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

IN RE: RULE 61N-1.027,
EMERGENCY USE MEDICAL OXYGEN

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DBPR
RULE HEARING

DATE: August 6, 2015
TIME: 1:00 p.m. - 1:10 p.m.
LOCATION: Professions Board Room
1940 North Monroe Street
Tallahassee, Florida 32399

Reported by:

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ORIGINAL

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
APPEARANCES:
REGGIE DIXON, DIVISION DIRECTOR
RENEE ALSOBROOK, CHIEF OF COMPLIANCE
DINAH GREENE, ADMINISTRATIVE ASSISTANT
JAMIE ROYAL, GENERAL COUNSEL
MR. DIXON: Good afternoon. My name is Reggie Dixon. I'm the Division Director for the Division of Drugs, Devices, and Cosmetics. We are here today -- today is August 6, 2015. We are here to conduct a rule workshop on rule 61N-1.027, Emergency Use of Medical Oxygen. I guess we don't have to take a role.

Before we start, I would just like to ask anyone on the phone or the folks in the room that if you have a phone or pager or whatever, please to turn it to silent or vibrate so that -- or if you're on the phone and you're listening in that you put your phone on mute so that we don't get any of the background noise or anything that we get during the course of this meeting.

We're here today to conduct a rule workshop on this rule. The statutory guidance or basis for the rule, this is mandatory rulemaking. Chapter 499 -- I'm sorry. Section 499.85, Subsection 6, states as follows: "The Department shall adopt rules that govern the distribution of medical oxygen for emergency use by persons authorized to receive emergency use oxygen. Unless the laws of this state specifically direct otherwise, such
rules must be consistent with federal regulations, including the labeling requirements of oxygen under the federal act. Such rules may not be inconsistent with Part 3 of Chapter 401 or the rules adopted thereunder."

Just a bit of history: We previously published this rule and conducted a workshop and had published a language. And at that time, we got some significant feedback from the industry regarding the potential negative effect that the previously proposed rule would have under industry.

And so at that time or subsequently after that, we decided to withdraw the rule and to renotify the rule and to conduct this workshop with the hopes that we would come up with language that the industry would be able to work with, be able to continue to operate with, and to set some parameters under which those folks may engage in the distribution of medical oxygen for emergency use.

In your packet, which you should have, Tab 1 has all the information in it that was at the June 10th rule workshop, and Tab 2 is information for this particular workshop. What we have is -- to
just kind of -- I guess -- cut to the chase, we have some proposed language now that was recently sent out. That language is on the -- it's on the next to last page of the packet. The rule language starts at 61N-1.027, Distribution Of Medical Oxygen for Emergency Use.

We've brought this language forward with hopes that folks in the industry who would be impacted by this language would review the language and give us their concerns and their input on the language and how it may actually affect their business practices prior to us actually noticing this language and using this language as the basis for the rule.

So unless there's any other comments from the folks at the table, we would open it up to anyone on the phone or anyone in the room to provide us any input they may have or to ask us any questions that they might have about the intent of the rule. And we do ask people, as you come up or if you're on the phone and you have comments that you go ahead and give us your name and tell us who you're with.

MR. HART: Good afternoon. This is Peter Hart. I'm with Airgas. I want to say
thanks very much for your rewriting, and I find this to be extremely good. As far as we're concerned with industry, it fits with what we talked about. It fits with what we're doing.

I have only one question. I think it's a simple one. And it is in the wording in No. 5 where we say -- excuse me -- "A Florida-permitted medical gas wholesale distributor or medical oxygen retail establishment may distribute a medical oxygen cylinder." Is that a generalized term, not a limit to one?

MR. DIXON: It is my understanding -- and Ms. Alsobrook, correct me if I'm wrong -- I do believe that that is general, not limited to one.

MR. HART: Right.

MR. DIXON: Maybe if anyone -- if we think it may be something -- it may change the language to say, A Florida-permitted medical gas wholesale distributor or medical oxygen retail establishment may distribute medical oxygen cylinders or cylinder, you know, just to make --

MR. HART: Or --

MR. DIXON: I mean, we want to do something like that maybe.

MR. HART: Or maybe just say, medical oxygen.
MR. DIXON: And I think the reason we put -- I think we put "cylinder" in there because, I think, we used "cylinder" in some of the previous ones, so we want to just keep --

MR. HART: Right. And I feel that -- I think I understand your -- the spirit of what you're saying. It's nothing I want to greatly challenge.

MS. ALSOBROOK: Mr. Hart, I think I understand what you're saying. And, you know, we debated -- I was looking at my notes. The debate interestingly enough -- as the director indicated -- was over the term container, cylinder, or vessel. And we never debated the term "a."

We wanted to make sure that we gave the industry plenty of flexibility as to cylinder or vessel, because we knew that was the federal terms.

MR. HART: Right.

MS. ALSOBROOK: And so we vacillated on the term "container," and we just ignored the term "a". And I do not believe it was meant to limit --

MR. HART: Right.

MS. ALSOBROOK: -- to a single.
MR. HART: Sure, okay.

MS. ALSOBROOK: So I think we can work on --

with Jamie, if she's willing to do that -- how not
to make it a "a," meaning one --

MR. HART: Right.

MS. ALSOBROOK: -- distribution. So

that's --

MR. HART: Right. Because I do think in many

instances that -- from our last conversation --
one would fit. But there are those exceptions,
especially when we talked about the catastrophic
possibilities of someone coming in and being down
on vacation and having two or three in those
catastrophic spots.

So I'm really good with the spirit of what

you wrote. I didn't want us to get fenced in if

that could be a simple change. Other than that, I

think the language that permeates the rest of it

is great. I thought you did great work there, and

it works for us as industry. So on that, I'm

good.

MR. DIXON: Did we have any other comments

from -- or any questions from anyone on the phone?

MR. WILLENBROCK: No. This is

John Willenbrock and other members of CGA, and we
do not have any other additional comments.

MR. DIXON: If there are no other comments --

let me make sure we look at the notice, because I

think the notice --

MS. GREENE: I did not put a time.

MR. DIXON: Okay. I just want to make sure.

Okay. Well, if we don't have any other comments

from anyone else on the phone or anyone else in

the room, what we will do from this point forward

is we will go back and look at it, because I think

that's a minor change to that language.

And what we'll do is we'll make that minor

change to the language, and we will route it

through the appropriate channels here for the

Notice of Rulemaking -- Notice of Proposed

Rulemaking. And then we'll publish the

Notice of Proposed Rulemaking.

If there's no further comments, then we can

go ahead and conclude this rule workshop. Thank

you, everyone.

MR. HART: Thanks a lot.

(Thereupon, the proceedings were concluded at

1:10 p.m.)
CERTIFICATE OF REPORTER

I, JESSICA RENCHEN, Registered Professional Court Reporter, certify that I was authorized to and did stenographically report the foregoing proceedings and that the transcript is a true and complete record of my stenographic notes.

DATED this 6th day of August, 2015.

JESSICA RENCHEN, Court Reporter