STATE OF FLORIDA

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL

The above entitled Meeting convened at 1940 North Monroe Street, Tallahassee, Florida on the 25th day of February, 2016, commencing at 9:30 a.m.

Reported by:

JEFFREY R. BABCOCK

Court Reporter

APPEARANCES:

REGGIE DIXON
STEVE MAYS
DEAN ELLIS
SCOTT BROCK
DINAH SKRNICH (GREENE)

TELEPHONIC APPEARANCES:

GARY CACCIATORE, CHAIR
ARLENE ELLIOTT
WILLIAM MAHONEY
PATRICK BARNES
JEENU PHILLIPS
PETER HART

P R O C E E D I N G S

MR. CACCIATORE: This is Gary Cacciatore, I'm going to go ahead and call the meeting to order, and let's start with the roll call, Dinah, please?

MS. SKRNICH: All right. Gary Cacciatore?

MR. CACCIATORE: Present.

MS. SKRNICH: Mike Ayotte? Steve Mays?

MR. MAYS: Present.

MS. SKRNICH: Scott Brock?

MR. BROCK: Here.

MS. SKRNICH: Arlene Elliott?

MS. ELLIOTT: Here.

MS. SKRNICH: Dean Ellis?

MR. ELLIS: Here.

MS. SKRNICH: Bill Mahoney?

MR. MAHONEY: Here.

MS. SKRNICH: Patrick Barnes.

MR. BARNES: Here.

MS. SKRNICH: Michelle Mendez? Jeenu Phillips?

MR. PHILLIPS: Present.

MS. SKRNICH: And Peter Hart?

MR. HART: Here.

MR. CACCIATORE: Thank you, everyone, it sounds like we do have a quorum.

MS. SKRNICH: You do.

MR. CACCIATORE: So the first order of business is the approval of the minutes. We've got an abbreviated minutes from the December 3rd meeting, but we also have a transcript that was provided later of the conference call that we had. Are there any edits or changes to the minutes? If not, I will entertain a motion to approve the minutes.

MR. BROCK: So moved.

MR. ELLIS: I second, this is Dean Ellis.

MR. CACCIATORE: Moved and second. Any discussion? Hearing none, all in favor signify by saying aye.

(Chorus of ayes.)

MR. CACCIATORE: Any opposed, like sign. Motion passes.

Okay, so as I usually do, I'm going to start out with reading our goals and objectives of our council. This is the Drug Wholesale Distributor Advisory Council of the Department of Business and Professional Regulation, my name is Gary Cacciatore, I'm with Cardinal Health and I serve as Chair of the council.

This council is charged with reviewing

Chapter 499 and the rules adopted under Chapter 499 at least annually, and provide input to the Department regarding all proposed rules to administer Chapter 499; make recommendations to the Department to improve the protection of prescription drugs and public health; make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs; and make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.

And I think everyone can see by the items on the agenda today we're really working towards that goal of improving coordination, particularly with the federal regulations. And most of the agenda today covers legislation and rules to accomplish that goal, so I think we're moving in the right direction.

I don't have a particular report under Tab 2, so I'm going to turn it directly over to Tab 3, we've got a lot of information. I'll turn it over to Mr. Dixon to go through the legislation that's been changing on a daily basis, and then the

proposed rules that the Department has put out regarding the track and trade. Mr. Dixon?

MR. DIXON: Good morning, thank you, this is Reginald Dixon with DBPR. Just want to kind of start off by going over -- as you can see, like the Chairman said, we do have a lot of information for you guys today. I guess we can start going through the legislation.

I was going to jump around a little bit because there's some of these bills that aren't really going anywhere, and then we can get back to the first two. Just to give you guys an update on -- under 2016 Legislation C, House Bill 261; House Bill 261 and Senate Bill 176 are both bills that remove the cosmetic registration. As of today, it does not appear that either of those bills are -- will be moving forward.

The House bill was on a committee in January and hasn't gone anywhere so far. The Senate bill went to two committees, it last was in Senate appropriations, but it was introduced in January of 2016 and doesn't look like it has moved anywhere at all. I'm not sure if those two bills will move, or if some of the subsequent language in those bills may be amended at some point later

to either the House or the Senate bill if it goes to the floor, which is a possibility. We don't have any indication that it would happen, it's just that those bills right now do not appear to be moving anywhere.

The same goes for Senate bill -- under E, Senate Bill 7038. That bill does not look like it was going anywhere as well. It was introduced in January and has not moved into any further committees.

For those of you who are unfamiliar with the legislative process, in Florida, each bill that is proposed has to go through three committee references. Once it gets out of those three committee references, you have to have a House -- or if it's a Senate -- if it's a House bill, it's got to have a Senate companion bill which both comes out of three committees a piece, and then go into conference or to the floor where those two bills are reconciled, and ultimately gets approved by the governor, and the language becomes law.

So with that kind of background, and like I said, that's a very-general background, I would like to move back to House Bill 1211. We're going to probably to spend the majority of the meeting

talking about Senate Bill 1604. The House Bill 1211 actually has gone through three committee stops, and is prepared to go to the floor.

