DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL

AUGUST 18, 2016

Reported by:

CLARA C. ROTRUCK

Court Reporter
CHAIRMAN CACCIATORE: Good morning everyone.
This is Gary Cacciatore. I would like to call this
meeting of the Drug Wholesale Distributor Advisory
Council to order.

I would like to start with a roll call. Do we
have a court reporter on the line?

THE COURT REPORTER: Yes, I am on the line.

CHAIRMAN CACCIATORE: Thank you very much. I
just want to remind everyone we do have a court
reporter. Rather than taking Minutes for the
meeting we will just have a transcript prepared by
the court reporter. So please identify yourself
before you speak so the court reporter will know
who is speaking on the call.

And those that are on the line, if you can put
yourselves on mute that will help unless you would
like to speak and obviously come off of that.

So let's start with a roll call. Ms. Greene.

MS. GREENE: Mike Ayotte.

MR. AYOTTE: Here.

MS. GREENE: Steve Mays.

MR. MAYS: Here.

MS. GREENE: Scott Brock.

MR. BROCK: Here.
MS. GREENE: Arlene Elliott.

MS. ELLIOTT: Here.

MS. GREENE: Dean Ellis.

MR. ELLIS: Here.

MS. GREENE: Bill Mahoney.

MR. MAHONEY: Here.

MS. GREENE: Patrick Barnes.

MR. BARNES: Patrick Barnes here, yes.

MS. GREENE: Jeenu Phillips.

MR. PHILLIPS: Here.

MS. GREENE: Peter Hart.

MR. HART: Here.

MS. GREENE: Gary Cacciatore.

CHAIRMAN CACCIATORE: Here. Thank you everyone for your participation.

So a couple of things just to start out. Tab one we have got the Chair's report. You will notice there is not a lot of stuff on the agenda this time.

So first of all let me thank everyone for showing up at a meeting where we don't have a lot to discuss. So I really appreciate that. This is my last meeting as you guys know. So I am sure that is why everybody showed up.

But I just wanted to say a few words about
that. There is not a lot of stuff on the agenda and I think that reflects upon two things. It reflects upon where we are as a council and where the Division is and the Department is. We have come a long, long way. This council was put together, I think it was 12 years ago or so, yes, 10 years, 11 years ago.

And at the time when the council was put together there were a lot of issues, there was a lot of problems. There was not a lot of cooperation I think between industry and the Department, and the agenda was full. So this council was put together to address a lot of those issues.

And more importantly to protect the public health and there were problems with that at that time as well. And as Florida started to address that very aggressively it formed fruit and we have a very well run council now, a very well run Division and Department.

And so as I have been on here for eight years what I have seen is there has been less and less things, items on the agenda. And part of the reason for that I have to say is the Division and the Department, all the work that they have done to
work with the industry. Their open door policy to allow, to meet with people to address issues. All of that I think has contributed to the success of the council. So I want to thank the Department, Mr. Dixon and Ms. Greene and everyone at the Division for all the work that they have done.

I always like to start the meetings by reading what the goals of the committee is and what the council is. So let me start by doing that. This is in Chapter 499.0121(1).

The council shall review, this part being Chapter 499, and the rules adopted to administer this part annually. Provide input to the Department regarding all proposed rules to administer this part, to make recommendations to the Department to improve the protection of the prescription drugs and public health. Make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning wholesale distribution of drugs, and make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of public health.

And that really speaks to what we have been
doing over the past eight years that I have been here.

I do want to introduce three new council members who have been appointed. Leaving the council are myself and Mr. Mike Ayotte, our Vice Chair, and also Mr. Bill Mahoney. And I want to thank Mike and Bill for their service on the council for all these years.

The appointments were just made like a week ago. So there wasn't time to allow the new members to officially be here, be on the council for this meeting, but they are in attendance today, or at least two I think are here. We may have the third come.

So it will be one from the pharmacy, representing the pharmacy at CVS, Mr. Bryan Files, and then for prescription drug wholesaler, Michael Mone, from Cardinal Health and Jeffery Toler from Wellgistics.

