AGENDA

Department of Business and Professional Regulation
Drug Wholesale Distributor Advisory Council

Floridays Resort, Orlando, 12562 International Drive, Orlando, FL 32821, 321-329-4029,

Conference Call Number 888-670-3525
Conference Code 9259887749

May 10, 2018
8:30 a.m.

Council Members:

Steve Mays, Chair, Prescription Drug Wholesalers
Jeenu Phillips, Vice Chair, Board of Pharmacy
Vacant, Retail Pharmacy
Michael Mone, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Arlene Elliott, Agency for Health Care Administration
Dean Ellis, Secondary Prescription Drug Wholesalers
Jeffrey Tuller, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Peter Hart, Medical Gas
Jennifer Goldman, Physician

DBPR Staff:

Drew Winters, Division Director
Paul Waters, Deputy Secretary
Renee Alsobrook, Compliance Manager
Dinah Greene, Government Operations Consultant
Rebecca Burnett, Regulatory Supervisor

Call to Order: Steve Mays, Chair

TAB 1: Chair’s Report – Steve Mays, Chair
   a. February 15, 2018 – Meeting Transcript (informational only)

TAB 2: Division Director's Report – Drew Winters
   a. DDC Rules Report
   b. Presentation Bureau of Education and Testing
      Certified Designated Representative
      Andy Janeczek, Chief
      Alex Bosque, Exam Development Specialist
   c. House Bill 675

TAB 3: Other Business
Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics
The Division of Drugs, Devices and Cosmetics announces a public meeting to which all persons are invited.
DATE AND TIME: May 10, 2018, 8:30 a.m.
PLACE: Floridays Resort, Orlando, 12562 International Drive, Orlando, FL 32821, (321)329-4029
GENERAL SUBJECT MATTER TO BE CONSIDERED: General Business.
A copy of the agenda may be obtained by contacting: Dinah Greene, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, FL 32399-1047, (850)717-1800, Dinah.greene@myfloridalicense.com.
Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Dinah Greene, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, FL 32399-1047, (850)717-1800, Dinah.greene@myfloridalicense.com. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).
If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.
For more information, you may contact: Dinah Greene, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, FL 32399-1047, (850)717-1800, Dinah.greene@myfloridalicense.com.
STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DRUG WHOLESALE DISTRIBUTOR ADVISOR COUNCIL

COUNCIL MEETING

February 15, 2018
9:30 a.m. - 10:34 a.m.

Homewood Suites
2987 Apalachee Parkway
Tallahassee, Florida 32301

Reported by:
JEFFREY R. BABCOCK, FPR
For the Record Reporting
1500 Mahan Drive - Suite 140
Tallahassee, Florida 32308

ORIGINAL

FOR THE RECORD REPORTING TALLAHASSEE, FLORIDA 850.222.5491
COUNCIL MEMBERS

STEVE MAYS, CHAIRMAN
MICHAEL MONE
SCOTT BROCK
DREW WINTERS
ELIZABETH ALSOBROOK
DINAH GREENE
PATRICK BARNES
JENNIFER GOLDMAN
ARLENE ELLIOTT
JEFFREY TULLER

(Appearing Telephonically)
DEAN ELLIS
JEENU PHILLIPS
MR. MAYS: Good morning everyone, this is Steve Mays I would like to call this meeting of the Drug Wholesale Distributor Advisory Council to order. We do have a court reporter in the room present, I want to remind everyone to identify yourself before you speak so that the court reporter will know who's speaking for the record. And please speak up, it's kind of a large room and we want to make sure that the court reporter can hear everything that's been said.

For anyone on the phone, please mute your line when you're not speaking, but please do not put us on hold so we don't have to listen to your hold music. Ms. Greene, I think we're ready for our roll call.

MS. GREENE: Steve Mays?
MR. MAYS: Present.
MS. GREENE: Jeenu Phillips?
MR. PHILLIPS: Present.
MS. GREENE: Michael Mone? Scott Brock?
MR. BROCK: Here.
MS. GREENE: Arlene Elliott? Dean Ellis?
MR. ELLIS: Here.
MS. GREENE: Jeffrey Tuller?
MR. TULLER: Here.
MS. GREENE: Patrick Barnes? Peter Hart?
And Dr. Goldman?

DR. GOLDMAN: Here.

MR. MAYS: All right, I want to start the meeting off as we normally do by reading the goals of the council as stated in Chapter 499.01211 of the Florida Statutes.

"The Council shall review this part and the rules adopted to administer this part annually; provide input to the Department regarding all proposed rules to administer this part; 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 to make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health."

Okay. We have no -- as you probably noted, we have no items on the Chair's report today. I did want to bring up one thing, we do have a vacancy on the council and Brian Files has resigned his membership to the council, and I thought -- I'm not sure how we've done it in the past, but I thought it
would be good because it's -- I know for members it's a hardship to travel a couple of times a year and participate in these meetings, and I thought it might be good when someone leaves, like Brian, that the council would send a nice letter of thanks or appreciation for your service on the council. Anyone want to make a motion that we do that?

    MR. BROCK: So moved.

    MR. BARNES: Second.

    MR. MAYS: Okay. All in favor say aye. Aye.

    (Chorus of ayes.)

    MR. MAYS: All opposed? Okay. All right, so the only thing else on the first tab, you'll find a meeting transcript from our December 7th meeting for informational purposes. So if you get a chance, if you haven't gone through that, you might want to go through that and see if there's anything you might have questions about. And with that being said, I'll turn it over to Mr. Winters for the Division Director's report under Tab 2.

    MR. WINTERS: Thank you, Chair. I would like to back up just one second --

    MR. MAYS: Sure.

    MR. WINTERS: -- for your Chair's report to make one other note for the council members and those

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on the phone. Because of the vacancy, we have gone ahead -- after Mr. Files did notify of us his change and that he would no longer be on the council, we went ahead and notified the interested parties list regarding the vacancy and requested that anybody that was interested in filling that position that they would go ahead and submit the application to us so that we can provide that to the secretary for review and determination.

Again, for anybody on the phone or any of the members that are aware of members or individuals in the industry that are an employee -- again they do have to be an employee of a retail pharmacy -- but if they are interested in serving, to please let them know of the vacancy. The more members we have, you know, obviously we want to get somebody that's interested in wanting to serve, but we want to make sure that we have everybody given the opportunity to do so. Just so with that in mind, that we go ahead and just get that out there as much as possible, I believe Dinah, we have one applicant --

MS. GREENE: We have one application so far.

MR. WINTERS: -- right now, we generally will give it at least 30 days. Dinah, what date did we actually note that -- send that out?
MS. GREENE: About the 2nd or 3rd of February.

MR. WINTERS: So we'll --

MR. MAYS: We got until right after the first of March.