In the agenda materials that you have in front of you, you have the House bill, and there were a number of amendments to that House bill. We can go -- we're prepared to go through the amendments, but just to give you a little bit of background, the -- as of yesterday on the Senate bill, there were four amendments that were filed last night by the 5:00 o'clock filing deadline, so to the extent that the House bill and the Senate bill need to be reconciled, what would probably happen -- and the Senate bill is being considered today at 10:00 o'clock -- if the Senate bill is approved with the amendments, and the Senate bill goes to the floor with the House bill that goes to the floor that does not have those same amendments, there is a lot of negotiation going on, but it is expected probably that the House bill will be amended -- there might be a strike-all which replaces the House bill with a bill which is identical to the Senate bill. So that's why I think the majority of the conversation might lay around the Senate bill,

because the Senate bill will have the most recent amendments.

Some of these amendments were amendments that were brought forth from folks in the industry who worked with our Division to try to reach a goal and try to solve the problems that may have come up inadvertently by the passage of this language.

So we can kind of go through the first amendment to the House bill. This first amendment it's on -- I'm sorry, I don't have page numbers on the agenda, but this first amendment basically allows the Department to adopt rules setting the limit on the amount of prescription drugs that can be distributed by a retail pharmacy before that retail pharmacy has to obtain either the retail pharmacy wholesale distributor permit; or alternatively, a wholesale distributor permit.

What this language basically says is that amount -- the limitation on what they can distribute is set right now at 3 percent, and that the Department has the authority to write a rule to basically define what minimum quantities is.

The hope with this amendment is that it would give the Department some flexibility so that if the federal government at some point came down

with a rule as they implement their DQSA and said, "Well, that limitation is 9 percent," well then the Department could then have the rule-making authority to write a rule that says 9 percent as opposed to having to go back to the legislature to get legislative authority to change it. So that's why it's initially set at 3 percent, and then gives the Department rule-making authority.

Did anyone have any questions about that amendment before I -- I thought it would probably be better to have -- to discuss the amendment and then ask for questions, and maybe we can do it that way.

MR. CACCIATORE: Mr. Dixon, is that restricted only to retail pharmacies?

MR. DIXON: Yes, sir. There's an exemption to the definition of wholesale distribution which allows retail pharmacies to distribute limited amounts of prescription drugs for office use, and "limited amounts" is not defined in the federal act.

And so the legislative staff thought it would be better for us to at least -- because we do have the retail pharmacy wholesale distributor permit, and if they're capped at 30 percent, the issue was

how do you reconcile that 30 percent with the -- limit with the retail pharmacy wholesale distributor permit, and then also this exemption to the wholesale distribution? And that's how the legislative staff -- that 3-percent cap, at least until the Department got rules done, was specifically requested by staff from the Senate.

MR. MAYS: Mr. Dixon, this is Steve Mays, I guess the section in the bill indicates minimal quantities of a drug licensed -- drugs -- distribution of minimal quantities of drugs by a licensed pharmacy to a licensed practitioner for office use, so it would be limited to that?

MR. DIXON: Yes, sir.

MR. MAYS: Okay, thank you.

MR. DIXON: Where there any other questions from council members? Mr. Chair, I'm not sure if you -- is this the time that you wanted to open it up for questions from anyone else that may be on the line?

MR. CACCIATORE: Yeah, I guess that's better to do it while we're talking about a particular subject, rather than going back, so let's go ahead and open it up to the public for any comments on that as well. Anyone in the room there?

MR. DIXON: There doesn't appear to be any comments in the room, are there any comments from anyone -- any questions from anyone on the phone?

MR. CACCIATORE: All right, let's move on.

MR. DIXON: Okay. The second amendment here is more of a technical amendment. As you all know, under the DQSA, distributions by a manufacturer are no longer considered wholesale distributions. And so this is an amendment to strike the word "wholesale" from the provision in 499.01 which establishes our manufacturer permit.

So what this basically does is to just kind of line it up with some other provisions in 499 where now the wholesale distribution by a manufacturer is no longer a wholesale distribution. So that's why we just removed that term. Did anyone of the council members have any questions about that amendment? Did anyone on the phone have any questions or concerns or -- that they wanted to discuss about this amendment?

All right, I guess we'll move on to the third amendment. This third amendment is basically an amendment which it clarifies what the Division believes is the current law already in a sense that it allows the end-stage renal pharmacy to

distribute to a commonly-owned end-stage renal pharmacy prescription drugs to meet the immediate emergency need of a patient. And then it gives the Department the authority to develop rules to say when those distributions exceed what you would normally be considered meeting the emergency need of a patient.

In a sense, if you've got two facilities that are commonly-owned, and a patient comes in and during the course of that treatment, that patient runs out of medication and they need it immediately, it should not be such that a facility is afraid to ship it from one of their sister facilities because they don't have the restricted distributor permit which facilitates that distribution.

We've always taken the position at least that -- at least from, I know, since I've been here, I know that a pharmacy is allowed to do an emergency distribution to another pharmacy to meet the immediate need of an identified patient. So we wanted to make sure to clarify that because we were approached by a group representing the end-stage renal dialysis folks, and so we wanted to make sure that -- they wanted to make sure that

this was clarified, so that's why this is in the law, which is -- this is why this amendment came about.

Are there any council members that had any questions about this amendment? Is there anyone on the phone on the conference call that may have had some questions about this amendment?

MR. CACCIATORE: None here.

MR. DIXON: Okay. The fourth amendment deals with distributions of repackaged medications by rural hospitals. One of the things that this bill does is it actually allows -- it relieves some of the requirements on the rural hospitals that have the restricted distributor permit who want to repackage prescription drugs for those rural hospitals.