So Michael, do you want to introduce yourself and give everyone a little bit of background?

MR. MONE: Good morning. My name is Mike Mone, I am a pharmacist and an attorney. I have been with Cardinal Health about 10 years, but I actually started my career at then called BPR, then
it became DBPR, then it became BPR. I was a prosecutor for many regulatory boards back then. Left and went to the USP and spent a couple of years setting standards at the USP. Came back to the Attorney General's Office and worked for Bob Butterworth as general counsel for a number of regulatory boards. Left there, went to Kentucky as the Executive Director of the State Board of Pharmacy for 10 years.

Left there, went and taught at the Pharmacy School at the University of Minnesota and then went to Cardinal Health about 11 years ago, first at Medicine Shoppe and then at Cardinal Health proper.

And thank you very much, I look forward to working with you all and to come back to Tallahassee and see a whole bunch of friends that I don't get to see very often.

CHAIRMAN CACCIATORE: Thanks, Michael.

Mr. Toler.

MR. TOLER: Yes. My compliments to Michael, that sounds like an impressive resumé. I started in the business when I got out of college. I went to grad school, I was recruited by a company called McKesson, and then I got recruited by a company called Cardinal. Worked for Cardinal for a decade
or better and then I went to run an Amerisource company for a couple of years, and always in drug distribution mainly.

Then I started off working for startup medical services, both in manufacturing distribution, logistics and I have doing that for about the last eight years.

CHAIRMAN CACCIATORE: Welcome.

MR. TOLER: Thank you.

CHAIRMAN CACCIATORE: And if Mr. Files joins us, Mr. Files was appointed as the retail pharmacy representative replacing Mr. Ayotte and is employed by CVS.

Next on the agenda is election of officers.

MR. DIXON: Mr. Chair, if we could take a minute. We have got our Deputy Secretary here, Tim Vaccaro. He is the Deputy Secretary responsible for our Division.

We had a couple of presentations we want to do, and I figured since we have him here, it would be a good opportunity for us to do some presentations for your guys who have been serving our Division and who are departing since these are your last meetings.

I first want to present Mr. Ayotte with a very
nicely wood grain, carved plaque which basically says, "Presented to Mike Ayotte, Vice Chair, in appreciation for your valuable leadership and service to the Florida Drug Wholesale Distributor Advisory Council." And it has got the dates on there from April 28th of 2008 to August 18th, 2016.

MR. AYOTTE: I look the same, don't I?

MR. DIXON: We don't have a picture.

MR. AYOTTE: Thank you. I will just take a point of personal privilege. This means an awful lot to me. I have been part of Florida for a long time and to me was here when the original, I guess when the drug issue occurred.

So to see where we are at today truly it is a credit to you and to everybody around this table, because we have changed a good part of the world and it really makes you feel proud. So thank you.

MR. DIXON: And last, but not least, to our esteemed Chair. This is presented to Gary Cacciatore, the Chair of the Drug Wholesale Advisory Board in appreciation for your valuable leadership and service to the Florida Drug Wholesale Distributor Advisory Council.

This date is also April 2008, to August 2016.

CHAIRMAN CACCIATORE: I knew it had been a
long time, but I didn't remember exactly how long.

    MS. GREENE: We have Mr. Mahoney's and I will send it to him.

    MR. DIXON: Bill Mahoney is actually on the phone. So he missed the meeting. When you miss the meeting this is what happens.

    MR. MAHONEY: Sorry about that, guys.

    MR. DIXON: It is just a short drive. Thank you so much for your service though.

    MR. MAHONEY: Thank you for letting me be a member of this, it has been a great organization and such a great experience.

    CHAIRMAN CACCIATORE: Yes, and let me echo that as well. I mean, although I no longer live in Florida, as many of you know I am originally from Florida and have spent a lot of time here. And although I do regulatory work throughout the country for Cardinal Health, anytime there is an opportunity to do things in Florida to serve Florida I always jump at that because it is a chance to come home actually. I appreciate that.

