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

Conference Call Number 888-670-3525
Conference Code 9259887749

August 6, 2015
1:00 p.m.

Rule Workshop for 61N-1.027 Emergency Use Medical Oxygen

DBPR Staff:
Reggie Dixon, Division Director
Renee Alsobrook, Chief of Compliance
Dinah Greene, Administrative Assistant
Jamie Royal, General Counsel

Call to Order: Reggie Dixon, Division Director

TAB 1: June 10, 2015 – Rule Workshop
a. Proposed Language
b. June 10, 2015 Meeting Minutes
c. Withdrawal Notice
d. Re-Notice for Development of Rulemaking

TAB 2: August 6, 2015 – Rule Workshop
a. Proposed Language from Airgas, Inc.- Peter Hart, Director of FDA Compliance
Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Drugs, Devices and Cosmetics

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

DATE AND TIME: August 6, 2015 1:00 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.

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.
TAB 1: JUNE 10, 2015 RULE WORKSHOP –

61N-1.027 EMERGENCY USE MEDICAL OXYGEN
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.

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.: 61N-1.027  RULE TITLE: 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.
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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

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
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

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
STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DIVISION OF DRUGS, DEVICES, AND COSMETICS

IN RE: RULE NO. 61N-1.027,
Distribution of Emergency Use
Medical Oxygen

RULE HEARING
June 10, 2015
10:30 a.m. - 11:16 a.m.
1540 North Monroe Street
Board Room, Northwood Centre
Tallahassee, Florida

Reported by:
SCHEDULE WOODS, Court Reporter
For the Record Reporting, Inc.
1500 Mahan Drive - Suite 140
Tallahassee, Florida, 32308

ORIGINAL

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA
677-260-6406
PRESENT

REGINALD DIXON
RENEE ALSOBROOK
DINAH GREENE
BRITTANY GRIFFITH

* * *

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA
958-220-5463
MR. DIXON: Good morning. My name is Reginald Dixon. Today is June 10th, 2015. The time is approximately 10:32. We're here this morning to conduct a hearing on the rule, that was Rule 61N-1.027, entitled "Distribution of Emergency Use of Medical Oxygen."

This is actually a proposed rule. It's not currently a rule. It's not as if we're amending a current rule. This is actually a notice of a new rule in the Florida Administrative Code.

The meeting was noticed and set for 10:00 this morning -- I'm sorry -- 10:30 this morning. In response to the actual notice of rulemaking, we received correspondence with some alternative language. That alternative language is posted on our web page and is also included in the meeting agenda materials.

I guess I just wanted to start by saying if there's anyone in the room who would like to testify, we ask that as you come up, that you state your name, who you're with, and provide your comments. If there are folks on the phone who would like to provide a comment, we would ask you to do the same thing. Identify yourself before you
speak. If you'd like to tell us who you're with, and then to provide us your comments.

As a preliminary basis, I think it would be easy -- I think it would be good to give some foundation on the background of what -- where the Department, we believe the status of the rule is with respect to maybe the input that we had. And then we'll have those folks to come up and provide comment for the Division to consider.

The -- the initial draft of the rule that the Department put together, the Department put together this rule based on the belief that the rule was intended to allow certain entities to distribute emergency use medical oxygen during situations where the normal distribution lines of medical oxygen are unavailable or cut off for whatever reason.

So in a sense, it is a -- the -- it is the distribution of emergency use of oxygen during times of emergency or so to speak, as opposed to the distribution of medical oxygen to entities that deal with emergencies on a normal course of business. And, I guess the -- hopefully, the easiest way for me to explain that is for an example.
Let's say for instance you have the Leon County, and I just pick Leon County because we're here on Leon county. The Leon County EMS -- yeah. Leon County EMS has a Medical Director who directs their efforts. And that Medical Director is authorized to purchase prescription drugs, including medical oxygen on behalf of Leon County EMS.

So Leon County EMS is authorized to purchase emergency use of medical oxygen and medical, you know, medical oxygen to provide and use during the course of their normal business, which is dealing with, by nature, emergency situations.

In the Department's -- in the Division's eyes, the supply of emergency -- the supply of medical oxygen to Leon County EMS would not be considered an emergency distribution, because Leon County EMS can purchase medical oxygen from any number of authorized providers.

