

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

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

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:

JESSICA RENCHEN, Court Reporter
For the Record Reporting, Inc.
1500 Mahan Drive, Suite 140
Tallahassee, Florida 32308

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APPEARANCES:
REGGIE DIXON, DIVISION DIRECTOR
RENEE ALSOBROOK, CHIEF OF COMPLIANCE
DINAH GREENE, ADMINISTRATIVE ASSISTANT
JAMIE ROYAL, GENERAL COUNSEL

P R O C E E D I N G S

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2 MR. DIXON: Good afternoon. My name is
3 Reggie Dixon. I'm the Division Director for the
4 Division of Drugs, Devices, and Cosmetics. We are
5 here today -- today is August 6, 2015. We are
6 here to conduct a rule workshop on rule 61N-1.027,
7 *Emergency Use of Medical Oxygen*. I guess we don't
8 have to take a role.

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

17 We're here today to conduct a rule workshop
18 on this rule. The statutory guidance or basis for
19 the rule, this is mandatory rulemaking. Chapter
20 499 -- I'm sorry. Section 499.85, Subsection 6,
21 states as follows: "The Department shall adopt
22 rules that govern the distribution of medical
23 oxygen for emergency use by persons authorized to
24 receive emergency use oxygen. Unless the laws of
25 this state specifically direct otherwise, such

1 rules must be consistent with federal regulations,⁴
2 including the labeling requirements of oxygen
3 under the federal act. Such rules may not be
4 inconsistent with Part 3 of Chapter 401 or the
5 rules adopted thereunder."

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

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

22 In your packet, which you should have, Tab 1
23 has all the information in it that was at the June
24 10th rule workshop, and Tab 2 is information for
25 this particular workshop. What we have is -- to

1 just kind of -- I guess -- cut to the chase, we
2 have some proposed language now that was recently
3 sent out. That language is on the -- it's on the
4 next to last page of the packet. The rule
5 language starts at 61N-1.027, *Distribution Of*
6 *Medical Oxygen for Emergency Use.*

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

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

24 MR. HART: Good afternoon. This is
25 Peter Hart. I'm with Airgas. I want to say

1 thanks very much for your rewriting, and I find
2 this to be extremely good. As far as we're
3 concerned with industry, it fits with what we
4 talked about. It fits with what we're doing.

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

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

15 MR. HART: Right.

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

22 MR. HART: Or --

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

25 MR. HART: Or maybe just say, medical oxygen.

1 MR. DIXON: And I think the reason we put -- ⁷
2 I think we put "cylinder" in there because, I
3 think, we used "cylinder" in some of the previous
4 ones, so we want to just keep --

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

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

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

19 MR. HART: Right.

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

24 MR. HART: Right.

25 MS. ALSOBROOK: -- to a single.

1 MR. HART: Sure, okay.

2 MS. ALSOBROOK: So I think we can work on --
3 with Jamie, if she's willing to do that -- how not
4 to make it a "a," meaning one --

5 MR. HART: Right.

6 MS. ALSOBROOK: -- distribution. So
7 that's --

8 MR. HART: Right. Because I do think in many
9 instances that -- from our last conversation --
10 one would fit. But there are those exceptions,
11 especially when we talked about the catastrophic
12 possibilities of someone coming in and being down
13 on vacation and having two or three in those
14 catastrophic spots.

15 So I'm really good with the spirit of what
16 you wrote. I didn't want us to get fenced in if
17 that could be a simple change. Other than that, I
18 think the language that permeates the rest of it
19 is great. I thought you did great work there, and
20 it works for us as industry. So on that, I'm
21 good.

22 MR. DIXON: Did we have any other comments
23 from -- or any questions from anyone on the phone?

24 MR. WILLENBROCK: No. This is
25 John Willenbrock and other members of CGA, and we

1 do not have any other additional comments.

2 MR. DIXON: If there are no other comments --
3 let me make sure we look at the notice, because I
4 think the notice --

5 MS. GREENE: I did not put a time.

6 MR. DIXON: Okay. I just want to make sure.
7 Okay. Well, if we don't have any other comments
8 from anyone else on the phone or anyone else in
9 the room, what we will do from this point forward
10 is we will go back and look at it, because I think
11 that's a minor change to that language.

12 And what we'll do is we'll make that minor
13 change to the language, and we will route it
14 through the appropriate channels here for the
15 Notice of Rulemaking -- Notice of Proposed
16 Rulemaking. And then we'll publish the
17 Notice of Proposed Rulemaking.

18 If there's no further comments, then we can
19 go ahead and conclude this rule workshop. Thank
20 you, everyone.

21 MR. HART: Thanks a lot.

22 (Thereupon, the proceedings were concluded at
23 1:10 p.m.)

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CERTIFICATE OF REPORTER

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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