    So next on the agenda we are going to do election of officers. So we need to elect a Chair and a Vice Chair. Only the current members of the council should be eligible in voting at this time.
since this is our last meeting. But you can't
nominate me since I am going off since I know you
guys like to do that.

So I am going to open the floor for
nominations. Should we do Chair or Vice Chair
first? Let's do the Chair first and get that out
of the way. So I am going to open the floor to
nominations.

MS. ELLIOTT: This is Dean Ellis. I would
like to nominate Steve Mays as our Chairman.

CHAIRMAN CACCIATORE: Steve, you are on the
phone I believe. Do you accept that nomination
with enthusiasm?

MR. MAYS: This is Steve. Sorry, I had myself
on moot. Yes, that is fine, I will accept that.

CHAIRMAN CACCIATORE: Thank you, Mr. Mays.

MR. MAYS: Unless there is someone else, I am
very definitely humbled by that.

CHAIRMAN CACCIATORE: Do I hear any further
nominations for Chair? You can nominate yourself
by the way.

MR. MAYS: This is Steve Mays. I would like
to nominate Dean Ellis.

CHAIRMAN CACCIATORE: Mr. Ellis.

MS. ELLIOTT: I think Steve would be a really
good candidate for it. I really do, Steve.

CHAIRMAN CACCIATORE: All right. I am not
going to force anyone to do that. So that sounds
like you are going to decline that nomination, Mr.
Ellis.

All right, hearing no further nominations, I
will entertain a motion to close nominations.

MR. HART: Motion.

MR. PHILLIPS: Second.

CHAIRMAN CACCIATORE: Motion by Peter Hart,
second by Mr. Phillips. No discussion. All in
favor signify by saying aye.

(Chorus of ayes.)

CHAIRMAN CACCIATORE: Any opposed? All right,
motion carries. Nomination to close and now we get
to vote. All in favor of Mr. Steve Mays being
elected Chair, say aye.

(Chorus of ayes.)

CHAIRMAN CACCIATORE: Any opposed?

Congratulations, Mr. Mays.

MR. MAYS: I didn't have time to oppose.

CHAIRMAN CACCIATORE: Sorry, that was the
Chair's fault for not following the proper
procedure that time by the way.

MR. MAYS: I need to make sure I show up next
CHAIRMAN CACCIATORE: Yes. Listen, I know you are on vacation, so I appreciate you even calling in. So thank you.

We will open up the floor for nominations for Vice Chair. Really the Vice Chair just fills in when the Chair is not there. Mr. Mays indicated he would be at every meeting.

MR. MAYS: Yes, as long as my wife does a better job of scheduling vacation.

MR. BROCK: I nominate Jeenu Phillips.

CHAIRMAN CACCIATORE: Nomination by Mr. Brock of Jeenu Phillips.

MR. PHILLIPS: I will accept.

CHAIRMAN CACCIATORE: Jeenu says I will accept that nomination. Any further nominations?

MR. BROCK: May it be closed.

CHAIRMAN CACCIATORE: All right, nomination by Mr. Brock to close the nominations.

MR. HART: Second.

CHAIRMAN CACCIATORE: Second by Mr. Hart. Any discussion? All in favor of Mr. Phillips as Vice Chair signify by saying aye.

(Chorus of ayes.)

CHAIRMAN CACCIATORE: Any opposed like sign.
Congratulations, Mr. Phillips.

MR. PHILLIPS: Thank you very much.

CHAIRMAN CACCIATORE: I believe the council is in very good hands going forward and I appreciate everyone stepping up to the plate to take on those leadership roles.

I am trying to think if I have anything else under the Chair's report. I do not believe so.

So I will now turn it over to Mr. Dixon to give us the Division Director's report.

MR. DIXON: Thank you. What you see on the agenda, we basically wanted to just go through our rulemaking to give you guys an idea of where we are at today.

We have gone through a lot. You will see that we did a lot working on out applications. Hopefully your permitting folks, if you do have an opportunity to talk to your permitting folks as they go through these, we would ask you if you have any questions or concerns about some of the new applications as we put them out there that you shoot us an e-mail or give us a call or something.

One of the things that we have tried to do is, we tried to put in what was statutorily required and only what was statutorily required that would
help make those decisions.