MR. WINTERS: -- right after the first of March, take a look at what we've got, and then coordinate with the secretary about possible appointments. And so again, just to let people know that they have that time in order to do that so -- thank you Mr. Chair, for the turnover, and again, starting with the director's report, again, Drew Winters on behalf of the Division.

The first item up for us to review at this point time is the rules report. Again, just to give an overall summary of the primary status of our rules, our primary efforts currently have been to adopt our forms in rule. We are required by law when we promulgate forms that we adopt them via rule. You've got the report as prepared by our office, a big thank you to Dinah who's always, again, tracking these items for us.

Going down the list, there's a few that we're still working on as far as developing and getting a finalized initial draft for both the -- again, the
application for device manufacture permit and the
application for limited prescription drug veterinary
wholesaler. So we are going -- the limited
prescription veterinary wholesale distributor, we
actually do have almost a final draft at this
particular moment in time. I believe it has gone
through both Rebecca's shop and Chief Alsobrook's shop
for that, and I'll be reviewing that so we do expect
that do be done here very, very shortly.

We have next on the list is the application
for restricted drug, drug distributor, the blood
establishment permits; we have filed that with JAPC as
a notice of proposed rule. We did receive comments
back from Ms. Holladay from the Joint Administrative
Procedures Committee, and we have submitted a response
and we're waiting for her to have an opportunity to
review that. We expect that our -- we've also been
able to speak directly with Ms. Holladay and go over
our response. She seemed very receptive to it, so we
don't anticipate a problem, but we'll still allow her
to continue to review that. And so we expect to
continue that process and to have that done shortly.

The applications for restricted drug
distributor for the charitable organization,
destruction permit, government programs permit, and
the health care entity permit, those drafts have been completed at this point in time, we reviewed and moved through the initial process. If the council members would like, once now that we've got a finalized draft as we get it through, we'll provide that to the council members at the next meeting so you can actually see the draft of those applications.

We are still working on the initial draft of the institutional research permits. Again, that one has also been through most of our shops and we anticipate finalizing that draft and getting it moved on shortly; but we'll, again, continue that process.

I did want to note one of the things that we do do is we get comments back from the Joint Administrative Procedures Committee or OFARR, that we try and go back, as we do in the process, and the forms that are still in process we'll go back and make sure that any comments we receive during that process are also applied to the other ones to make sure that we don't continue to run into those issues.

The institutional research permit, again, is still finalized in draft, but we do have final drafts of the reverse distributor; and skipping down to third party logistics provider permit, so we will have those. Again, those are the ones that we anticipate
coming very shortly to be able to provide you drafts. The retail pharmacy drug wholesale distributor permit, the veterinary prescription drug retail establishment and the veterinary prescription drug wholesale distributor permit, again, are under draft. The veterinary prescription drug establishment and the veterinary wholesale distributor, again, those have also both been through Ms. Burnett's shop and Ms. Alsobrook's shop, and I am looking at those final drafts now, so we expect to have those shortly and we'll be moving those on through the process.

We did take a little bit of time recently because, in review of the information from our program office, Ms. Burnett keeps a very good track of what we are seeing and some of the items that we felt were prudent to go ahead with. We noted that we've added the applications for changing of mailing address and change of name, and for the certificate of resale, and those three were actually added. While they're just administrative forms, they're going to be forms that are going to be very helpful to individuals to clear up those processes for them. And we have submitted those, JAPC has provided us comments, and we will, again, have provided draft responses to them, and talk with Ms. Holladay. We expect that those responses
will be acceptable.

The application for physical location which is a little more involved, again, we do have a final draft and we will be moving forward with that hopefully soon as far as a proposed rule and getting it over to Joint Administrative Procedures Committee.

The final one, the one that we spent the most time on, which is the application for certification of a designated representative, again, we have filed that, we have not received a public comment back on that one at this point in time.

MS. GREENE: No, we have not.

MR. WINTERS: And so we'll -- we're going to give it just a little more time, and then we will file that for adoption shortly. So that is kind of the status that we have on the rules report.

The application for certified designated representative, one of the things we do want to note, that does have the effective date for the 18 months as opposed to the six months, and so once that rule -- and we anticipate the effective date on that will be April 1st, and we've already coordinated with Pierson View and they have that date and are already setting up the implementation so that we'll have a seamless implementation, so that individuals applying for that,
once they've -- if they apply to take the exam or
approved on or after April 1st, they would be given
the 18 months, so we look at that process.

We will continue, obviously, in this
particular case if a rule itself has not gone, we will
probably still move forward, as April 1st as are
proposed. An analysis of that indicates that at this
point it's a benefit to them and it would be
beneficial to go ahead and move forward in the -- that
the risk of the rule would be outweighed by the
benefits, so we will continue that discussion.

That concludes the information on the rules
report. I'll stop there and ask if anybody's got any
questions or concerns regarding the rule or any other
items that you think -- and this is just for our
current proposed rules, obviously we've got a few
items after this that we'll address regarding
possibility of, again, increasing our -- some
additional items on that rules report, but for current
activity, is there any questions or concerns that you
might have?

Seeing no questions or concerns, I will go
ahead and move forward. I did want to stop just for a
second because we were speaking about the CDR, and
give the council members a heads-up. I did anticipate
the ability to provide a more detailed presentation at
this meeting for our CDR examination; I know we talked
about it previously. Unfortunately, due to an error
on my part, the scheduling just did not work out for
that. I have, however, talked with our bureau of
education and testing and we anticipate, assuming if
we do have the next physical meeting, whether they
will be able to attend, whether that be in May or in
August, we'll be able to have them attend. So again,
I anticipate that, and I apologize we were not able to
close that loop at this meeting. It would have been a
good item to have.

The next item on the director's report is
Item B is discussion of a potential rule workshop on
virtual manufacturers and prescription drug wholesale
distributors. And the reason I brought that -- and I
will also, with a nod to Ms. Price, our chief
attorney, with any comments that she may have -- is
that one of the items that we have looked at in both
our enforcement realm with Chief Alsobrook and our
legal realm on virtual and broker-only permits is that
we don't have a rule that specifically indicates what
they do and do not have to comply with.

We provided you the information on the
permits under 499.01, and that's Sub (2)(a) and (2)(c)
and (2)(e) are the indications in the statute that basically allow the Department to adopt a rule from which we can exempt these virtual manufacturers from certain establishment, security, and storage requirements. That's because based on their requirements, they're not allowed to actually take physical possession, so there's certain items that if -- currently we may enforce because we don't have a rule adopted that we may be able to develop that they won't have to comply to save them some regulatory costs, and to be able to move forward with that and to identify that.