Now, let's say for instance that there is a tornado or a hurricane that hits all of the medical gas facilities in the area, except for maybe one or two, and that -- or for whatever reason, and now Leon County EMS is dealing with emergency of epic proportions and then normal suppliers are out.

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Then entities that normally are not authorized, such as the medical retail establishment, would then be able to supply medical emergency use medical oxygen to Leon County in a sufficient amount to keep them running, but hopefully not on an ongoing basis for infinity. And that's kind of the thought behind it.

But we wanted to -- we wanted to try to make that distinction and as folks go through so that we could talk about it. And I know that we have some -- there is an interest or a misunderstanding from some of the other folks that we may have had comments from before the rule was noticed, but I wanted to kind of lay that framework so that -- for folks on the phone who are in here or haven't had the benefit of maybe giving us a call to try to decipher or, you know, figure out what it is that the Department or Division was thinking.

So we're kind of laying that ground work. We're going to ask for folks, that if you have any comments, suggestions, or want to discuss the alternative language and to bring that forward to come before the Division and make a presentation. Okay. I know -- well, you can introduce yourself.

MR. HART: Me?
MR. DIXON: Yes, sir.

MR. HART: Okay. All right. Good morning. My name is Peter Hart. I'm with Airgas. We submitted the -- some alternate language. And I appreciate your example, because it was one of the questions we had in our correspondence was -- was that process.

But I would also like to bring up another example, because I think examples are good ways to work through this process because it's those oddball entities that catch us.

There is a product that has hit the market in recent years and it's registered as a medical device and they're called emergency oxygen kits. And we see them all around. And they're marketing now to put them next to the AED devices you see everywhere. And it's been a natural progression for companies selling and marketing those, excuse me, to go and put those beside us.

And where that becomes a challenge for us as an industry is that when the device manufacturer makes that, they come to companies like ours and we will initially fill that. And we can do that properly and legally as we should. With a medical device and manufacturer we will fill the cylinder.

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Then they will then, in turn, sell that to a customer. And so ownership of that changes to, you know, the various mall maintenance people, whoever's doing those things.

And then we have those instances where that becomes consumed in an emergency situation. That new owner then comes to a company like ours and says, hey, I have a refillable container. Please refill this. And under the current wording, the way I understand this is that I can then do an initial fill for them. But if that is then a repetitive process and they again use that, my understanding, the way it's worded now is that we want to discourage that relationship.

And I think that is a process that could get us in trouble, because then it essentially turns that AED or the emergency oxygen kit into a disposable unit after we do the first fill for that customer, is the way I read it.

MR. DIXON: Just for the record, there's -- someone out there has their phone and it's apparently not on mute. So we're going to ask you guys if you could mute your phone.

I guess I have a couple questions, because this was something that --
MR. HART: Please.

MR. DIXON: -- that we weren't aware of. I hadn't seen it before. When you talk about emergency oxygen kit, is it a -- I'm just trying to get a visual.

MR. HART: Uh-huh.

MR. DIXON: Is it sort of like -- almost like a first aid kit, but just in the -- that would be something that -- for instance, if I had a first aid kit, and I guess it may be a bad analogy. If I had a first aid kit and I had like certain things in it and I take it out, is it the thought that this is something that I should be able to replace instead of having to scrap the whole kit, and then have it do it again? Is that --

MR. HART: Yes.

MR. DIXON: Is that the thought?

MR. HART: Yes. These kits are to -- and there's variety of models, any one of the manufacturer. But in essence, they are an extremely small-capacity cylinders. They will come either with a traditional regulator or they will come with the vipers, the valve-integrated pressure regulators that have both the regulator and the valve built in together, so that the user then can
see a simple three or four, five step instruction
just like they have with the AEDs. And you turn it
to the pressure setting and there's a hose and
there may be an adult mask. There may be a
pediatric mask. There may be no mask. So they
come in a variety of shapes.

And then so for us, where we get involved is
when they say, we’ve used it. We had Grandma Smith
down from Idaho on vacation, too much shopping. We
had to assist her. So now we’ve used it and we
want to refill it. And so that for us is -- and as
these are becoming very prolific around the
country, that to me is a scenario I think that is a
new and upcoming process.

MR. DIXON: Let me ask a question. And we may
not readily have an answer. The folks who
manufacture these emergency oxygen kits, and I
would think if they're distributing, therefore,
they would have to have some type of permit to do
that, because the medical oxygen --

MR. HART: Uh-huh.