So we are looking to get our deficiency rates down, applications so that the lower the deficiency rate the quicker you get someone in the business so you don't have people waiting around having products sit around. So most of our rulemaking deals with our applications.

We will start with 51N-1.001. That is the one on this report that doesn't necessarily deal with our applications. That is the rule that deals with our definitions. We recently had a rule workshop in Orlando. The basics, the two items that were addressed at that rule workshop was to get industry input both on the exception to wholesale distribution which allows retail pharmacies to distribute up to a certain amount.

The language that we provided set that amount at five percent based on the fact that was kind of the industry standard of what the FDA was going by as well.

The second issue on there was there was an exemption put in the statutes recently to allow for the distribution or movement of drugs between end stage renal pharmacies that are in end stage renal dialysis clinics that are in common owned
pharmacies.

And so what we wanted to do was to put some guidelines in place as to when those distributions actually were distributions which necessitated you having a license as opposed to the distribution for an emergency medical need, of immediate medical need for a patient.

So we did it centrally in Orlando and we got some feedback, we got some testimony. We have a transcript of it also. And based on having done that, we went ahead and proceeded with development of the language. So the language should be published and hopefully going into effect pretty soon.

With respect to the rest of the report, and one of the things, I don't know if you all noticed this, we actually tried to create a part two of 61N-2.001, and as we go through the applications, all of the applications will now be in 61-2. So what we are trying to do is eliminate a lot of the excess language and verbiage that deals with all of the different things and basically saying you have to submit a complete application and the fee, and then the application itself ask for all information.
So hopefully for your permitting folks, now you look at the application and see this is what I have to give and you don't have to kind of search through the different rules saying, okay, if you are here you need this, you need that, you need this. So the plan is hopefully by this time next year to have all of the applications done. We have done about a third of them, and we created a couple of new permits.

So when you look at this report, everything that is in blue, those applications are now effective. We highlighted which is kind of a light brown highlight, those are the rules that are open for development and those are the applications basically that we are working on.

Does anyone have a question about anything on the rules report?

I wanted to give you just kind of an legislative update. I am pretty sure by now everybody knows that Senate Bill 1604 went into effect. We are still working, we have pretty much implemented most of it. We have done training.

Some of the high notes that I think you guys would have noticed is the fact that the language is in there about the bond requirement, that if you
are a wholesale distributor and you distribute less than $10 million a year, the bond requirement is no longer $100,000, but it is $25,000. We have created the forms, the bond forms, and we have made them available. So if you want to go on our web page those bond forms are available.

As far as the language that deals with the implementation of the DQSA, that language is in place. We have had at least one meeting with the folks from the ACMA on some questions that have come up. So we are kind of reviewing some of their input to make sure our interpretation of our statute is consistent with what the federal authorities want.

One of the issues quite frankly is that sometimes the FDA is a little slow to move. So we do have a little bit of -- we have got a couple of challenges that we want to make sure that we don't get in front of them on some issues. But other than that everything has been going along smoothly.

Hopefully the wholesale application will be out there soon and that is the next big issue is to implement the renewal, so that instead of having you all, at least as wholesalers, renewing every year, we are going to try to get to a point where
wholesale permits are at least two years and then it will be staggered so that you won't have to have someone constantly in the stage of submitting a renewal application.

One of the things hopefully that your permitting folks would notice is that we are going to allow them if you have already submitted a personal information statement and it hasn't changed, just to submit an affidavit that your personal information statement hasn't changed along with the prior information statement.

So we hope that some of those changes will expedite the permitting process, and hopefully what you will see is that your folks will have a positive response to it. If not, that is definitely something we need to know about. We really haven't gotten any negative input right now, but if we do that is have something we can address pretty quickly. I mean, most of our units here, we have got a pretty small unit. So it doesn't take a lot for us to kind of respond to stuff.

CHAIRMAN CACCIATORE: Mr. Dixon, this is Gary Cacciatore. From my company's perspective the changes in the licensing and permitting process have been very well received.
MR. DIXON: Other than that we didn't really have any other updates or anything. But we are open to ask any questions that any of your council members might have.