Today's conversation is mostly to determine if there's any concerns from the council initially as to us going ahead and moving forward with a proposed workshop. The idea currently would be for us to actually move forward, and in order to get the most benefit and anticipated participation, would be to try and hold this meeting in May of this year and to possibly have the council have a physical meeting in May in alternative to a physical meeting in August. So we would have a physical meeting in May in order to coordinate the rule workshop with that council meeting.

The other option is, in coordination with
that, is to have it physically moved from Tallahassee
to Orlando to allow for more participation. The
Orlando area has more of our wholesale distributors,
manufacturers, and permit holders in that area. It's
also much closer to the south Florida area,
Dr. Goldman, obviously, I think it would be much
easier to travel for you. The -- so we would look at
that.

Again, we would have to make sure we had a
budget for that, we'll look and see if the council
approves with us moving forward with that particular
rule workshop, we would be able to try and make sure
that occurred; one, that we would have a physical
meeting in May, and then we would try and move it to
Orlando.

Some of the items, of course, that we want to
do is to get a consensus from the council members, but
also from the industry which is why we wanted to
coordinate the two. What would occur is that we would
have the rule workshop, we would have it on the same
day and then immediately following the rule workshop
we would have a council meeting for the council
members; that would allow you to attend the workshop,
provide any type of input you wanted there, and then
also ask individuals in the industry, and then
afterwards we could hold a council meeting, and that
would also allow for a little more participation from
the industry.

So that would be my request from the
Department's standpoint. We do have this as one of
our goals to really try and pinpoint some items that
the industry will know these are the items that you
don't have to comply with, or if you do have a
compliance, that there may be a reduced compliance
regarding those that we could develop by rule, get it
in the administrative code so people will have
something to rely upon.

Chief Alsobrook, I know that you have some --
a lot of dealings with this because your enforcement
staff has to deal with this issue. Did you have any
input or any items that you wanted to put in?

MS. ALSOBROOK: Thank you, Director.

Mr. Court Reporter, just for the record, I hope you
indicated that Mr. Barnes arrived so that we have an
additional member of the council so we need to make
sure we have that on the record, and --

MR. MAYS: Thank you, I was going to mention
that.

MS. ALSOBROOK: -- before we started.

MR. BARNES: Sorry I was late.
MS. ALSOBROOK: No, no, no --

MR. MAYS: I've already slapped him on the wrist.

MS. ALSOBROOK: There you go. I think one of the most important things to remember is without a rule addressing what the virtual manufacturers do and do not have to have as far as compliance to pass an inspection -- the storage requirement is a good example: They're prohibited from possessing any drugs, and yet they have to meet the storage requirement, which is humidity, temperature control, monitoring, all those kind of things. Well, the absurdity of that, as you can see, is immense. And government doesn't need to be absurd, and regulators don't need to be absurd, and they even looked to the council, and "Why are they doing this?" Well, you know, the council doesn't pass the rules, but -- so when I spoke to the director, he and I both agreed that this is something that is long overdue.

Now, the security equipment, the premises and all of that kind of stuff, we can have long conversations about what needs to be changed and modified in that regard, but the storage is just a no-brainer. I mean, they don't have drugs there, they don't need to have refrigeration and all that stuff,
so we really thought it would be a good idea. But we're not distributors or manufacturers, so we really need input from the industry as to how far-reaching the modification to the rule should be. Because I don't want to be hoodwinked, but I also don't want to not do enough, so to speak, Chairman Mays.

So that is why, when I spoke to the director about it, who is very interested in trying to be accommodating to both sides of the regulatory scheme, thought this would be a good way to approach the virtual manufacturers, as well as the virtual -- as well as the brokers, for example; they, too, have the same issue as distributors. They can't possess any drugs but --

MR. MAYS: I -- this is Steve Mays, I think it's good -- I think it's a great idea to, you know, have the workshop and just to give you an example, I'll -- you know, a state inspected one of our sites that has a virtual wholesale license, and the state will remain unnamed, but they were actually re-inspecting them for storage requirements which, you know, were kind of like "that really doesn't make sense and it's a waste of time."

I do think it's important to make a physical visit to those sites, you know, just to see what's
there, let them know that, you know, they're being regulated and I think it's a good idea to do that.

But yeah, it makes total sense to look at what type of requirements that you wouldn't, you know, apply to a virtual wholesaler.

MS. ALSOBROOK: Yes, sir.

MR. WINTERS: And I think, like I said, the main focus we had, especially bringing it before the council, is that we do look to you for some guidance on what the industry is seeing and whether this is an issue or any concern regarding the actual process.

And I really do believe this is going to be a good process, and will, again, provide us an outstanding --

MS. ALSOBROOK: Speak up.

MR. WINTERS: Sorry. I'm being told to speak up. That this will provide that information. And again, as Renee had said, one of the issues as a director that I do want to make sure that we do is compliance is mostly knowledge, you can't comply until you have the knowledge, and until we get that out there, there's always a question of, you know, making sure we have the knowledge; this will be the method through which we will do that.

So if the council would simply give me either a vote that they are okay with one -- two items
specifically: That you're okay with us having a
physical meeting in May that is different than our
normal, it would two physicals in a row, and that you
approve of that; and two, also that in this particular
instance, that if budget does allow and we can get the
approval, that we would move this to an in-person
meeting in May in Orlando, in the Orlando area, to
allow for more participation.

MR. MAYS: So do we have a motion from the
council that we're okay with moving the council
meeting to Orlando in May?

MR. BROCK: So moved.

MR. BARNES: Second, this is Patrick.

MR. MAYS: All in favor say aye.

(Chorus of ayes.)

MR. MAYS: Those opposed? Okay. I would
much rather -- personally I'd much rather -- no
offense to the Tallahassee folks, but I'd rather go to
Orlando in May than Tallahassee in August, so it works
good for me. I don't want to be in Orlando in August,
either, for that matter. I lived there for eight
years, it's a little muggy.

MR. WINTERS: It will be a little warm,
but --

MR. MAYS: Yeah.
MR. WINTERS: -- but I think also the travel will be better for everybody and --

MR. BROCK: Mr. Chairman, question.

MR. MAYS: Yeah, Mr. Brock?

MR. BROCK: On the workshop, do you envision that being -- I know that there have been a couple of manufacturers that had some questions about the virtual manufacturing permit process and various issues, would that be the appropriate venue for them to bring anything forward, or is it going to be -- is it going to be limited to certain topics?

MR. WINTERS: This will be -- in some respects it will be limited to a development of the rule which will specifically go to the sections that we can exempt virtual manufacturers from under the establishment, security, and storage requirements under 499.0121. That very well may fit into many of their questions, because that is the primary aspect difference between virtuals and the actual manufacturers, and the brokers versus the full distributors.