And so what this amendment does is it gives the Department rule-making authority to implement rules or to adopt rules that deal with those drugs that are being repackaged by rural hospitals in a sense that, even though we lessen some of their burdens, we do want to be able to have, and we thought it was appropriate to have, some rule-making authority so we can set some standards just to ensure that the safety of those

prescription drugs, and the patients that they serve, is not compromised. So that's how that came about.

Are there any questions from any council members on that amendment? Were there any questions from anyone on the conference call about the amendment?

Okay. So just kind of re-cap, those amendments have already been incorporated into what is now -- and let me make sure I have this straight -- it is now called -- the current House bill is the Committee Substitute for -- it is the Committee Substitute for the Committee Substitute House Bill 1211. So that's -- so if anyone wants to take a look at that, go online and look at it. If you go onto the Florida House of Representatives' page and you type in House Bill 112 (as spoken), the most-recent version of it is the Committee Substitute for the Committee Substitute for House Bill 1211, okay?

Moving on to the next -- the next bill is actually the committee substitute for House bill 1604 --

MR. BROCK: Senate bill.

MR. DIXON: Oh, I'm sorry. It's Committee

Substitute for Senate Bill 1604. Okay. That particular bill, as I said, there were four amendments filed last night to this particular Senate bill, and we can go through those amendments rather quickly.

And some of these amendments are just to bring the Senate bill into alignment with the House bill. For instance, the first amendment is the amendment dealing with the minimum quantities by prescription drugs distributed by retail pharmacies. So this is same amendment which sets that limit at 3 percent and then gives the Department rule-making authority to determine what that limit should be.

The one nuance that should be noted in this amendment is it sets that 3 percent to 3 percent of the retail pharmacy's total annual purchases; whereas in the House bill it didn't have language "retail pharmacies," so there may have been some confusion as to whose purchases that 3 percent was limited to.

In other words, was that 3 percent limited to the purchases by the practitioners, or was that 3 percent limited to the purchases by the retail pharmacy? And so that phrase "of the retail

pharmacy's total annual purchases," was included in that amendment.

Were there any questions about that amendment from anyone on the council? Any questions from anyone on the phone?

Okay. The second amendment to the Senate bill is the one that talks about the end-stage renal pharmacies. It's the same language that allows them to distribute between commonly-owned end-stage renal pharmacies to meet the emergency need of a specified patient, and it also gives the Department the same rule-making authority.

Were there any comments from anyone on the council, or questions about 1? Any comments or questions from anyone on the phone about it?

Okay. The third amendment is the same amendment that talks about the distribution of repackaged drugs by rural hospitals. Were there any comments or questions from anyone on the council regarding that amendment? Were there any questions from anyone on the phone about the amendment?

The fourth amendment is actually a little bit different. The fourth amendment is an amendment which actually talks about -- it actually sets out

those basic business records that need to be maintained by those entities that are regulated under Chapter 499.

There was some -- and just to give you a little bit of background, there was some concern that the provisions under Section 499.0121(6) which talks about record keeping, there was some concern that those provisions may have conflicted with what the federal law says with respect to tracking and tracing.

The difficulty here, quite frankly, is that our statutes deal with both the prescription drugs and the API, and the subset of the prescription drugs is a product which is addressed under the product tracing and -- tracking and tracing requirements under the DQSA.

So we worked with the industry to try to come up with language which set out the record keeping requirements that said, "Look, these are the records that you ought to have. These are basic business records. We didn't want you to create and maintain anything that you wouldn't normally create. So you should know your sources, you should know if they're licensed. You should know where the drugs are actually physically coming

from. You should know what the drugs are. You should know how much they cost and how much of it that you received, and what you did with it ultimately."

So those basically are what the requirements are. There's a requirement that you be able to run an inventory -- which you would think any business could run an inventory of what it actually has -- and there's also a provision in this new statute that basically says to the extent that those basic business records that you are keeping, the information contained in those is subsumed or contained in the DQSA tracking and tracing requirements, then you only have to follow the tracking and tracing requirements, because that's what you're supposed to do.

And the point was not to have record keeping provisions that are in addition to, in contravention of, et cetera, et cetera, of the requirements of the DQSA, at least with respect to those products. If it's not a product, then you have some basic record keeping requirements that shouldn't be a onus because it's kind of expected those are the records that you would keep anyway.

Are there any questions from the council

members about that, because I know this amendment is -- was late-filed yesterday. I know we did have some conversations with the folks from HDMA about these, but I'm not sure if everyone from the council had an opportunity or if the people from the industry had a chance to actually fully look at this language.

MR. BROCK: Reggie, just to clarify, make sure I understand what you -- the comments you just made, if your product is covered under the federal act, then you follow those record-keeping requirements under the federal act.

MR. DIXON: Yes, sir.

MR. BROCK: If it is an API or a prescription drug that is not covered under the federal act, then this language would apply.

MR. DIXON: Yes.

MR. BROCK: Okay, thank you.

MR. DIXON: Were there any questions from anyone on the phone? Okay. Well, and again these amendments have not yet been incorporated into the Senate bill, it is expected that they will be today. The Senate bill is up before -- the Senate bill is on the Senate Appropriations Committee meeting agenda at 10:00 o'clock this morning, so

we expect that these amendments will be incorporated into the Senate bill, so we want to make sure we brought those to your attention.

I guess we -- if we didn't have any questions regarding any of the other legislation, we can move on to the tracking and tracing rules that we have in front of you today.