MS. ELLIOTT: This is Dean Ellis. What time frame are you in on the renewal process as it relates to going from a year to two years?

MR. DIXON: Right now we are drafting the language on the rule. What complicates it a little bit, and quite frankly, I don't know that we anticipated this part of it, was as you know all your permits expire a year or two years from the end of the month or the date in which it was issued.

What that means is as far as the wholesalers you will all expire in a certain month during the year. So if we want to stagger those so that we don't have everybody renewing at the same time, we are contemplating saying, every other month will be a two-year permit, and then every other month after that will be a two-year permits. So only half of your permits will expire every year.

So it is a little complicated trying to write that language. We have got -- in one of the other areas of our department they have a rule that kind
of sets out the dates and time frames and things. It is in the professions area. It is a very good rule. It tells you when you renew and all these other things. So we are looking at doing something like that.

MS. ELLIOTT: Will the body of that application, is that going to change any or is that for some workshops later on?

MR. DIXON: The body of the application, the wholesale distributor application will change. It will -- some of the things like the primary versus the secondary wholesale distributor determinations, that is no longer necessary.

Some of the information with respect to like the picture. You only need a picture every, I want to say it is 180 days now, not every 30 days. Fingerprints, you are going to be able to submit your fingerprints electronically. So now you don't have to submit a fingerprint card.

So a lot of that we think will cut down on the days as far as the application. We need to kind of shore the application up, because some of the things on the application that are asked for are no longer necessary. So that is one of our primary focuses right now is to get the application.
MS. ELLIOTT: Thank you.

INVESTIGATOR GRIFFIN: As far as time frame I bet we will have a draft of the application next month. It is already open. So I would anticipate filing a rulemaking on the application itself probably in the next couple of weeks.

MS. ELLIOTT: Thank you.

CHAIRMAN CACCIATORE: This is Gary Cacciatore. Two things that come to mind. You mentioned the DQSA and the tracking, the federal tracking legislation. That is continually evolving waiting for guidance from FDA.

I had found it very helpful in the past when we have had updates on that, and I know in the industry we have people who track that. Someone in my group that is their full time job and Mr. Mays' company has someone as well and I think everyone does that. So bringing those people in is something to consider maybe for the next meeting. At least once a year to kind of see where things are, to get an update on what is happening on the federal level.

It might be a good idea I think for the next meeting to consider or maybe the next live meeting which would be the one after the next one. But
just to get an update on what is going on because that stuff is constantly changing with guidelines from the FDA. It is a 10-year implementation period on that law. We need to make sure we are staying up-to-date with that, make sure everyone is doing everything consistently, which I know the Department is doing that, but for the council I think it will be helpful to consider that.

And the other thing I just wanted to ask a question and Mr. Phillips might be able to assist with this being the Board of Pharmacy representative. I was at the Board of Pharmacy meeting, I think it was last week, and they were discussing 503-B pharmacies under the federal law which are the outsourcing facilities. For those of you who don't know, there is two parts to that DQSA.

There is the compounding part and then there is a track and trades part. Discounts mainly deals with the track and trades part, but for pharmacies, the compounding part of that federal regulation is a big issue as well.

The Board of Pharmacy is licensing those pharmacies that are not doing any patient specific medications in state. There was talk on the
sterile compound committee that they were creating
a sterile compounding permit for those facilities,
correct?

MR. PHILLIPS: I am not on that committee.

MR. DIXON: I can tell you what we know.

CHAIRMAN CACCIATORE: I was curious if they
interacted with you guys on that.

MR. DIXON: That is something that we watch
very closely and we look at really closely because
of two things. The 503-C -- I am sorry, the 503-B
facilities, they have to be run and supervised by a
pharmacist, but they do not have to be pharmacies.

CHAIRMAN CACCIATORE: Correct.

MR. DIXON: So I know the Board of Pharmacy
passed a statute that basically said if you are
outside of the state and you are distributing or
shipping sterile compounding products into the
state you have to have a non-resident sterile
compounding permit.