But you know, obviously, if anybody has any questions or concerns, they can always contact the Division, but we would be limited to those topics as part of the rule workshop. If somebody were to bring
an issue and it's identified as possibly not being on
topic, with the help of counsel and we could -- if it
was identified outside, we could simply take that as
an informational item during that and just we'll take
that -- please -- you know, we'll be happy to talk
with you outside of this rule workshop and see if
there's some other assistance we can provide, but we
would want to confine it solely to kind of that
portion of the workshop so that we don't get too far
awry of what we're doing.

One of the things that you'll notice, we are
being very specific about what we're doing in these so
that we can bite off only what we can chew. We know
there are other items that we can try and fix or focus
on, but if we try and focus too wide a beam, we're not
going to be able to accomplish what we're looking for.
So I really want to take them in those bits that we
know we can address in rule work. But yes, we could
-- most likely I'm guessing most of it is going to be
fitted into what they're looking at in those areas.

MR. BROCK: Thank you.

MS. ALSOBROOK: Mr. Mays, if I might --

MR. MAYS: Go ahead.

MS. ALSOBROOK: -- add onto that, this is

Renee, many of the questions that I get regarding
these applications are directly related to the fact
that these are virtuals, and the application currently
addresses a manufacturer whether they're virtual or
not, and the virtuals are very frustrated by the fact
that our application would require them to meet all
the requirements; and that, I think, is the
frustration that is driving some of the complaints
you're hearing. And we're hoping that when we get
this rule in place, we'll be able to create a virtual
manufacturer-type application which should resolve
many of the issues that you're probably hearing
complaints about, but we got to get the horses in
front of the cart, so to speak.

So that's why I think that this meeting is
tremendously-important today, as well as in May, to get
the input so we'll know more of what to do. Because if we
just start exempting certain requirements, we're liable to
put the public health and safety at risk. So we kind
of really need some serious input from folks that
won't let us make some mistakes. I'm sorry,
Mr. Tuller.

MR. TULLER: Yes, and Mr. Director, this is
Jeff Tuller, I just have a couple of questions. Who
is our target audience for this workshop? Is it the
ones that are currently trying to acquire a virtual
manufacturing license, is it those that have a virtual license, is it all of the above and more?

MR. WINTERS: It's actually all of the above and somewhat more, because there may be people that currently are in the full manufacturing realm when -- because as people were originally given licenses, we didn't have the virtuals, so a lot of virtuals, as we deem it, have those manufacturer's licenses, and they may very well be trying to move to a virtual manufacturer. They're -- even in our program office as far as applications we see on a regular basis somebody that comes through and our renewal or inspection of their facility, they're like, "Well, I'm a virtual," we have to look at it and say okay, we need to help you transition because you have a full manufacturer's license and you can actually take possession of drugs under your physical license, so we expect you to meet all those criteria.

So those are some of the main groups that we're looking for, but this will also, again, I think will be helpful overall to the industry to have that kind of more direct bright -- not necessarily full bright line, but a much more clear line as to where the virtuals will sit versus the manufacturer; where the brokers are going to sit versus the full
distributors who are taking possession of drugs.

And so that's the anticipation is that we are
going to try and umbrella that to where anybody that
may possibly be thinking about it or that just is
unaware of what it is, we clarify that rule, that may/help them determine whether they can move to a virtual
if they want to move to a virtual --

MR. TULLER: Right.

MR. WINTERS: -- or not.

MR. TULLER: So my follow-up question is
would it be helpful if you sent notification to the
industry perhaps that this workshop was going to
occur, and perhaps target that -- those segments you
just mentioned somehow? I don't know if we have a
social media account or we're on Twitter, I don't know
but --

MR. WINTERS: We actually -- we can work with
communications on items such as Twitter --

MR. TULLER: Because I think this is cutting
edge stuff.

MR. WINTERS: -- but we -- also, one of the
things that we will do is that we will identify our
interested parties list, but I think it's a great
point that you make that perhaps what we can do is get
the license database --
MS. GREENE: Email list.

MR. WINTERS: -- pull those permit holders currently and get the email list from that; that we can go ahead and shoot a mass email to them.

MR. TULLER: Yes.

MR. WINTERS: "We are going to be developing this rule. It would be great if we could have your input" and have, then, the opportunity, I think -- like I said, one of the reasons we want to move it to the Orlando area is simply Tallahassee is difficult to get to, no matter how you look at it, and so we'll do that, and I do appreciate you mentioning that because that will spur us to put that in our follow-up to go ahead and have our technical director and knowledge team pull those email addresses out.

MR. TULLER: May I also add to that if I may, this is Jeff Tuller again, perhaps when you solicit that market place that you would request probably top two or three concerns that they have, and then you can ferret through all of the information you receive and then pretty much channel down if you wanted to address the key issues by the majority of the constituency to save time and be focused, I think that may be an opportunity for us.

MR. WINTERS: We will take a look and make
sure that we tailor the message out there, and what information we give them. One of the items that we will give an opportunity is, if they may not be able to attend, that they can submit a comment to us as part of the rule workshop that we can take into consideration; but that may be helpful if somebody wants to submit a comment beforehand and then -- even and still attend -- for us to have pre-consideration. We'll make sure that we tailor that message so that we can -- they can gather that and we'll garner such an item from them.

MR. TULLER: Terrific. One last point:
Every -- the trending of manufacturing here in this country, obviously we all know it's off-shore and a lot of these are virtuals and so on and so forth, so I think we're -- I think this is spot on what we're trying to do with the council, and far as this trip.

You know, as a board member, I look at this that every single virtual does have some distributor on record of some nature, and they must have a standard operating procedure for the things that may not be within that four walls. And there may be a common denominator that we must obtain -- in terms of temperature requirement or humidity requirement, ambient storage, whatever it may be, security.
protocols, procedures -- as a minimal. Because that
SOP is very important.

Whether that virtual is in a strip mall and
it's whatever it is, I would have to believe that they
would have some kind of SOP for storage and security
of their product which is part and parcel why we have
this committee; correct?

MS. ALSOBROOK: Yes.

MR. TULLER: So just for the record, I'd like
to note that, I think --

MR. WINTERS: I've got it noted, and I'm sure
that will be part of -- you know, one of the reason
why I do look to the council and want you to be able
to -- and move the meetings in conjunction is because,
as council members, like you said, you have the
industry information just as much as you -- our other
interested partners, if not more. And the fact that
you're here means you're extremely valuable to us
so --

MR. TULLER: I drove through the night.

(Multiple speakers, unintelligible.)

MR. MAYS: Yeah, and this is Steve, I think
that there's also -- and again, not being an expert on
the virtual manufacturers, but I know that there could
be situations where you have one that they're using a
CMO to manufacture their product, but then they may
maintain a lab to test that product before it's
distributed, or test something from each lot, and they
maintain a lab and -- again, we're probably getting into
FDA's realm but --

MR. WINTERS: But I think that --

MR. MAYS: -- there's a lot of different
situations out there, I'm sure.