MR. DIXON: -- so the medical oxygen part of
it is a prescription drug. So if you're -- and
again, and this for the folks -- this is just us
thinking out loud. It is not --
MR. HART: No. Of course.

MR. DIXON: -- because if you're a kit
distributor and it's got medical oxygen in it and
it doesn't fall under the exemption under DQSA,
which we have discussed but --

MR. HART: Right.

MR. DIXON: -- then they could only sell it to
folks in the state who are authorized to purchase
it.

MR. HART: Well, let's pause, because they're
selling. You got to back up. Remember when we
fill it up, and that -- that oxygen then becomes a
component of the device.

MR. DIXON: Right.

MR. HART: So they're selling a device.

They're not selling the drug. The drug is in a
component within.

MR. DIXON: Right.

MR. HART: So their license says device.

MR. DIXON: Manufacturers.

THE WITNESS: Right. And so they're -- and so
then that sort of gets confusing, because now it's
a component within a device. Does that make sense?

MS. ALSOBROOK: It's still a prescriptive
drug.
MR. DIXON: Right. Yeah. The one -- I guess
the one thing we have to really look at in Florida
-- and I'm not sure how the other states are.
Generally speaking, in Florida a device that has a
prescription drug in it and it may be that we have
to do the research. We usually will treat those as
prescription drugs and not as devices unless --
well, is it an FDA-approved device?

MR. HART: Yes.

MR. DIXON: Is it FDA --

MR. HART: Yeah. There is a device product
listing for that.

MR. DIXON: Okay.

MS. ALSOBROOK: Mr. Hart, do you know if --
you indicated, for example, that the family member
could bring it into the state, use it on --

MR. HART: I'm sorry. I -- the --

MS. ALSOBROOK: -- that --

MR. HART: A family member comes in and they
go shopping at the --

MS. ALSOBROOK: And it's used.

THE WITNESS: -- at the Orange Blossom Trail
Mall in Orlando, you know. And they -- they have
an incident. Maintenance or security grabs the AED
in the oxygen kit and comes over, administers until
the EMTs get there. That -- that would be -- it wouldn't be something that -- these -- these don't get -- historically. And there's exceptions to everything.

MS. ALSOBROOK: Right.

MR. HART: But historically, my understanding of the -- the companies that are selling these, is they're -- they're -- they're selling to businesses who already own the AEDs.

MS. ALSOBROOK: You are right, I think we probably need to explore how the FDA classifies them, because if they're selling them to businesses, there's a possibility they're selling them to patients who would bring them into the state and we would have the same scenario with a patient then going to a medical oxygen supplier, whether it be a distributor, manufacturer, or retailer and asking for them to be refilled.

And there wouldn't be a prescription for that patient for that. So I think it's worthy of us doing some research on these types of medical devices certainly.

I do know that, and we have the pharmacist who can look in the -- for it. There is some emergency refilling capability of a pharmacist, and certainly
not for a full supply of a prescriptive medication, but for some. So maybe we could run a parallel to that. But I -- it clearly is something that, as you indicated, we were not aware that the industry is aware of and we need to explore further.

MR. DIXON: Because the -- because the -- definitely, the problem that you have is, I mean, because initially you wouldn't think it would cost a person -- because it wouldn't be you -- I think in part of our research and reasons we looked and -- and initially said that we did not believe that it would cause a problem in the industry, because it would not be something that would be outside. We didn't have the variable of this particular type of a kit because -- because normally, you think, well, it's the hospital and the hospital uses their medical oxygen. And they would just do their normal change and purchase something else.

But something of this nature, it would seem that it would definitely cause a hard -- it would cost a lot in a sense that now you have a device that is classified as a device. It could be separable, but you could take out the cylinder. But now that you have that cylinder, you know, how do you get that cylinder refilled. Can you just
simply -- can you replace the cylinder, you know.
And that -- and with all the hardware costs versus
just taking it somewhere and having it refilled.
So that is definitely something that we need to --
we need to do more research on that -- on that
part, because I'm not -- I don't know that's an --
I don't know if that's an emergency situation, but
it is a -- it can be very quickly an emergency
situation because they don't have a normal supply
line for the filling of that, that canister.
And so maybe -- do you have -- and I guess,
maybe, I don't know if we want to do it offline,
but I think it would be nice to get contact
information from the manufacturers.

