documentation for their own files.

Choices abound

Again, there is a wide range of systems available on the market. Some are basic units, consisting of little more than a cylinder, a regulator, and a mask. Some of the basic systems include carry bags, or offer them as an option. Other systems are considerably more sophisticated, offering wall mounting systems, or featuring all the system components cleanly packaged inside a plastic shell, which both provides a clean look and protects the system components.

For ease of use, we recommend systems that come with the mask pre-attached to the outlet as opposed to systems that require attaching the mask before use. An important aspect for any system is a cylinder contents gauge. A gauge allows the cylinder contents to be periodically verified and replaced if there is any leakage.

Only buy FDA-registered devices

One final issue for firms considering the purchase of these systems – all of these units should be FDA-registered medical devices. Currently most of these units are Class I devices; however, the FDA published a notification about 14 months ago stating they wanted to make all medical gas valves, with integrated pressure regulator devices, Class II medical devices. If the emergency oxygen



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Don't neglect labeling requirements

When filling/re-filling these systems the filler will need to place its label on the cylinder – unless the unit is being re-filled under contract for another medical gas manufacturer/distributor using a qualified label.

Keep in mind that the same label requirements that apply to traditional medical gas cylinders also fully apply to emergency oxygen units.

For example, if the units you are filling come with a plastic jacket encasing the cylinder you will have to have a **second label** applied on the outside of the unit as well. You will also need to perform a **leak test** of the cylinder and valve/regulator. If the plastic jacket is of a style that prevents performing an adequate leak test, then the jacket will have to be removed to do a proper leak test.

When re-filling units we highly recommend you supply a new mask with each unit. While old masks can be cleaned and re-used, supplying a new unit eliminates any concerns related to potential mask contamination from the prior use. We also recommend modifying the fill log so that

you can record replacing or cleaning the mask when re-filling the units.

We are seeing emergency oxygen systems popping up in many venues. Some firms are even starting to package portable defibrillator units together with emergency oxygen units. In our litigious society managers of public venues like sports centers, airports, and concert halls are installing emergency oxygen systems simply to reduce their potential liabilities. We predict that sales of emergency oxygen systems will be steady for the foreseeable future. If you are considering adding emergency oxygen systems to your business lineup, or have questions on medical gases in general, feel free to contact us. [SGR](#)

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