I just kind of want to start off by giving you the general background. I know the council members have heard us say this before at different meetings, but what we wanted to do and -- what we wanted to do and I think what we were required to do is to implement the federal rules as much as we could into federal statute -- the federal statutes into our Departmental rules, I'm sorry -- in the sense of this: There's a provision under Florida law which prohibits the state from delegating rule authority to entities outside of the state.

And so it was a difficult thing to try to do in the sense that we realize the tracking and tracing set standards that are statutorily set at the federal level, but we also realize that the FDA has to actually go through and do their federal rule making to further define, further implement those federal statutes.

And so the difficulty that we have from the divisional standpoint is getting legislation through the legislature is not always the easiest and the best -- the quickest process. And so what we wanted to do was, instead of putting the federal statutory requirements in our statute, to put those requirements in our rules. And so as the federal government goes through its rule making, then we can go through our rule making to further clarify, like these product tracing and -- tracking and tracing requirements.

And of course, as we go through rule making, similar to what we're doing today, the rules come before the council, the rules get published in the FAR, interested parties can call in, can request a hearing. We can do a workshop, we can do a bunch of different things to get industry input to make sure that our rules are where they need to be at so that we're compliant with the DQSA.

Had we done this in statute, we would not necessarily be able to have that flexibility, so that was the purpose for putting these tracking and tracing requirements in our rules, as opposed to actually sticking them in the statute.

And what you'll see is, in addition to the

tracking and tracing requirements, we actually incorporated the federal definitions as well into our rules with the thought that, as the federal folks go through and implement it, we will be able to be more responsive, and you won't have -- like we did with the implication of the DQSA, you won't have a two or three-year gap where you've got a federal statute in place, and then the federal -- and then we are, as an agency, are trying to catch up to what the current federal law says.

So without further ado, I guess we'll start with the first proposed rule. We have 61N.028 (as spoken.) What this rule attempts to do is to bring in the federal definitions for the purposes of tracking and tracing products.

And let me back up. Procedurally where we're at right now is, in Florida, what you have to do is you have to do what's called a notice of rule development where you open up the rule, and you say, "Hey, look, we're going to be doing rule making in this area." Once we say we're going to be doing rule making in this area, you have to come up with language and then you tell the public this is the proposed rule. So we file what's called a notice of proposed rule where we actually

put the language out to the public for comment.

So right now, we're at the point where we have notice of language, and we've put the language out there for comment. And so if we don't receive any comments, if we don't receive, like, a hearing or we don't have -- or we don't make any changes, these are what the rules are.

So it's really important that, to the extent that there are changes that need to be made to the rule -- things that may not be in compliance with the federal act, things that we have missed -- it's very important that we have that input now rather than later.

So we do ask that, to the extent that you can, if there are issues that you see with these -- some of them couldn't be avoided, and I think we may know what some of those are -- but if they're ones that we can fix, things like that, this is a very-important time for us to try and do that; because otherwise, we may end up with rules that are in place and then the folks wouldn't be able to comply. And we do not want people to be in a position of noncompliance right from the bat because we failed to do something in our rule making part.

MR. CACCIATORE: Mr. Dixon?

MR. DIXON: Yes, sir.

MR. CACCIATORE: This is Gary Cacciatore. And just to clarify on the procedural aspects, these rules were published, I think, on February the --

MS. SKRNICH: 17th.

MR. CACCIATORE: -- 17th, and there's a 21-day time period where the public can request a hearing on the rules; correct?

MR. DIXON: Yes, sir.

MR. CACCIATORE: I thought -- is that same 21-day time period apply to written comments or was it a different time period for that?

MR. DIXON: What we can have -- and there's a difference between comments and folks who request the rule -- like a workshop. A workshop is where -- let's say today someone -- we decided that there's not enough time to kind of go through this stuff and vet it, or if someone later on determines, "Hey, look, this impacts me in a way that it shouldn't because the federal statute says X, Y, and Z," the best way to ensure that your input is gathered that -- is to request a workshop. And it's not some big formal thing that

you have to do, you can just write in and say you request a workshop, and what we would have to do is we would suspend rule making -- well, not necessarily suspend rule making, we would actually notice another meeting where then the specific content of whatever particular rule is at issue would be brought up and it would be further vetted.

And if that after that workshop a determination is that changes need to be made to that rule, what we would have to do is we would have to file what's called a notice of change which would actually be a notice changing the language to address whatever comments or concerns we receive from those parties who are effected by the rule.

But if we don't get any of that comments, we have to review those comments and determine whether or not those comments subsequently change the rule. Like if someone just rolled in and said, "Hey, look, you know, we don't necessarily like the formatting of the rule, we wish you had renumbered it a different way," that's a comment that we would accept, but we wouldn't have to do anything with it.

If someone wrote in and said, "Hey, look, I think the way this rule is written is different and it adversely impacts, and it's going to cause a financial strain on our business to do X, Y, and Z," that's a substantive comment that I think, as a Division, we have an obligation to maybe do a workshop and then bring that back to the council and say, "Look, here's a comment that we received. Here's a response; here's the Division's; we've done an analysis, and we think maybe the person's off here, or maybe they're right on," and we've tried to come up with a different language to address that.

So that's kind of the process that we have to go through so that -- you know, the last thing you want is someone to challenge the rules and say that you didn't have an open proceeding and you didn't follow the appropriate procedure for actually adopting rules.

MR. CACCIATORE: Okay, thanks. I just want to make a courtesy -- make sure all the council members and members of the public understand that if you have comments, this is -- as Mr. Dixon said, this is the time, either to express them verbally through the council here, or to submit

formal comments. Or if you think it's a major issue and want to request a workshop or something like, then that's the proper procedure to do that.