MR. HART: We could do that offline, I can get
-- I can send you the -- so they can get a place
listing and all that.

MS. ALSOBROOK: I could search on the FDA
website and look for device and pretty easily find
it, too.

MR. HART: It's called an emergency oxygen
kit. That's what it is. It's the product class.
I apologize for not knowing the classification off
the top of my head.

MS. ALSOBROOK: No. That's not a problem. We
can find it.

MR. HART: Google is our friend.

MS. ALSOBROOK: There you go. We can find you. Okay.

MR. TILLER: Grant you, this is -- this is Mike Tiller from CGA, if I can have an opportunity to chime in when it's appropriate. It would be appreciated.

MR. DIXON: All right. Mr. Hart, did you have anything --

MR. HART: I'll yield.

MR. DIXON: Mr. Tiller, did you have -- what were your comments for us?

MR. TILLER: I would say on behalf of the Compressed Gas Association, we support what Mr. Hart is communicating. As he said, the devices are generally owned by businesses, whether they be malls or manufacturers or dive shops that need to have that supply in case one of their customers has a situation where they need oxygen and an AED.

And so what Mr. Hart was describing the need to be able to refill these is very important to the citizens of Florida and visitors to Florida. I'd appreciate everything you guys can do to work that into the modifications of the rule. The

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emergencies as you describe, the emergencies that
the -- the new regulation was proposed to do was
talking about emergency situations such as
hurricanes and other public catastrophes.

And when we, the industry, talk about
emergency use oxygen, we're talking about when our
products are used in emergency situations for an
individual. And as you were trying to describe up
front, those are very different scenarios that have
not yet been considered in a way this wording takes
place. The way this wording was laid out. And
hence, why Airgas's recommendation was to make the
verbiage changes and specifically to eliminate this
14-day duration, which only makes sense in
hurricane type of public emergencies.

So we are very supportive of what Mr. Hart is
proposing and any further work that you guys need
to do to expand the scope of this verbiage to
include all types of emergencies, public and
personal. Thank you so much.

MR. DIXON: Thank you. Do you have any
questions?

MS. ALSOBROOK: Yes, I had a question. Mr.
Tiller, this isn't necessarily just directed at
you, but it's, I guess, directed at anyone who
might comment on it.

It seems like there is -- there's sort of two issues that we, the Division, need to address in crafting a rule or addressing emergency distribution. I'll say it that way.

The one is the use in an emergency device kit or in the situation we have been discussing with Mr. Hart and you. And the second is, in the situation where we need to get medical oxygen supply to someone in a setting before the Governor would declare an emergency disaster, the retailer needs to get gas delivered and there's no permit there or the distributor needs to get gas to the retailer, but the retailer doesn't have a license. That's a scenario that we're trying to address, also.

So we have got to figure out a way that we can allow the transmission from the distributor or the manufacturer of gas to the retailer so that the patient can get the gas, or there's no prescription there, so the retailer can get the gas to the patient in that distribution scenario for an emergency setting, as well as this setting that you're talking about in resupplying the devices.

So we kind of have a two-fold purpose of this
rule that we're trying to resolve. And it's -- do 
you have any suggestions, either Mr. Hart or Mr. 
Tiller, on that? Thank you. It's driving you nuts 
now, isn't it?

MR. HART: Yeah.

MS. ALSOBROOK: We got a drip in the room, Mr. 
Tiller. Mr. Hart's going to help me out here --

MR. HART: I'm not a drip. Just clarifying.
My suggestion for consideration might be that --
and I was just trying to find it here in 449.82 in 
the regulations on definitions, but I -- it escapes 
me. There's a -- I'm sorry.

MR. WILLENBROCK: With CGA. Peter, I think 
what you're trying to refer to is there is 
currently a definition in 499-82 number 4, which 
talks emergency medical reasons. And that would 
include the emergency distribution of not only 
oxygen, but other medical gases as well.

I'm not sure it addresses in preparation for 
an emergency, but I would think it does if, you 
know, that was, you know, at least when we were 
looking at this rule, we saw the difference between 
what emergency medical reason was verses an 
emergency use oxygen, which in theory is actually 
-- I mean, if you take a look at the labeling on
the medical gas, it talks about the administration of emergency use oxygen. And further says, "for all other applications RX only."