MR. WINTERS: I think they're -- and that's
one of the reasons why we will send out that blast,
because one of the things that we'll note is that
sometimes we have the bigger picture, but we also need
to have people with the smaller picture to be able to
look into, or a different picture. And that's really
what this workshop is going to be about is to gather
everybody's input and get the full picture and try and
develop -- again, it is a rule which means it is a
broader brush --

MR. MAYS: Um-hmm.

MR. WINTERS: -- but it means that we are
going to have to, again, try and get everybody's
input, see if we can get a consensus and try and
develop a rule so that everybody at least will be on
notice as to what we expect. Dr. Goldman?

DR. GOLDMAN: Just a question -- yeah, this
is Jennifer Goldman, can you clarify for physicians
and for patients what constitutes a virtual
manufacturer and how it would impact, you know,
patient safety and prescribing for those of us?

MR. WINTERS: Yeah, and like I said, I know
that we provided just the basic information, and a lot
of this will also be, again, provided in much more
detail during the rule workshop. But again, the
virtual manufacturer is an individual that is -- the
key is a manufacturer, they meet the qualifications
bother under FDA and under Florida law that they meet
as a manufacturer, but they may not take physical
possession -- or they're not supposed to take physical
possession of any drugs. That means that they're
coordinating with a contract manufacturer, they're
coco-licensed by the actual manufacturer in order to be
the product marketer. And so we deem them under law
to be a manufacturer, but they're not --

DR. GOLDMAN: But they're not, okay, okay.

MR. WINTERS: -- they're not actually one
that's holding the drugs, they don't receive the
drugs, nor do they receive any of the prescription
items that are going into it. So they're not
physically taking possession or handling the actual
pharmaceuticals, which is why some the requirements
that we have, as noted by Chief Alsobrook and
Councilman Tuller and Chairman Mays is that having a
requirement that you have all this storage
requirement, humidity and temperature controls and
things like that, you're not storing anything but
computers and paper, you know, you have a hard time
meeting those requirements.

And so the health, safety, and welfare issue
is that we still need them to maintain compliance with
good manufacturing processes through their contract
manufacturers, and also that record keeping
requirements -- that they know that their labeling is
required, we know who is actually manufacturing and
distributing the product, whose name the people are
going to be seeing out there on the product, those are
all items that we still need to make sure that they
comply with in their licensing. That's kind of a
major overview, Chief Alsobrook, anything that you
wanted to add?

MS. ALSOBRUCK: I would add that some of
these virtual manufacturers, not actual manufacturers,
purchase the raw ingredients or active pharmaceutical
ingredients for the product and control the
laboratories that do the testing of the product. So
the individual making -- and by "individuals" we mean
corporations for the most part -- making the product, which are usually overseas and are not inspected on a routine basis by the federal Food and Drug Administration, could be bringing product into the United States that is substandard and is not caught until it has caused some damage.

Frequently, products are recalled; you probably know that as a physician, because of particles in the product or glass in the product or whatever that happens, and it's only when something bad happens that we know of the recall.

So when you set up a corporation that's a virtual manufacturer, it has nothing to lose; it's not like AmerisourceBergen that's got physical land and buildings invested that has something that can be sued and taken from them, these are just businesses that may be in a very-small, 200-square foot facility. What can you sue? What can you take away from them? They have no real name or anything.

So the thought process is that we have to really think through what we're going to exempt them from, because 499.121 that places the responsibilities on these manufacturers and distributors, requires due diligence of suppliers, due diligence of purchasers, all kinds of responsibilities that we want them held

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to, but it does allow us to exempt a few things, and a few things they should. As we indicated, the storage; what are they storing?

But if they do have a laboratory there, then there are things that we do need to think about, you know, they need to maintain those at proper temperatures and that kind of stuff, so those are the areas that we need to think about. But it is wrought for possible harm, we just need to be very careful. It's not the good people that you have to worry about, it's those that --

DR. GOLDMAN: Sure.

MS. ALSOBROOK: -- are in it for the buck.

MR. MAYS: And this is Steve Mays, and somebody can correct me if I'm wrong, I may be mistaken, I think typically those virtual manufacturers that have that label or code and their names on the label, I think FDA holds them responsible for any recalls that have to be done. I don't think they go back to the contract manufacturer, I think it's the label owner. I could be mistaken, but I -- so that's --

MR. WINTERS: I believe you're correct but we'll obviously make sure that's --

MR. MAYS: But they do have some skin in the
game, you know, for a bad product.

MR. WINTERS: They have skin in the game, they do, but we also need to make sure that we maintain that balance of level, which is to know that if we've got somebody that they're maintaining the requirements, that they can, if we go back to them and say you need to produce a recall --

MR. MAYS: Um-hmm.

MR. WINTERS: -- as you indicated, they can do that. That's really a health, safety, and welfare record. We need to know where the product is and where it came from; all those items, the SOPs, things like that. So those are all issues that we have to weigh when we start to decided what we can and cannot exempt. Again, we're limited to what's in 0121 for those categories, but we'll take care of all that as part of the rule workshop, and we'll provide a very specific notice to everybody plus outreach, and then also have a rule workshop package that will include a lot of the reference materials that we'll have for everybody to look at, so that -- we'll do that. And -- and --

MR. MAYS: Mr. Barnes?

MR. BARNES: Patrick Barnes. So I'm glad you asked that question, because I was sitting here and
didn't want to be ignorant sounding. So if they have the bulk product, some sort of a chemical, I would think that would need to be stored under proper humidity and temperature and that. So what we're doing here is not going to remove that; correct?

MR. WINTERS: Correct. This is for --

MR. BARNES: Okay.

MR. WINTERS: And we keep saying "virtuals," it applies to the broker-only, too. But they're not taking physical possession of those pharmaceuticals or the --

MR. BARNES: The finished product, but the --

MR. WINTERS: The finished product --

MR. BARNES: But they're --

MR. WINTERS: -- or the API.

MR. BARNES: Oh, they're not -- oh, they're not --

MR. MAYES: Yeah, that -- that contract manufacture typically is handling the API, and doing the actual --

MR. WINTERS: Now, they may -- as Chief Alsobrook indicated that there is a line there you got to remember, though: They may be responsible for ordering that API and having it shipped directly to their contract manufacturers, so we will still need to
know that they're getting it from an authorized
source, or what's going on, that it's meeting the
requirements. And so those are all part of that chain
of information that we need to maintain while also
trying to balance out not having them have to have a
storage locker or a cage for controlled substances,
other items, you know, that just don't apply. But we
do need to make sure that we look at that, other
items, SOPs things like that; what happens if they do
get an inadvertent drug sent to them and they didn't
realize it, what they do with it, things that we'll
expect them to have the ability to handle.