MR. DIXON: And you'd have -- and just a reminder, I think it applies per rule, so you would want to do that per rule. So if you had a question -- let's say you had a question about only the definitions, and you didn't -- and no one had any questions about anything else, the other rules could possibly go into effect, and then we'd still be working on the definitions.

So I think if you have questions, you know, or you have comments, or you have issues that we need to resolve, it's best to kind of do it now or subsequent -- rather sooner than later, maybe that's a better way to say it.

MR. CACCIATORE: And just to clarify so everyone understands, if there is a rule hearing, that's run by the Division. The Division does a great job of working with the council, but remember we're an advisory council, so we don't actually decide and vote on the specific language, we can only make recommendations to the Division. But fortunately they work with the council.

So as Mr. Dixon said, if there is a major

issue, he may bring it back to the council; but any rule workshop would be held by the Division as a separate meeting.

MR. DIXON: So with having said that, the first rule that we have is 61N-1.028 -- or the proposed rule -- and as I indicated, what we tried to do in this rule was to incorporate the definitions that are set forth in the DQSA.

Normally, when we do something like this, we don't necessarily go through line-by-line, unless -- what I think would be a better idea, unless, Mr. Chair, you want to do it differently, was to ask for any comment on a specific part -- either the rule in general, or specific sections of the rule -- and then we can try to address those one at a time.

MR. CACCIATORE: Yeah, I think that makes sense, especially for this particular section, we just ask if anyone has any comments on any particular issue with any particular definition.

MR. DIXON: Were there any comments or questions from anyone on the council regarding 61N-1.028?

MR. BARNES: Mr. Chair, this is Patrick.

MR. CACCIATORE: Go ahead, Mr. Barnes.

MR. BARNES: So just reviewing this, it looks like we've done a really good job, Reggie, on kind of trying to mirror it. I know one of the issues that, at a national level, some of the pharmacy organizations are working with the FDA on drug shortages as far as when a hospital needs to transfer a product -- or the borrow-and-loan process like -- if you will, on that, where you're -- you may need to transfer a limited supply to take care of a patient.

And so far there hasn't been anything back from the FDA on that, and I guess I'm assuming that if the FDA comes out with something on that, that the State of Florida would then mirror what the feds are doing in that regard. That would probably be a true statement, do you think?

MR. DIXON: I believe so. It would just depend -- like I said, without knowing exactly what the language would be, I think the best answer I can give is we would do whatever we could to try to come into compliance with the federal act as long as it's not something that is just outright violative of Florida law.

For instance, if it's something that we need a statutory change, I don't know that, by rule, we

can do something that would require statutory change, but I mean, you know, that's obvious now.

MR. BARNES: So one of the things that I hear is having -- under the exemption phase, Number 4, the dispensing of a product pursuant to a prescription executed in accordance with 21 U.S.C. and so on and so on. Could that be referred to as an order -- prescription or order?

MR. DIXON: I'm sorry, what page are you referring to? What line are you referring to?

MR. BARNES: This is 61N-1.028 on the second page.

MR. DIXON: Okay.

MR. BARNES: Number -- let me find it again. I'm sorry, the last page under exemptions, so that's 25, which is transaction. And then there's -- D talks about exemptions. So exemptions to the term transaction does not include. Do you see that?

MR. MAYS: B4, I think.

MR. DIXON: Okay. Yes, sir.

MR. BARNES: And then Number 4 talks about the dispensing of a product pursuant to a prescription. So what -- I know in the retail setting what a prescription is, but what about in

a hospital setting? Could that be interpreted as an order?

MR. DIXON: I think that the definition of prescription, I want to say, is under 456, and I think it is also under 893. And if I'm not mistaken, I think that does include an order from a physician.

MR. BARNES: Okay, very good.

MR. DIXON: I'm going to -- while we're talking about it, I'm just going to look it up real quick just to make sure, but I want to say that that is a yes. Are there any other questions -- I guess, while we're looking that up, were there any other questions about the definition -- about this particular rule?

MR. MAYS: Yes, this is Steve Mays. Under definition on Number 26, Transaction History, the last sentence states "transaction history for a grandfathered product begins with owner of the product on January 1st, 2015." The FDA has extended by enforcement discretion accepting that history by wholesalers up until May of 2015; and then actually for dispensers, it's next week, March 1st.

So I'm just wondering if that's going to

cause issues for the Department as far as enforcement, and I'm not sure about your authority to exercise that same enforcement discretion.

MR. DIXON: That's actually a very good question, because what we did was we took this language to try to mirror what the DQSA says. So we -- that may be one we definitely need to consider. If they're exercising enforcement discretion, what we may be able to do is -- if we leave the language, what we may be able to do is if it comes across, if it's applied to someone, they may be able to maybe receive a waiver of the rule. But I don't know if -- if changing that may be not -- changing that date may not be a big deal either, because it isn't a rule.

MR. MAYS: Yes, because I think the industry -- as of January 1st, the industry -- it was found to not be ready to exchange that data, and in fact, probably there were some manufacturers that weren't even passing that data as of January 1st, 2015, so it's pretty much the entire supply chain. So it would -- I can see it being problematic for a pharmacy if you go back to look to see if they're accepting that data before March 1st of 2016.

