

## **AGENDA**

**Department of Business and Professional Regulation  
Division of Drugs, Devices and Cosmetics Workshop  
1940 N. Monroe Street  
Board Room  
Tallahassee, FL 32399**

**Conference Call Number 888-670-3525  
Conference Code 9259887749**

**June 10, 2015  
10:30 A.M. – 12:00 P.M.**

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**DBPR Staff:**

Reginald Dixon – Division Director  
Renee Alsobrook – Compliance Manager  
Dinah Greene – Government Operations Consultant II  
Brittany Griffith- General Counsel

**TAB 1:           Rule 61N-1.027- Distribution of Emergency Use Medical Oxygen**

**TAB 2:           Airgas - Proposed Language- Peter Hart**

Notice of Meeting/Workshop Hearing

**DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

**Drugs, Devices and Cosmetics**

RULE NO.:       RULE TITLE:

61N-1.027       Distribution of Emergency Use Medical Oxygen

The Division of Drugs, Devices and Cosmetics announces a workshop to which all persons are invited.

DATE AND TIME: June 10, 2015, 10:30 a.m. - 12:00 p.m.

PLACE: Department of Business and Professional Regulation, Professions Board Room, 1940 N. Monroe Street, Tallahassee, FL, 32399

GENERAL SUBJECT MATTER TO BE CONSIDERED: The subject area to be addressed in this rule is the distribution of medical oxygen for emergency use by persons authorized to receive emergency use oxygen.

61N-1.027 Distribution of Emergency Use Medical Oxygen.

A medical oxygen retail establishment permitted under Chapter 499, F.S., Part III, shall not engage in the distribution of emergency use medical oxygen unless it meets the following requirements:

- (1) The permittee's permit is current;
- (2) The permittee has a policy and procedure in place governing its distribution of emergency use medical oxygen that complies with the requirements for wholesale distributors set forth in Section 499.90, F.S.;
- (3) The permittee creates, contemporaneously and no later than 24 hours after the distribution of emergency use medical oxygen to persons authorized to receive emergency use oxygen, records pertaining to the distribution that comply with the recordkeeping requirements set forth in Section 499.89, F.S.; and
- (4) The distribution of the emergency use medical oxygen does not occur between the parties for a time period of more than fourteen (14) calendar days.

Rulemaking Authority 499.85 FS. Law Implemented 499.83, 499.85, 499.86, 499.89, 499.90 FS. History-  
New\_\_\_\_\_.

A copy of the agenda may be obtained by contacting: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, (850)717-1802.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, (850)717-1802. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, (850)717-1802.

**61N-1.027 Distribution of Emergency Use Medical Oxygen.**

A medical oxygen retail establishment permitted under Chapter 499, F.S., Part III, shall not engage in the distribution of emergency use medical oxygen unless it meets the following requirements:

- (1) The permittee's permit is current;
- (2) The permittee has a policy and procedure in place governing its distribution of emergency use medical oxygen that complies with the requirements for wholesale distributors set forth in section 499.90, F.S.;
- (3) The permittee creates, contemporaneously and no later than 24 hours after the distribution of emergency use medical oxygen to persons authorized to receive emergency use oxygen, records pertaining to the distribution that comply with the recordkeeping requirements set forth in section 499.89, F.S.; and
- (4) The distribution of the emergency use medical oxygen does not occur between the parties for a time period of more than fourteen (14) calendar days.

*Rulemaking Authority 499.85 FS. Law Implemented 499.83, 499.85, 499.86, 499.89, 499.90 F.S. History-New* \_\_\_\_\_.



May 22, 2015

Dinah Greene  
Division of Drugs, Devices and Cosmetics  
Department of Business and Professional Regulation  
1940 N. Monroe Street, Suite 26A  
Tallahassee, Florida 32399-1047  
Sent via e-mail to [Dinah.Greene@myfloridalicense.com](mailto:Dinah.Greene@myfloridalicense.com)

RE: 61N-1.027 Distribution of Emergency Use Medical Oxygen

Ms. Greene,

On April 9, 2015, the Department of Business and Professional Regulation (DBPR), Division of Drugs, Devices and Cosmetics published a Notice of Proposed Rule Development in the Florida Administrative Register, originated by Reginald D. Dixon, Division Director, and approved by Ken Lawson, Secretary. The notice states the purpose and effect of the proposed rule is to set forth the parameters under which an entity permitted under Chapter 499, F.S., Part III, may distribute emergency use medical oxygen. The subject area addressed in this proposed rule is the distribution of medical oxygen for emergency use by persons authorized to receive emergency use oxygen.