So those will all be part of the rule
workshop in doing that, and then I think --
Dr. Goldman, I think your question, though, has
pointed out that perhaps as part of the rule workshop
would be a good lay-out from us to maybe get with our
legal team to provide a good presentation on the
actual virtual manufacturer from our side, to give
everybody an understanding of generally where we see
that virtual manufacturer's at, and then we'll roll
into what we think we can and cannot exempt them from.
So I think it's an excellent comment, and it's going
to help us when we start the rule workshop process,
and -- which is really the purpose why we're out here
to day is to kind of make sure we launch the ship in
an upright and even fashion. We don't want to have it
upside down before we get going, so --

MR. MAYS: Any other questions from council
members? Okay, so I know we've got other folks on the
line, so I just wanted to open it up for any questions
from any other interested parties on the line before
web move on? Okay. Mr. Winters, anything else?

MR. WINTERS: No. I think what we'll do is
move on because the next item is very similar to this,
but it's one that's going to a little more -- I think
this one's going to be a little more -- not
contentious or difficult, but just it's going to have
a little more exacting nature to it.

We are currently wanting to also, at the same
time, have another rule workshop on a different item
which is administrative services. When the DSCSA was
adopted, there was a exemption from the definition of
wholesale distribution for an entity providing solely
administrative services. The provision under the FDA
Statute is actually in 21 USC 353(4) and it is --
excuse me, (c)(4) -- the issue is is that one of the
items that we're seeing right now in cases in other
individual areas is that people are not necessarily
misinterpreting, but we don't an exact definition of
administrative services, what it constitutes; where the line is from where you cross over from just providing solely administrative services to you're providing actual distributions under the wholesale distribution.

Again, I want to be careful with this one right now because we are not to really get too far into conversation regarding this, so -- because I think this is going to be a rule workshop that's going to be very interesting and coordinated with the industry, because this will have some substantial effect for them regarding who and where licensure would be needed.

Again, the idea would be is to get all the individuals in the industry to go ahead and send a blast email out to them to know where that line for administrative services is. I can't -- won't go into any detail, but it's something that our Office of the General Counsel has dealt with this, our Enforcement division has dealt with this when we find individuals that have indicated, "Well, I'm only providing administrative services." When we review it, we don't believe that they have -- are providing only administrative services; that they're actually maybe going beyond that, and that they don't fit into that
exemption. If you don't fit into that exemption, you need licensure, they don't have it, then of course we've got an enforcement method.

And so we want to look at really trying to provide an administrative definition at this rule workshop trying to get a consensus inside the industry that we can go ahead and develop for Florida the definition of administrative services; and that is, again, what we're looking at.

If you're wanting to know inside obviously from a reference in 499 -- under 499.003(48) under the exemptions from wholesale distribution is the administrative services -- it says solely for administrative services. We would want to hold a rule workshop to discuss that and see if we can't develop an administrate definition to be developed into the administrative code.

That is, again, going to be something that will be beneficial to the industry and to us that we can at least put into rule the line that we have by definition in trying to develop that so everybody's aware whether they do or do not meet the definition.

Some of the items regarding this one that make it a little more difficult and a little different than our virtual is the fact that this is developed
and was implemented based on the exact language being
in to the DSCSA. So we have a counterpart here in
Florida, we could only develop the definition based on
what Florida has; it would not be applicable to any
other state, it would only be applicable here.

Currently there has not been a definition
defined by the FDA, and it does not look like we're
going to have -- they're still developing it
through the -- and through guidance documents, we see
that they are working on it, but again, we feel like
it's time that we may go ahead and try and get this
clarified for Florida and for our permit holders to
try and get that definition put in place.

It will be, again, held at the same time, and
we would, again, provide a blast email outreach to the
industry so that we can get as much input as possible,
and that we would provide a package ahead of time for
people to see the items that we would be looking at
and go forward at that particular moment in time at
that May hearing, and that would be what we would do.

This one, like I said, is probably going to
be a little more lengthy than the virtual, I think,
but -- they could both be a substantial discussion but
we want make sure that we're, one, want to go there,
if you advise it, we think it would be beneficial to
get your input if we want to try and develop that --
that definition. If there's anybody who has any
comments, concerns -- Chief, did you have anything
that you wanted to add?

MS. ALSOBROOK: You know what I would add --
Mr. Court Reporter, Renee Alsobrook -- during our
investigations, we run upon individuals and we receive
complaints that individuals are conducting wholesale
distribution of prescription drugs without permits.
And within our rules, Dr. Goldman, there are
exemptions from wholesale distributions that are based
upon what the drug -- what the federal government
passed as the Drug Security Chain Act. And Florida
passed exactly that verbiage into our statutes in
2016, thinking that eventually -- and eventually they
will -- the Food and Drug Administration will develop
some definitions and rules, et cetera.

So we didn't define certain terms because we
thought they would be forthcoming -- and they will. I
will be retired, but they will -- so one of those
terms that we've run into in our investigation is the
claim that we're only doing administrative services.

And I'll give you an example: We walk into a
facility and we find six people on the telephones and
they're calling all around selling products to

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hospitals, to doctor's offices, and they're buying
them, and they're bargaining for the prices and
they're telling the doctor we can get you this cheaper
and they're actually calling their warehouse and
shipping it there too, and they tell me "we're only
doing administrative services." Well, I don't agree
with that, I don't think that's right, but I don't
have a definition so I don't know.

So I've gone to the director a couple times,
and of course those people go to the director and say
"I'm not doing wholesale distribution, see, it's
administrative services." But I think that that's
anti-competitive to the people that pay the price to
regulate -- be falling within the regulation and get
the permits and have the CDRs and post the bonds and
all that stuff. And I think that we need a level
playing field one way or another, and this a big hole
that people keep falling into and diving into and
claiming that it's just administrative services. So
we don't know what it is.

We do know that it says including processing
of orders and payments. Well, that's okay. You know,
you've already decided what drugs you're going to buy,
you've already decided the price, and I've done it all
and I send it to somebody to do the paperwork, I've
got that; that's probably administrative services.
But what does the industry think that is? You know,
do you think that that's all there is to it; that
that's administrative services? So we don't know. I
mean, I'm a regulator, I don't know.

But that's when I went to the director and I
said can't we figure out from the industry what this
is? So we had a long discussion. But this is a
federal term. Yeah, it is, but do we wait ten years?

So what we know is when the feds do define
the term, Florida's term will probably have to go
away, because we'll have to defer because it's
preempted. But in the meantime, are we entitled to
implement Florida law for the safety of the public?
And I think that we probably are. But that's part of
the, I think, the conversation that will come out at
the rules workshop.