So the -- the actual requirement for a prescription comes into play for the -- the patient that you were talking about, the donor you were talking about. A person coming into the state of Florida would then -- that is on oxygen for therapeutic purposes would have a prescription, would probably be working with a home care firm within the state that would, you know, and it would be the normal license relationship between the manufacturer and the wholesaler and the retailer.

MS. ALSOBROOK: Sir, could you state your name again for our court reporter?

MR. WILLENBROCK: Sure. This is John Willenbrock, W-i-l-l-e-n-b-o-r-o-c-k, with the Compressed Gas Association. I report to Mr. Tiller.

MS. ALSOBROOK: Thank you.

MR. HART: So for Florida being a coastal state is a big unique thing and the emergency use oxygen takes on a big significance when we hit hurricane season. There's no doubt that that's -- that's a unique process. And I think it would
behoove us to have a unique description built into
our definition processes and maybe it is a
different terminology to differentiate to where
it's not just emergencies, but it's disaster supply
or some qualifier. Because I do agree that it is
very much is an apples and oranges situation. And
it's true -- a true emergency.

And we, as an industry, have relationships
with the hospitals in the state where we stock
large amounts of what we call hurricane stock, you
know. We -- your -- your -- if you talk with your
inspectors, they'll tell you they see it and when
they go around it, they'll say, what's that massive
amount of oxygen cylinder? Well, we're coming up
on hurricane season, so we're gearing up and we're
getting prepared.

So I do think it would be good if we could
kind of separate the two and put some qualifiers to
say that I think we're in a disaster situation, but
not a state of emergency. And -- and maybe the
agency can help us come up with some parameters to
say, okay, we have defined state of emergency, but
in an imminent situation, or whatever would be
appropriate language, say here's some rules that we
can follow so we're not putting the public at risk.
And kill -- still keep the -- the spirit of emergency oxygen as a separate entity.

MR. DIXON: Yeah. This is Reginald Dixon. I think the concern that it poses and the difficulty I think we all kind of see is when you look at the statute that actually authorizes what the Department can do, it says that the Department shall adopt rules that govern the distribution of medical oxygen for emergency use by person's authorized to receive emergency use oxygen.

So the statute limits what we can write a rule for so it only deals with -- with medical oxygen. So some of the other gases and some of the things where in the definitions where it talks about emergency reasons, those deal with all gases. And so we're kind of limited by that perspective, by what the language says.

And then when you turn to the emergency use of oxygen, it basically is, you know, the use of oxygen without a prescription. And so we've got to figure out a way, we've got to figure out a way to craft this rule so that it -- so that it -- it sets out the parameters under which an entity can distribute medical oxygen to entities who are authorized to receive medical oxygen without a
prescription. And I think that's -- and so I think that that -- what we, you know, in a different kind of way, we may actually be able to list those entities who can receive medical.

We may be -- I mean, that's something we'd have to look at. But this rule may in a -- it may not intend it to, but the rule may authorize us to identify those entities who are authorized to receive medical oxygen without a prescription.

MR. HART: If I'm hearing -- I guess since we've been talking, what comes through to me is, I believe, if I'm hearing correctly, is that your legitimate concern is not -- not really the person receiving the oxygen without a license, but it's more the emergency disaster situation where we may need to look to an oxygen supplier to be able to supply medical oxygen when they're not licensed, to someone who's licensed to receive it. Am I understanding that correctly?

MR. DIXON: Well, let me -- let me go ahead and give you a caveat.

MR. HART: Sure.

MR. DIXON: The problem that you have is that the folks who are working on the rules are lawyers. And when you look -- I mean, I say that honestly in
a sense that when you look at the rule and you look
at the statute, it looks like it's very narrowly
tailored to direct us to only write a rule that
says, here is how you govern the distribution of
emergency use of medical oxygen to those entities
who are authorized to receive it.

And then when you go to the definition of
emergency use of oxygen, it is oxygen administered
in emergency situations without a prescription. So
just -- if you just cut that sentence out and put
that definition in to fulfill that sentence, it
almost seems to limit us to exactly what we could
do. But there's no definition in -- there's no
ready -- readily available definition that talks
about who's authorized to receive emergency use
oxygen in emergency situations.