CHAIRMAN CACCIATORE: Correct.

MR. DIXON: If you are in the state I know
there are a couple of permits in the state. There
is a special sterile compounding pharmacy permit
that you get in the state, and there is other like
an interim sterile compounding permits as well that
are offered by the Board of Pharmacy.

I think the revolving issue probably in the next couple of years with that particular 503-B facility is going to be the fact that some of the facilities, and it is not just Florida, some of those facilities are not as aware that sterile compounding is not manufacturing. And sterile compounding by itself means that you are making a product that is different from what you start off with.

And you have some entities that may be repackaging as opposed to compounding. So I think that is going to be an issue because I know the federal government has put out some guidelines about those outsourcing facilities compounding as opposed to actually -- I mean, repackaging as opposed to actual conducting sterile compounding. So I know the FDA is working on that.

I know that from the Board of Pharmacy perspective we had some interactions with them as well from the perspective of trying to delineate where their jurisdiction starts and our jurisdiction stops.

CHAIRMAN CACCIATORE: And that was kind of my question. And I have seen this in other states. A
lot of those facilities do patient specific as well as non patient specific. If they're doing patient specific based on a prescription, they are licensed pharmacies.

MR. DIXON: Right.

CHAIRMAN CACCIATORE: But I have seen odd situations in other states where they have said that if they're not doing any patient specific, like you say they don't have to be a pharmacy then, so the State Board of Pharmacy in some states are saying, we not going to license them as a pharmacy.

And then you have similar to Florida a different agency that does manufacturing and they say they're not a manufacturer either. So no one is going to license them which is probably not a good idea and that is not happening in Florida.

But I just wanted to make sure those lines of who has got the jurisdiction are clarified and then you have got the repackaging issue it gets a little bit complicated.

MR. DIXON: Right, that is something that we are definitely drafting.

CHAIRMAN CACCIATORE: It occurred to me when I was at the Board of Pharmacy meeting. I wanted to make sure that the Department was involved and was
tracking those issues.

MR. PHILLIPS: I had another question.

CHAIRMAN CACCIATORE: Mr. Phillips, go ahead.

MR. PHILLIPS: I guess for those of you who
have experience around the country with multiple
states, Gary and Michael, maybe you can help. I
have a question for one of the pharmacists that
works in the state around donation of HIV
medications.

Do you know if any of the wholesalers ever
take back an redistribute those medications? Have
you heard of anything like that?

CHAIRMAN CACCIATORE: This is Gary Cacciatore.
When you say, take back?

MR. PHILLIPS: They donate them, you know,
those patients, the ones who have donated them back
so that they can be reused again. I was told that
there are some states that do that.

CHAIRMAN CACCIATORE: Mr. Mone, go ahead.

MR. MONE: This is Michael Mone. I can give
you some places to look. Both Kentucky when I was
there we drafted a regulation at the Board of
Pharmacy to be able to engage in that activity, and
Ohio as well has a regulation that allows the small
team distribution. It is never to a wholesaler.
It is going directly from the pharmacy to the
charitable institution. It is going directly from
the pharmacy to the physicians. It may in fact
even be going overseas with the drugs. So there
are rules that establish the policy and procedures
around that as well as the recordkeeping
requirements.

MR. ELLIS: The pharmacy regulation?
MR. MONE: The pharmacy regulation.
MS. ELLIOTT: This is Dean Ellis. Reggie,
would that fall under the cancer donation program?
Wouldn't those drugs --
MR. DIXON: No, sir. Our cancer donation
program right now is benefit only to cancer drugs
and those drugs that treat cancer.
MS. ELLIOTT: Okay. Thank you.
MR. MONE: It is really a legislative thing.
MS. ELLIOTT: You could expand the drugs on
the donation list because there is a mechanism for
cancer drugs you have to expand it to HIV drugs,
that might be the best way to do that.
CHAIRMAN CACCIATORE: But to answer your
question specifically, I think that Mr. Mone's
point, I am not aware of that going through the
wholesaler in other states. There is mechanisms
and laws in other states that allow it to be
donated directly from pharmacy to be donated, take
them back into a pharmacy to be donated.