Is it a good thing for us to do, can you give
us some definitions, do you think that we should just
let all this happen all around us and have this
definition be an exemption for all regulations. But
anyway, that's what I'm finding in the field.

MR. MAYS: I think -- this is Steve -- I
think it would be important to kind of take a look at
it, because I'm sure in the industry, I think there's
probably some confusion about where you cross that
type line from being just a call center which, you know --
I know, you know, AmerisourceBergen has call centers
around the country, and they're just basically taking
calls from customers, and basically that's where
customer care is, so it's a more-centralized process
in some of the larger companies. So you know, that --
I think there's probably some confusion about where
that line gets crossed to where you're a call center,
or you're actually providing those administrative
services.

MS. ALSOBROOK: Um-hmm.

MR. WINTERS: And that's exactly the point.
And this is truly when I call it -- this is purely get
the knowledge to everybody and so that we can all
hopefully come together all in agreement that this is
where we all think that that line is after a
discussion; because without that, again, it's on a
case-by-case basis, it leads to situations where,
again, we may be getting good people, good companies
that are trying -- think they're doing something okay,
we don't think they're doing something okay, or we
have a case that we believe cross that threshold. If
we had it out there inside of the industry for
everybody to be able to have the full definition or
something to better define that -- because let's be
hones, "administrative services" is kind of an
amorphous term, all right? We don't know -- you could
take that from any which direction you want to. If we
can -- we want to try and bring that in for a landing.

And again, as we've said, this is because we
don't have one now. If we get one we -- as 499 says,
we always have to do the best we can and always stay
in compliance with federal law, so if this were to
later be reassessed and we get a FDA determination
administrative services is more or less restrictive
than what we have defined it as, we will either remove
our rule completely or we'll tweak it so that it
conforms with what FDA is, so that everybody has that
information.

But that would be down the road; until then,
we want to try and be a leader for our industry here
in Florida and give them the tools that they need to
work, and for our regulatory scheme to be able to
work, we need those tools as well.

MR. TULLER: So this is Jeff Tuller, what I'm
hearing you tell me is -- I see this as most
businesses today obviously out-source lots of
different functions. I think that's probably a
reasonable situation everywhere within our industry.
So you have a legal -- kind of a contractual legal
line to these companies that you can pretty much
ferret out with your due diligence -- I think Florida
does a pretty good job of that -- and also you have a
physical side of this. So you really have really --
if I'm thinking this through properly, there's a
physical side.

All right, if I have a telemarketing group
and a warehouse that's distributing product, that is
an administrative services, correct, that's you know,
we're -- like you walked into that situation in your
example, that's somehow a stretch of administrative
services unless those people have different uniforms
or in a cube that -- I don't know --

MS. ALSOBROOK: There you go, I mean --

MR. TULLER: So I think, you know, when you
look at your due diligence on this, you really have
two things to consider: One is what is the legal tie
to that particular administrative service; and two,
where is the physical presence of that administrative
service?

So you know, in my old days at the big boys,
we were -- we may have been in one city, but we were
in a lot of other little cities. And some of those
little city were different contractual arrangements.
So if I am licensed in that particular place, am I
burdened by my license in this state even -- so
there's a lot of gray --

MR. WINTERS: Well, there's a lot of that --

MR. TULLER: -- I don't know --

MR. WINTERS: -- I think you're point -- and

I think that the conversation today is really to look
at -- there's so many different permutations --

MR. TULLER: Oh, gosh --

MR. WINTERS: -- what are out there --

MR. TULLER: Yes.

MR. WINTERS: -- depending even from small
size to big size, how you out-source. Even if you're
not out-sourcing, you may be splitting up the
functions inside of your realm --

MR. TULLER: Um-hmm.

MR. WINTERS: -- and you may have different,
as we talked about, call centers in multiple cities;
that you're a large corporation that, you know, you
have to centralize certain functions to one location.
Is that location providing administrative services or
not? That's all part of the conversation that we're
going to have and look at that, because there's so
many ways as -- there's a thousand shades of gray here
that you could apply if -- and so you're really
looking at a situation where, because the rule
workshop is intended for us to get each person's idea,
their shade of gray where they think it's at, and get
on more of a consensus and get that determination
where it's at, so it's going to -- it's going to be --

MR. MAYS: Just for the record, Michael Mone
has joined the meeting. Better late that never.
Right here.

MR. WINTERS: We'll put you --
MR. MAYS: Right there on the -- right there
on the corner.

MR. MONE: Oh, okay. All right, sorry.
MS. ALSOBROOK: One of the things,
Mr. Tuller, I think is important: As regulators
trying to be fair, when a law is passed, businesses
are businesses, you know, and I think --

MR. TULLER: Yes.

MS. ALSOBROOK: -- hopefully we got input and
got the involvement of businesses when the statutes
were written -- and that's kind of pie in the sky
because that doesn't happen, but anyway, so maybe we
can hope that happened -- but businesses evolve and
they change and they -- more quickly than regulations
do.

And if we don't try to get this input from
the business entities, then our regulatory scheme is not going to address the changes in business. And we're going to be running around wasting the few resources we have, the nine inspectors I have, chasing what I think is unlicensed activity when it's not. And the public will be harmed from that, because running around chasing -- I'll use AmerisourceBergen's -- customer care contors thinking that they're unlicensed activities, is not the way to protect the public.

   The way to protect the public is finding unlicensed manufacturers of prescription drugs that are actually making the drugs, substandard distributors who are actually not maintaining adequate temperatures and monitoring those properly; that's where I need to put my resources. So the clarity that I have in the law is what allows me to do a better job, and this does not allow me to do a better job.

   I may not like that you can split up your functions, I may like that AmerisourceBergen or Cardinal has to be responsible for every single aspect of a distributor's job, but I don't know that legally that has to be the case. As you indicated, I think you can subcontract out a bunch of functions and still be perfectly legal.
MR. MAYS: I mean, the traditional wholesale
distributor model from years ago, and probably some
still today, is all those functions were in one
building. You know, you had accounting, you had
accounts receivable, you had accounts payable, you had
customer service, telephone sales, and the operation.
And now those -- those functions are centralized,
especially for the larger companies, they're in
different places, so I guess my question for you,
Renee, is do you really feel that comfortable that FDA
is going to adequately define that?

MS. ALSOBROOK: I always live in hope.

MR. MAYS: You think they'll define that in
the wholesale licensing --

MS. ALSOBROOK: I think they have to.

MR. MAYS: Yeah.