And so -- and truthfully, the folks who are
receiving it are -- basically two classes of
people. Folks who are -- it's actually being
administered to and those folks who will be
administering it to them. And so what -- what, you
know, we hadn't looked at it from that perspective
in a sense that this rule may authorize us to
designate those people.

It may be us writing a rule that says this
group of people are authorized to receive emergency use. I mean, a person who is non-responsive and on the ground and who is receiving emergency treatment, I mean, why do we have to authorize that person because it seems inherent in the nature of the situation, that they would be authorized to receive it. But I don't -- I'm not aware of anything in 499 or anything that authorizes them to receive it.

And so -- and we -- it may not be -- to authorize the patient but authorizing the person who receives it to immediately administer it, and maybe identify who those people are right now. But I don't -- we have to get with -- we have to get with our legal folks because that's not the way that we initially looked at it.

MR. HART: Sure.

MR. DIXON: And so that may be because the folks at -- in the mall situation or the scuba stops, those would be people who have -- I mean, even here at DBPR. I mean, if we -- if we had someone who fell out right now, and we had first responders in the building, you may have someone here that grabs and administers oxygen to a person without really knowing whether or not they're
authorized to do it other than that they've got
first aid training, or they may be a nurse, they
may be a doctor. But I mean -- but that doesn't
authorize you to grab out an emergency kit oxygen
and administer to a person.

I mean, I would hope that it does, but I don't
know that it does. But I don't know that we've
provided any direction to the industry that it does
do that. And that may be -- I mean, that may be
the benefit of this statute. It allows us to do
that. And you got some good samaritan protections
and some of those things in the law. But it
doesn't talk about how you all as an industry
supply and -- and actually replenish --

MR. HART: Replenish --

MR. DIXON: -- replenish that supply that is
being used for emergency purposes, particularly in
the case of it being a kit versus, you know, you
just selling canisters, the cylinders to someone
for purposes of that.

MS. ALSOBROOK: Well --

MR. TILLER: This is Mike Tiller. I think
where you're going makes sense. And the definition
of emergency being both personal emergency and
weather or other kind of emergencies kind of make
-- makes a lot of sense.

Perhaps, in the definition of who's allowed to receive medical oxygen, the statute or the regulation could be written to include those entities allowed to receive the device that are sold with the oxygen in the first place. That only makes sense to allow them to replenish part of that device if -- if they had to use, you know, the oxygen contained in the device they purchased in the first place.

And I certainly hope that somebody doesn't hesitate to give someone oxygen who needs it solely because there's not a prescription and we let them die because of that.

And in addition, that makes it consistent with what John Willenbrock described, that the label that's used on oxygen is accepted by FDA. It states that the oxygen may be provided in an emergency and in all non-emergency cases, a prescription is needed. That is what's on the label and that's what's accepted by FDA.

So I think the intent of providing this to someone who's down on the ground is the thought process that's on the oxygen label today and has been for years.
MR. HART: Right. And if we visualize and maybe this will help clarify a bit, because when we all think of emergency oxygen, I think our default, you should think of a cylinder. But the reality is if all I have is that cylinder, I'm out of luck for that person. Plus I have to have a regulator. I have to have the tubing. I have to some way, you know, the nose piece, a mask, something to concentrate that oxygen to the person that needs to get it.

So -- so for us it isn't, our challenge isn't -- and I -- and maybe I'm beating a dead horse. If I am, I apologize. Is it -- we're just looking at how do we reach everyone's supplier. And I think we're unintentionally stifling out of that. So anything I can do or I'm sure Mr. Tiller and the team as well, we'll be glad to help you with -- with the emergency oxygen kit information discussions on that.

And we -- but the thing is -- but -- and I'd also like to go back a bit and -- and expound a bit, I think, a path Mr. Dixon started down a bit, and some lessons we learned from Katrina in Louisiana.

When that hit, and when that catastrophic
experience hit, there was truly a situation where
random people were walking into our facility
saying, my house is gone. But I got my tank,
because I drag it with me everywhere and I need
oxygen. My doctor's gone. Everything's gone. I
do see there. I think it makes very good sense to
have parameters to say, yes, we want to take care
of that person, but we don't want to establish a
life-long history.