MR. DIXON: Okay. I'm going to note on here that we need to come up with a new date, because what we may be able to do, if -- well, let's discuss it a little bit. If we came up with a new date, are there any thoughts as to a date? Like maybe do you think it would be, like, July 1st or something? Could the date that -- did the FDA give a date for --

MR. MAYS: Yeah, they publish those dates, and I mean, my recommendation would be to adopt those dates for the different supply chain members. I think, you know, like May 5th -- I think it's May -- I'm not positive, and Gary, maybe you know -- I think it was May 2015 for wholesale distributors, and then March 1st, 2016 for dispensers.

MR. CACCIATORE: That sounds right, I -- I think if you went with a March 1st, 2016, that would cover --

MR. MAYS: That would cover the whole -- if you wanted to do it that way.

MR. DIXON: Okay. So March 1st -- so we think March 1st, 2016 would cover everybody?

MR. MAYS: Yes.

MR. DIXON: Okay. So that may be a good idea

just -- we just -- we change the date to March 1st, 2016, then you don't have to worry about anything that's before that.

MR. MAYS: Right.

MR. DIXON: Okay. I'll bring that back to our folks and see, because changing that date now before the rule goes into effect is probably a very good idea. Okay. All right, I'm sorry, I'm just looking real quick --

MR. CACCIATORE: This is Gary Cacciatore, just a comment reflecting Patrick's question, and this is on Section 30, definition of Wholesale Distribution. Subparagraph (c), because Mr. Barnes talked about meeting the needs of a patient, this is emergency medical reasons, but I guess I'm a little concerned about this only addresses a public health emergency, so it doesn't really address Mr. Barnes' concern about an emergency for a particular patient, so Mr. Barnes is that language there going to be problematic for a hospital in an emergency situation in a drug-shortage situation?

MR. BARNES: Yes, Mr. Chair, this is Patrick. That's exactly the concern that pharmacies have. At a national level, we're working with the FDA

to, you know -- I mean, these drug shortages are certainly real, and there's times when we then, for emergency situations for a patient, we need to borrow product.

So it's pretty clear in the federal regs that these transactions are not exempt, and so we're still working with the FDA to see what can be done about it, and I think some of the things that people are doing, there's really a couple different kinds of, in my opinion, borrow-and-loan transactions: One could certainly be a drug that another entity certainly has enough product and it's really not a patient-specific transaction. And then in cases like that, you would probably need to pass on the T3 information.

But sometimes you're just needing a couple doses until you can do an order for that product yourself; and in those cases, that's more of a patient-specific transaction. Or -- and that's where I wanted to get the definition of prescription, as far as that construed as an order, and I think a lot of us are considering a prescription and an order as the same.

MR. CACCIATORE: That's made for those types of situations you believe, right, I --

MR. DIXON: Hi, this is Reggie. The definition for prescription under Florida law right now is contained in Chapter 893. Specifically it's 893.02, and it's Paragraph 22.

It's pretty-long paragraph, but what it starts off by saying is "Prescription means and includes an order for drugs, medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly-licensed practitioner licensed by the laws of the state to prescribe such drugs and medicinal supplies issued in good faith, and in accordance of professional practice intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting requirements of section 893.04."

So I think that will -- I'm sorry it took a minute to get that, but I think it does cover the situation that you were talking about, Patrick.

MR. CACCIATORE: Mr. Dixon, isn't 893 only for controlled substances, though?

MR. DIXON: 893 -- it deals with controlled substances, but to the extent that it has a definition of prescription drug, that definition

does not necessary -- is not limited to just controlled substances.

MR. CACCIATORE: Okay, thank you.

MR. PHILLIPS: Gary, this is Jeenu Phillips, if I can speak?

MR. CACCIATORE: Yeah, Mr. Phillips, go ahead.

MR. PHILLIPS: Yeah, so -- and it's not only in 893, but also in 465.003 under definitions, and it also includes -- it includes a definition of a prescription. "Prescription includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly-licensed practitioner authorized by the laws of this state to prescribe such drugs or medicinal supplies, and intended to be dispensed by a pharmacist" --

MR. CACCIATORE: Okay, thank you --

MR. PHILLIPS: -- continues and goes on from there --

MR. CACCIATORE: -- that helps.

MR. DIXON: Okay, I'm sorry. So right now with respect to 1.028, I think we did have -- we had the one question with respect to the grandfathering. I think the idea is to possibly

do a notice of change with respect to that date. And I think -- and Patrick I hope we answered that question with regards to whether or not a prescription included an order.

Were there any other comments or questions from council members regarding the definitions, at least in 1.028? Were there any questions or suggested changes from anyone on the phone?

Okay. Well, again, like I said, we are actively looking for, with respect to any suggested changes that there may be from anyone on the phone, as well as anyone on the council. Again, I just want to reiterate that it is really important that we kind of get input as early as possible so that we can give some clarity and some -- to the industry as to what the tracking and tracing requirements are.

Okay, so I guess we'll move to 61N.029 (as spoken) Manufacturer Requirement. Are there any questions or concerns or comments with respect to these from any of the council members? Were there any questions or concerns with respect to 1.029 from anyone on the phone or anyone on the call?

All right. Okay, I guess we're moving to 61N-1.030, Wholesale Distributor Requirements.

Are there any questions from anyone on the council regarding those requirements that we -- in the rule as drafted? All right. Are there any questions from anyone on the phone regarding the language that's included for wholesale distributor requirements?

Okay, so we're moving to 61N-1.031, dispenser requirements. Were there any questions or comments from anyone on the council regarding the rule drafted for the dispensing requirements?