MR. DIXON: And if there is a specific issue
that you have or a scenario, we can talk about it
afterwards and we might be able to find someone to
assist you.

MR. MONE: I think it is that specific. It is
actually much wider spread where we have
pharmacists that handle a large number of HIV
population. And so there is a large number of
medications that go unused. This is something I
think could be helpful to a lot of people and
decrease the amount of waste that is happening.

CHAIRMAN CACCIATORE: Mr. Dixon, anything
else? We did have in our packet I thought we had
something from the self inspection report.

MR. DIXON: Yes, I am sorry. One of the
things that we are trying to do as an agency, our
division recently instituted our risk based
inspection program. What we are trying to do is
maximize our resources. Given the fact as you all
are aware, we only have a few inspections around
the state.

And so one of the things that we did was when
we put folks on the schedule and came up with our program, we realized that it would be a while before we got around to doing inspections of health care clinic establishments.

And so what we decided to do instead of necessarily having our inspectors go out and try to some type of a surge or whatever you want to call it, doing inspections of health care clinics, we put together what is called a self inspection survey.

And the purpose of the self inspection survey is twofold. One, to conduct inspections of these facilities, but also two, to kind of give them a sense of a self-reflection of what they're doing and what the laws are changing and how that might affect them.

We have gotten some questions from folks who were not as aware of the changes to the DQSA. They didn't understand the difference between a product versus a prescription drug because the definition changed. So that was an opportunity for us to provide education to folks without actually having to go on-site and see them.

Our hope is to do that over the next couple of years with all the health care clinic
establishments, and also to use that model to assist with inspections of out of date facilities, so that sometimes I know especially with wholesale distributors there is a provision that requires you to be inspected before or soon thereafter you getting your permit.

So we think that the self inspection may be a tool that some folks may be able to use and say, look, we have been inspected with the Department of Business Professional Regulation. If for whatever reason during the course of the self inspection there is an issue that comes up, then that is someone that we can go back out and determine on the risk base schedule to go out and do an in person inspection.

What we hope to do is facilitate more inspections of those folks that fall in our jurisdiction without actually being in a facility and disrupting business and that kind of thing. It also helps us better with our resources. So the folks that are in the lower categories of risks that we don't necessarily go out to that often, now we have been able to look at them, and we will get the surveys back and have some analysis of what they are doing and then decide who we actually do
need to inspect. If you have got someone who is purchasing drugs and don't even know it is a drug for instance. If I have a person who tells me medicine gas, medicine oxygen is a drug, those may be folks that we go back out and inspect. It has been real useful. We sent out about 500, but is was actually 300 and something e-mails that represented 500 facilities. So we have gotten pretty good response rate so far, but they still have about a month and a half to respond.

CHAIRMAN CACCIATORE: This is Gary. I think it is an excellent example of the Department really doing a good job of using their limited resources in a smart way. And just to remind everyone that the health care clinic establishments were set up because you have to sell to someone who is authorized to possess prescription drugs, and you have got clinics with multiple doctors sometimes and you can only sell to an individual doctor for use for their patients.

So sometimes you have one facility and each individual physician. So this allows a clinic or a health care establishment to get a license for the facility and can be used by any of the physicians at that facility. And it is lower risks I think
because there is less drugs there normally and they
are under the supervision of a health care
practitioner or physician or under the practitioner
or someone there to store the drugs and watch the
drugs.

So excellent example I think of using limited
resources. So we will see how that goes.

MR. DIXON: We have gotten a pretty good
response.

CHAIRMAN CACCIATORE: I was surprised to see
how many health care clinic establishments there
were. I didn't realized there was so many.

MR. DIXON: There are about 4,300 health care
establishment facilities.

CHAIRMAN CACCIATORE: If I was a practitioner
at one of those clinics I would rather have the
clinic that has the responsibility for the products
than my personal license. It makes a lot of sense
if you are a practitioner in one of those
facilities I believe.