It was our belief upon receipt of the proposed rule, that there could have been confusion between a medical gas, including oxygen being distributed for "emergency medical reasons" and "emergency use oxygen" as defined in 499.82 (4) and 499.82 (5) respectively. Where "emergency medical reasons" includes situations, outside of normal distribution channels to alleviate emergency medical gas needs (not just limited to prescription oxygen), the latter is a special class of Oxygen, USP that both the State of Florida and the federal Food and Drug Administration (FDA) allow to be sold without a prescription for use in emergency situations, provided it is specifically labeled for emergency use in accordance with FDA requirements. Purchases of emergency oxygen are advanced purchases in anticipation of a potential emergency, as opposed to an emergency purchase.

During the May 14, 2015 DBPR meeting Mr. Dixon clarified that there was no confusion and that his intent was to assure establishments receiving "emergency use oxygen" obtained permits or licenses as appropriate for ongoing relationships. An unintended consequence of prohibiting a resupply of consumed "emergency use oxygen" without the establishment obtaining a permit or license, may cause harm to the public by limiting the availability of life saving oxygen. We believe the rule as proposed still allows the initial sale of emergency oxygen but for all intents and purposes prohibits the refill of that cylinder once used in an emergency.

Emergency use oxygen is often found in government, public, and commercial establishments throughout Florida in preparation to treat heart attack victims, often in conjunction with automated external defibrillator (AED) units. Listed below are examples of current customers purchasing medical oxygen for emergency use without permits or licenses:

- EMT services

- Local fire departments
- The US Coast Guard
- Retail and industrial customers (e.g., banks, Florida Power and Light, entertainment establishments and theme parks, etc.) with emergency oxygen kits

We are recommending the following modifications of the proposed rule 61N-1.027 "Distribution of Emergency Use Medical Oxygen".

61N-1.027 Distribution of Emergency Use Medical Oxygen.

A medical oxygen wholesale or retail establishment permitted under Chapter 499, F.S., Part III, shall not engage in the distribution of emergency use medical oxygen unless it meets the following requirements:

- (1) The permittee's permit is current;
- (2) The permittee has a policy and procedure in place governing its distribution of emergency use medical oxygen that complies with the requirements for wholesale distributors set forth in Section 499.90, F.S.; and
- (3) The permittee creates a record regarding the distribution of emergency use medical oxygen to persons authorized to receive emergency use oxygen, records pertaining to the distribution that comply with the recordkeeping requirements set forth in Section 499.89, F.S except that
  - a. only the name and address for the person or entity receiving the emergency use oxygen, is required if different from the information required under paragraph (b) of 499.89.
  - b. in lieu of the license or permit number and its expiration date, the permittee shall indicate "Emergency Use Oxygen" on the record

The reason for the modification (addition of wholesale) to the lead in paragraph is because both wholesale and retail operations may provide "emergency use oxygen". The reason for the modification to (3) and elimination of (4) is to bring consistency to the record keeping requirements between all other medical gases and emergency use oxygen as currently specified in Section 499.89. If the Agency disagrees with our rationale for the deletion of (4), we believe additional Agency rationale should be provided. Is the intent for a strict timeframe to only allow a one-time "emergency" supply to be provided? The reason for the addition /exception (through the addition of (3) a. and b., is because public and commercial establishments possessing emergency use oxygen do not have permits and to assure that wholesalers and retailers distributing emergency use oxygen to these establishment identify on their records that the transaction is for emergency use oxygen and not other medical gases (which would require the recipient's license or permit number and its expiration date).

Contrary to the "Summary of Statement of Estimated Regulatory Costs and Legislative Ratification" contained in the proposed rule's notice, we believe that the proposed rule as currently written and as put forth by Mr. Dixon, would likely have an adverse impact on small business or will likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. We do not believe DBPR considered the implication of permit or license costs on those establishments possessing emergency use oxygen or if those establishments could even obtain said permit or license.

We look forward to discussing our proposal at the upcoming workshop on June 10.

Peter Hart

## Greene, Dinah

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**From:** Peter Hart <Peter.Hart@Airgas.com>  
**Sent:** Thursday, April 30, 2015 3:11 PM  
**To:** Greene, Dinah  
**Subject:** New proposed rule

Dinah,

I would like to request a rules workshop to address the specific language surrounding the time limit restrictions on the sale of emergency use oxygen. I hope to have specific language change proposals in the very near future. I am speaking specifically about:

### Notice of Proposed Rule

Department: Department of Business and Professional Regulation

Division: Drugs, Devices and Cosmetics

Rule No.: 61N-1.027

Purpose: The purpose and effect of the proposed rule is to set forth the parameters under which an entity permitted under Chapter 499, F.S., Part III, may distribute emergency use medical oxygen.

[https://www.flrules.org/gateway/View\\_Notice.asp?id=15896377](https://www.flrules.org/gateway/View_Notice.asp?id=15896377)

Can you advise what are the appropriate next steps?

Kind regards,

Peter Hart  
Director of FDA Compliance  
Airgas, Inc.  
447 Anna Marie Drive  
Cranberry Township, PA 16066  
ph: (724) 504-6586  
fax: (724) 591-8875