MR. BARNES: Yes, Mr. Chair, this is Patrick.

MR. CACCIATORE: Go ahead, Mr. Barnes.

MR. BARNES: Reggie, so I guess part of the issue, I think, is the -- eventually everything will be electronic, and -- for all this T3 information -- and that's certainly, you know, slated to start, I believe it's July 2017, but it probably will subsequently be delayed.

But really right now the electronic solution is not fully-baked yet. I've spoken with many of the hospitals that are getting involved, and it's just not there. And I guess my main thing is when -- right now, most of your product is purchased from wholesalers, and wholesalers are storing that T3 information from the dispensers. You still

have to have mechanisms in place for products outside of that, which would be a direct order, or drop ships, which right now mainly is paper, but eventually will be electronic as well.

So I guess my real question really gets down to when the state inspects a pharmacy and pulls a product off the shelf, what will they be looking for? Is that something to be decided? Because I'm not going to be able to tell -- you know, I'm going to default to that I purchased it from the wholesaler, but lot number is not part of that T3 information yet, and that's not going to go into effect until serialization, so is there any idea on what's going to be required then?

MR. DIXON: That is actually part of the training that we have to go through when we talk about -- when we work with our folks in the field. I think everyone -- well, at least anyone who's been looking at this, we all understand the information that's contained and that's not contained, and what will be available at the time of doing the inspection. So probably the only thing our folks will be looking for is information that is available and that's required to be maintained.

So for instance, if you're not required to get it, it wouldn't make sense -- at least I would hope it wouldn't make sense -- for us to ask you for something that you shouldn't have.

And so I think that under this requirement, to the extent that you've got an agreement with a wholesaler to maintain that information for you, it may be as simply as asking you as the -- or whoever the person is at that facility, to contact the wholesaler and get whatever information they have, and then to provide that information to the inspector.

I think it would be inappropriate for an inspector to ask you to produce information when we know that the information isn't included in the T3.

MR. BARNES: Well, if I could suggest maybe at a workshop when you're thinking about developing all that and including wholesalers and then dispensers, just to go over the information that's out there and just so we're -- to kind of get it all in the open, and then, say, maybe the Department could get a good understanding of what is out there and then go from there. If I could suggest that.

MR. DIXON: Let me just -- I just want to make sure, because I think that there may be a little bit of a difference between actually doing a workshop versus having a public meeting.

A workshop is where you have an issue with a particular rule, and I don't necessarily know I hear you saying that there's an issue with the rule, as much as how we work with and train our inspectors regarding the information that's available to you guys on -- as recipients of the product. I think that that would -- may be more of an open public meeting where -- or maybe where we have meetings with folks who represent the industry participants, maybe Florida Health System pharmacies, or other entities like that who are the end users, where we can bring them in, they can give us examples of some of the concerns that they have, and then we can use that to help maybe train our inspectors in the field of what to look for, if that seems to be more of an appropriate avenue.

MR. BARNES: Yeah, that sounds fine.

MR. DIXON: Okay, well let me -- I'm going to just make a note so that that may be -- because we can do that pretty easily.

MR. BARNES: Great. I can get with you later, Reggie, and we can set that up.

MR. DIXON: Okay. Like I said, I just want to make sure I have -- I'm making a note on it. Okay. Were there any other questions or maybe comments or concerns about the language for 61N-1.031 for the dispenser requirements? Was anyone on the line, other than a council member, who may have some questions or concerns about the language?

Okay. Well, I think the last rule that we have is 61N-1.032, which is a product tracking and tracing for repackager requirements. Was there any comments or concerns or suggestions from the council members on that particular language? Any comments or concerns from anyone on the phone?

Okay. Hearing no further comments, I just want to back up just a minute before we kind of conclude this portion of -- and again, for the record, it's really important for us as an agency, as a regulatory department, to get as much input and feedback as we can from the regulated industry that helps us to make sure that we're not overly-regulating or passing or writing rules that we think are contrary to federal law, and contrary

to what folks in the industry can actually comply with.

These rules will be noticed, I think it -- is it 40? Is it next 30 days? And so in that timeframe, we're going to be asking folks if you have comments or something that come up after that, you can send those directly to me or to Ms. Greene. My email is included -- both our emails, I think, are included -- at least our contact information is included in the notice of proposed rule.

My email -- I thought it was on here -- but my email for the record is Reggie, R-e-g-g-i-e, dot Dixon, D-i-x-o-n, @myfloridalicense.com; and Ms. Greene's email is actually on the notice of rule, which is Dinah, D-i-n-a [*sic*] dot Greene, G-r-e-e-n-e, @myfloridalicense.com.

To the extent that anyone, if you share a rule with someone and they may have a comment or they may have some concerns and may request a notice of hearing, please submit those to either Dinah or myself. We will go through those and try to vet those as quickly as we can, and if we need to have another council meeting, we will try to set one up. If we need to have a workshop, we'll

set one up and we'll do the notice and all those other things.

Right now, my take-away from at least the suggestions that we have that we received is that with respect to 1.028, specifically sub -- at least Paragraph 26 when it speaks to transaction history, that the second line of that where it says "The transaction history for a grandfathered product begins with the owner of the product on January 1st, 2015," that the FDA has began using -- has exercised enforcement discretion and that we think -- or that the council members think that if we change that date from January 1st, 2015, to March 1st, 2016, that that would address the concerns hopefully of everyone in the industry, or at least in the supply chain.