MR. DIXON: I think the best thing about it
is, and I think a lot of folks don't understand as
a health care, if you have got three or four
doctors in a health care clinic and they are
purchasing under their own license, when you leave...
you take your drugs with you or you have to dispose of them. Because of this, now the doctor can leave and the drugs still belong to the clinic. So you don't have the kind of fight over what drugs belong to whom and we have seen that.

CHAIRMAN CACCIATORE: Yes, and I can tell you as a wholesale distributor we do have both. I mean, we still have a lot of places that we are selling to individual physicians at the address and you kind of wonder what the reason is for that. We open accounts both ways according to our licensing folks. Anythings else, Mr. Dixon?

MR. DIXON: I think the only other thing that we may have that may be of interest to folks is we did create -- well, two things, I take that back, I am sorry. We created a non-resident repackaging permit. I think it may not affect many, but there are some wholesale distributors, there are out of state wholesale distributors who only have the out of state wholesale distributor permit because we didn't offer a repackage permit.

So now if you are outside of the state of Florida and you have that wholesale distributor permit because all you did was repackage, now you can actually get a repackaging permit. You don't
have to have the $100,000 bond. You don't have to have the CDR. So we hope that is going to help some of those folks who specialize in repackaging to actually have a permit that fits their activity.

And you also have the virtual permits now. We are working on the applications for the virtual permits. And the virtual permits are there for those entities that previously had to get the prescription drug manufacturer permit and you really don't fit in there in the sense that you don't physically take the product.

You are more of an administrative office because you probably contract with somebody else to make your product and label it for you anyway. And so that virtual permit now allows you to get a permit that fits you. You don't have to comply with some of the physical requirements because you are not engaged in the possession of those prescription drugs. Someone else is making your product for you.

So we hope that those types of permits come about really from responses that we get from the industry about different things or things that we see during the course of our licensing folks. So we think that those permits will help a lot of
folks out.

CHAIRMAN CACCIATORE: Thank you. Any questions for Mr. Dixon? Okay.

Turning to tab three. Other than setting our meeting dates for 2017, is there any other business that any of the other council members, questions that the council members that would like to raise? Any of our new council members?

If not, before we do the meeting dates, let me open up to comments or questions from the audience or the public. Anyone here in the room? Anyone on the phone would like to bring up an issue or ask any questions?

Okay. Hearing none, let's move on to setting of dates for 2017. The proposed dates in your packet on tab three. As you recall we do, traditionally you have to have at least one meeting per year in person. We decided over the last couple of years we are going to do two in person meetings, I believe in August and February.

If we want to stick with that schedule if there is okay with everyone. Ms. Greene is proposing some proposed dates of February 16th, May 18th, August 17th, and December the 7th.

Any council members have any particular -- I
know my calendar is full in December of next year.

MS. GREENE: Just as a note, session is a regular session this coming year in Florida. It is not early.

CHAIRMAN CACCIATORE: It is not early.

MR. HART: This is Pete Hart. A motion for these dates.

CHAIRMAN CACCIATORE: There is a motion from Mr. Hart, a second from Mr. Brock. Any discussion? All in favor of setting those meeting dates signify by saying aye.

(Chorus of ayes.)

CHAIRMAN CACCIATORE: Any opposed like sign. Any opposed like sign? The motion carries.

All right, if there is no further business I will entertain a motion to adjourn.

MR. AYOTTE: So moved.

CHAIRMAN CACCIATORE: Moved by Mr. Ayotte.

MR. PHILLIPS: Second.

CHAIRMAN CACCIATORE: Seconded by Mr. Phillips. All in favor signify by saying aye.

(Chorus of ayes.)

CHAIRMAN CACCIATORE: Thank you very much.

(Whereupon, the proceedings were concluded.)
CERTIFICATE OF REPORTER

I, CLARA C. ROTRUCK, do hereby certify that I was authorized to and did report the foregoing proceedings, and that the transcript, pages 02 through 37, is a true and correct record of my stenographic notes.

Dated this 11th day of October, 2016, at Tallahassee, Leon County, Florida.

____________________________
CLARA C. ROTRUCK

Court Reporter

Commission No.: FF 174037
Expiration date: November 13, 2018