But I think that needs to be built a bit into
the process of what we talked about, the disaster
scope, and not normal-day operations. And on a --
just on a sidenote on another comment that we had
proposed was on the .3, where we said that we
talked about documentation.

I was -- I would suggest that that -- that you
consider adopting the language we put in rather
than putting in the language that's there, which
puts in a 24-hour time frame. And the reason I
would say that is I'd say it's unnecessary. We're
-- we're very -- I think, we as an industry,
especially in the state of Florida, have -- have
grown exponentially in performance and
documentation of paperwork.

And I can tell you it -- nothing -- nothing
moves off of a dock if there isn't a piece of paper
with it. And so -- I -- my suggestion is I think
with the language that we already have in the 499s,
about the immediacy of availability of a paperwork,
I think we're good there. And that would just be
my suggestion is that we would apply the same time
constraints and -- and expectations of -- of
documenting and -- and it's to monitor that -- that
I always promote and teach you need to say what you
do and do what you say. So you don't -- not going
to happen if you didn't document it. And we try to
promote that philosophy.

And I think it's -- I think as our industry
has matured and improved, especially in the state
of Florida, we've gotten very good at
documentation. And so I think it -- it could add
in another layer beyond what's already in 499.
Just it -- it puts us in two places. So that's my
suggestion.

MR. DIXON: Yeah. And again -- and this is
Reginald Dixon. Again, I think the initial
language in there was again contemplating, you
know, the kind of disaster type of thing that you
talked about, but not -- not all of the other
things. That -- that is definitely something that

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we need to -- we need to go back and look at again.

MR. HART: Excellent.

MR. DIXON: I did want -- I did want to ask
one question. I know that in our initial rule,
that we limit it to the medical oxygen retail
establishments. But in the draft that you all
provided, it looks like you all have also the
medical wholesalers.

Can you talk a little bit more about that?
And if you include the wholesalers, but not
necessarily the manufacturers -- I just -- I just
want to kind of have -- have a record of -- the
initial draft of the Department was to -- to limit
it to medical oxygen retail establishments.

And again, that was -- that was kind of based
limited thinking. But I noticed in the draft
language, it says the medical oxygen wholesale or
wholesale establishment. I'm assuming under
wholesaler, you also -- that's -- you're using it
in the general term, meaning a manufacturer or a
wholesaler and not -- not just a medical oxygen
wholesaler like the permit --

MR. HART: Well, and let's go back to our
example that we did with -- with the mall
experience. The reason we said wholesalers is that
that refilling that cylinder is a business sale.

So we're not -- we're not -- we're not retailing to
the end user. We're -- we're retailing to the
company that has been approached by the device
manufacturer or the sales person and say, hey, buy
this kit.

And so we're -- we're -- in that instance,
that's a situation where we are selling business to
business. And that's why we included that.

MR. DIXON: I just wanted to make -- one of
the things that I do, is we go through these and we
print a transcript and help us with it. It's good
to have the reasoning when we have the comments.
The reason behind the comments will help us, if
whatever reason, you know, we started to go and we
start to forget things and go left field, it helps
us kind of get back to where we need to be.

MR. HART: Absolutely. Absolutely.

MR. DIXON: And I'm sorry. I'm typing. But
if anyone else had any comments for us, could you
just identify yourself and give us those comment.

MR. HART: I'm good, unless you have another
question for me.

MS. ALSOBROOK: Thank you, Mr. Hart.

MR. HART: Thank you.
MS. ALSOBROOK: Anymore comments from anybody on the telephone? Anymore comments from anybody on the telephone? Anybody -- comments from anybody in the audience? No more comments from anybody? Director, any comments for anybody on the panel?

MR. DIXON: I guess the question is, where do we go from here? Because like I said, this is in response to a request for a rule hearing. So I guess our next step as a Division is we've got to get back together, take in all the comments, and then make a decision as to -- and maybe when -- I guess, pretty quick as to decide whether or not to toll the rule. Because as you guys know, during the rulemaking process, you have a limited time frame in which to get the rule out there and done.

So the question that -- for us as a Division, to make a determination on is, do we want to toll the rule, draft some language, either have another rule hearing, or to file a notice of change, which would extend the time and give the industry enough time to review the new language and to request another rule hearing, and then go back through that process.

I would imagine that that may be the preferred
method because it keeps the rule moving, and it
also gives the industry a formal point of entry so
that we can have this type of a rule hearing.