Is that -- and that's the only suggested change, I think, that -- that's the only suggested change that we have coming away from at least this particular meeting. Were there any others that we didn't get from anyone on the council or anyone else in the audience or maybe on the phone?

Okay. Well, I think we can work with our staff to kind of see if that's something that we can do. I don't think that will be an issue, we

may be able to just file a notice of change on that pretty quickly.

Mr. Chair, I think that we have concluded at least the portion with regards to the director's report. I think that under other business Ms. Greene may have some questions about our meeting schedule.

MR. CACCIATORE: Thank you, Mr. Dixon. Let's turn -- before any other business, I'll turn it over to Ms. Greene.

MS. SKRNICH: I just want you to be thinking of a future date for February of next year, and changing it, maybe, to March.

MR. DIXON: And just for the record, we -- in Florida they don't have a special session -- we don't have a early session every year. I think I attended a meeting about two weeks ago where the thought process was that they would have a January-type of session like this year every other year. So next year is probably expected that session will actually start, I think, in February or was it March?

MS. SKRNICH: March.

MR. BROCK: March.

MR. DIXON: March. So next year it will be

March and April, so -- February may be difficult because of the weather and stuff, but maybe, you know, you won't have people running with session in February so --

MS. SKRNICH: We just seem to have issues with having attendance in February.

MR. CACCIATORE: Yeah, I'm just curious if that's a weather issue, or is it just difficult with the session going on or what the issue is with February. Let me ask the other council members, we've got four meetings a year, we do two in person, generally they've been, what, February and --

MR. ELLIS: August.

MS. SKRNICH: February and August have been your in-person meetings, and the other two are conference calls. You do February, May, August, and December.

MR. CACCIATORE: So let me -- unless any other council members have any other suggestions, maybe I'll just coordinate with Dinah and come up with a recommendation for the next meeting on how to handle that. Does that work?

MR. BROCK: Yes, sir.

MR. CACCIATORE: What's our schedule, Dinah,

for -- are we okay as far as everyone's appointments and officers and so forth?

MS. SKRNICH: I think we have a couple that have just recently renewed about a couple months ago, so I'll have to look and see who's up now. Our next meeting -- our next conference call is May the 19th.

MR. CACCIATORE: May the 19th, okay. Is -- any other business any members of the public or any of the council members like to bring before the council?

MR. ELLIS: Yes, Gary, this is Dean Ellis.

MR. CACCIATORE: Go ahead, Mr. Ellis.

MR. ELLIS: I've had a lot of folks contact me, Reggie, that are confused about who's going to regulate them. I believe I know the answer, but could you address that, because I've just had that question quite a bit.

MR. CACCIATORE: Dean, can you speak up a little? I can't --

MR. ELLIS: I'm sorry. I received questions concerning who is going to regulate the folks here in Florida, and I believe I know the answer to that, but I would like Reggie to maybe share that -- how that regulatory environment's going to

be.

MR. DIXON: Are there -- are they specific license types or just --

MR. ELLIS: No, just wholesale distribution, as it relates to -- because I've had several people who thought that all the regulatory was going to go to the federal law, so I thought maybe you can answer that question.

MR. DIXON: No, it's my understanding with respect to wholesale distributors that there would still be dual-regulation with respect to licensing and compliance with tracking and tracing, and compliance with all of the other requirements that affect the wholesale distributors.

I think the purpose, hopefully, of the tracking and tracing requirements was to try to standardize things for the industry so that they didn't have to have, you know, 50 compliance officers in 50 different states, and world-wide rules and that kind of thing.

So to the extent, hopefully, that the other states were doing similar -- the states -- as Florida, the wholesale distributors that work at least in the -- nationwide, have one set of rules that they have to follow. But I think the

individual states still have jurisdiction to regulate the activity in their states. And so for at least Florida, that's what we would be doing.

MR. ELLIS: In Florida, we will have our inspections from a Florida inspector, not an FDA.

MR. DIXON: Yes.

MR. ELLIS: Thank you.

MR. CACCIATORE: Thank you. Any other business to be before the council? Okay, hearing none, I just wanted to say on behalf of the council, I wanted to thank Mr. Dixon and all the staff there at the Division for all their efforts. It's been a busy time, and I think there's been a lot of work put into both the legislation and the rules, and I want to thank them for their efforts to work with the industry to address our concerns.

I'm hoping that the lack of comments from the council members and from the public indicates that people are pleased with the rules, and not that they haven't read them yet, so -- but I think what you're finding is that the ability of the Division to work with industry, both on the legislative issues and the amendments, has been real helpful. And I also want to thank the legislative affairs group with DBPR for their efforts as well.

Hearing no other business, I will entertain a motion to adjourn this meeting.

MR. BROCK: So moved.

UNIDENTIFIED SPEAKER: So moved --

MR. CACCIATORE: So moved --

UNIDENTIFIED SPEAKER: -- second.

MR. CACCIATORE: -- and there's a second. It's been moved and seconded; all in favor of adjournment, signify by saying aye.

(Chorus of ayes.)

MR. CACCIATORE: All opposed? Meeting is adjourned. Thank you, everyone.

(The proceedings were adjourned at 10:39 a.m.)

CERTIFICATE OF REPORTER

I, JEFFREY R. BABCOCK, do hereby certify that I was authorized to and did report the foregoing proceedings, and that the transcript, pages 1 through 52, is a true and correct record of my stenographic notes.

Dated this 14th day of March, 2016 at Tallahassee, Leon County, Florida.

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JEFFREY BABCOCK

Court Reporter