So very shortly, I guess in the next week or
so we need to make that determination. Probably
within -- just so that we can get something noticed
and keep the rule moving. But we definitely
appreciate the folks who have taken the time to
provide this input.

I've done a lot of rule workshops and hearings
and I have never -- this is one of the few times we
ever actually got something where they brought
something to the attention of our department or the
department that I was representing that was
meaningful and actually changed what we were
looking at. So I really do appreciate that.

Unless, anyone else has anything else to
provide, I think we can conclude the rule hearing.
And we just ask folks to be on the look out. We do
try to e-mail things out to our -- to our
interested parties list. But we -- if we file a
notice of change or if we toll the rule, I think
the notice of change would be published. But if we
toll the rule, we don't necessarily have to do a
notice of publication of tolling the rule. And
what that means is that we just pause the rule or
we go back and try to decide, make better decisions
on the language that we want to use.

So -- but we will try to put that up on our
web page as well. So unless anyone else has any --
any comments, what we will do is we will go ahead
and conclude the rule hearing at this time. Thank
you, everybody.

(Whereupon, the proceedings were concluded at
11:18 a.m.)
CERTIFICATE OF REPORTER

STATE OF FLORIDA )
COUNTY OF LEON )

I, SCHEDALE L. WOODS, Court Reporter and Notary
Public, do hereby certify that the foregoing proceedings
were taken before me at the time and place therein
designated; that my shorthand notes were thereafter
translated under my supervision; and the foregoing pages
numbered 3 through 35, are a true and correct record of
the aforesaid proceedings.

I FURTHER CERTIFY that I am not a relative,
employee, attorney or counsel of any of the parties, nor
relative or employee of such attorney or counsel, or
financially interested in the foregoing action.
Dated this 18th day of June, 2015.

SCHEDALE L. WOODS
FOR THE RECORD REPORTING
1500 Mahan Drive, Suite 140
Tallahassee, FL 32308
(850)222-5491
MEMORANDUM

To: Ken Lawson, Secretary

From: Reginald D. Dixon, Director
Division of Drugs, Devices and Cosmetics

Date: June 11, 2015

Re: Withdrawal of Rule 61N-1.027, F.A.C. (Distribution of Emergency Use Medical Oxygen)

On June 10, 2015, a public hearing was held on the above-referenced proposed rule. Significant substantive input was received from the industry, such that the division believes it is best to withdraw the proposed rule at this time. The division intends to re-notice the rule for development and to conduct workshops to flush out language that accomplishes the goal of the implementing statutes while not having the unintended consequence of negatively impacting Florida businesses.
Notice of Change/Withdrawal

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
RULE NO.:  RULE TITLE:
61N-1.027 Distribution of Emergency Use Medical Oxygen

NOTICE OF WITHDRAWAL

Notice is hereby given that the above rule, as noticed in Vol. 41 No. 84, April 30, 2015 issue of the Florida Administrative Register has been withdrawn.
NOTICE OF DEVELOPMENT OF RULEMAKING

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Division of Drugs, Devices and Cosmetics

RULE NO.: RULE TITLE:
61N-1.027 Distribution of Emergency Use Medical Oxygen.

PURPOSE AND EFFECT: 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.

SUBJECT AREA TO BE ADDRESSED: 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.

RULEMAKING AUTHORITY: 499.85, F.S.

LAW IMPLEMENTED: 499.83, 499.85, 499.86, 499.89, 499.90, F.S.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Dinah Greene, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 1940 N. Monroe Street, Suite 26A, Tallahassee, Florida 32399-1047; Dinah.Greene@myfloridalegisl.com; 850.717.1802.

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS AVAILABLE AT NO CHARGE FROM THE CONTACT PERSON LISTED ABOVE.
TAB 2: AUGUST 6, 2015 RULE WORKSHOP –

61N-1.027 EMERGENCY USE MEDICAL 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 F.S. History-New
Proposed Language

Original

(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.

Modified

(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., the permittee will also use the phrase “emergency oxygen sale” in lieu of a customer permit number; and

(4) In the event of a catastrophe, the distribution of medical oxygen to those in need for emergency use shall not occur between the parties for a time period of more than fourteen (14) calendar days.

Peter Hart
Director of FDA Compliance
Airgas, Inc.