MS. ALSOBROOK: We've talked to them enough
to convince them that it is -- it's an absolute
necessity because we've addressed it in Florida, and
if you don't address that component, they're going to
have the same issue that we're having. How are you
going to properly identify who needs to be licensed if
you don't identify your exemptions, because that just
creates this massive hole.

MR. TULLER: Renee, your point -- this is
Jeff Tuller again -- your point is well-taken. It's really -- we have all of this stuff going on, as Steve said, that old box that had every department in it including the trucks that drove the drugs to your drugstore, is no longer. So as we change, and we try to interpret the law, let's come back to what that's supposed to be, and that's the safety of the patient.

MS. ALSOBROOK: That's --

MR. TULLER: And if we drive towards the safety of the patient in every single communication, and not get bogged down with all that other stuff that, in my opinion, can be onerous to a business and to a -- of course, to a facility, I think we're way ahead of the game.

MS. ALSOBROOK: Yes, sir.

MR. WINTERS: That's the hope. We'll get in --

MR. TULLER: We always hope, we always hope.

MR. WINTERS: And again, this is -- in talking about this, this is a hope that we will be able to get a good product out of the workshop. We always find the best product comes out of coordination, that's what this is going to be.

Again, we'll -- as the things change, we'll ebb and flow with that, but to try and get something
on paper and really take the effort -- we wanted to
make this year a year that we started trying to find a
couple of the items that we really wanted to tackle,
and this was one of the --

MR. TULLER: Might as well take on the big
ones.

MR. WINTERS: Well, if you're going to do it,
go for it.

MR. MAYS: I think to Mr. Tuller's point, you
know, it's just that -- you know, and I've had
conversations with you -- it's like, you know, the bad
guys are the unscrupulous players in the supply chain
will find those weaknesses and those holes in the
rules and in the law, so I think any time that we can
try to plug those, you know, where it doesn't disrupt
the whole supply chain, I think it makes a lot of
sense to try to find those weaknesses --

MR. TULLER: Agreed.

MR. MAYS: -- plug them.

MR. WINTERS: So the only thing I would ask
is just a vote of council that you're comfortable with
us going forward with a workshop and coordinating it
with the council.

MR. MAYS: Do I hear a motion?

MR. TULLER: (Indicating.)
MR. BROCK: Second.

MR. MAYS: All in favor say aye.

(Chorus of ayes.)

MR. MAYS: Those opposed? Okay.

MR. WINTERS: I think Mr. Tuller was the motion maker on that one.

MR. TULLER: Yes, I made a motion to --

MR. MAYS: All right. All right.

MR. TULLER: -- approve that one, for the record.

MR. WINTERS: And council members, that is all I have at this point in time for you.

MR. MAYS: Okay. Any other questions from council members on the subject? All right, Mr. Mone?

MR. MONE: The question I have is at what point would you guys like me either to come in to help with the examination?

MR. WINTERS: And I apologize, Councilman Mone, I addressed that in one of my prior comments. We hoped that I was going to be able to get a coordination or presentation here today, unfortunately due to a scheduling error, it didn't occur. We're going to try to move that to the -- also to the May council meeting.

MR. MONE: Okay.
MR. WINTERS: But I've also talked with them, we've got implementation April 1st for the 18 months, but I've also talked with them as far as a time frame to start working -- we're coming up to that time frame where we're going to start coordinating and overhaul -- again, the -- we generally do it on about a three-year cycle, and I think we're coming up on that, so what I will do is set a meeting for you and myself and -- to discuss that with Andrew Janicek, our Bureau of Education and Testing --

MR. MONE: Okay.

MR. WINTERS: -- just to get you some ground work --

MR. MONE: And it seems lately that I've been coming to Tallahassee a bit more, so if there's a -- if you want to do it live, that's also a possibility.

MR. WINTERS: And for sure what I will do is make sure that it's the most-convenient method for you because I don't want to inconvenience you. The fact that you're willing to help and the council's taking that effort to provide you that authority I think is going to be a great asset to us, so we'll make sure that --

MR. MONE: Okay. Perfect. Thank you.

MR. WINTERS: Dinah, if you could --
MS. GREENE: I got it.

MR. WINTERS: -- make sure my keeper keeps me keeping on.

MS. ALSOBROOK: She got you.

MR. MAYS: All right? All right, any questions from any other interested parties on the line before we move towards closing out? Okay. Any other business? All right, hearing none, do we have a motion to adjourn?

MR. TULLER: Motion to adjourn.

MR. MAYS: Second?

MR. PHILLIPS: Second. Second, this is Jeenu.

MR. MAYS: All in favor say aye.

(Chorus of ayes.)

MR. MAYS: Opposed? The meeting is adjourned, thank you.

(Whereupon, the proceedings were concluded at 10:34 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 55, is a true and correct record of my stenographic notes.

Dated this 4th day of March, 2018 at Tallahassee, Leon County, Florida.

[Signature]

JEFFREY BABCOCK, FPR

FOR THE RECORD REPORTING TALLAHASSEE, FLORIDA 850.222.5491
RULES REPORT

To: Drug Wholesale Distributor Advisory Council
From: Drew Winters, Director
Date: May 10, 2018,
Re: Division Rulemaking (rev.4/10/18)

The following chart is a summary of the Division’s current rulemaking efforts.

<table>
<thead>
<tr>
<th>Rule #</th>
<th>Title</th>
<th>Purpose</th>
<th>Status</th>
<th>Next Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>61N-2.003</td>
<td>Application for Device Manufacturer Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16;</td>
<td>Finalize draft of application; File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.007</td>
<td>Application for Limited Prescription Drug Veterinary Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule</td>
<td>Notice of Development filed 2/26/16;</td>
<td>Finalize draft of application; File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>1N-2.018</td>
<td>Application for Restricted Rx Drug Distributor – Blood Establishment Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Proposed filed 12/19/17.</td>
<td>Division has submitted the rule for adoption.</td>
</tr>
<tr>
<td>61N-2.019</td>
<td>Application for Restricted Rx Drug Distributor – Charitable Organization Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Proposed filed 3/29/18</td>
<td>DDC responding to letter from JAPC</td>
</tr>
<tr>
<td>61N-2.020</td>
<td>Application for Restricted Rx Drug Distributor – Destruction Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice Proposed filed 3/29/18</td>
<td>DDC responding to letter from JAPC</td>
</tr>
<tr>
<td>61N-2.021</td>
<td>Application for Restricted Rx Drug Distributor – Government Programs Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of proposed rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.022</td>
<td>Application for Restricted Rx Drug Distributor – Health Care Entity Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.023</td>
<td>Application for Restricted Rx Drug Distributor – Institutional Research Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.024</td>
<td>Application for Restricted Rx Drug distributor – Reverse Distributor</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Proposed filed 3/29/18</td>
<td>DDC responding to letter from JAPC</td>
</tr>
<tr>
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</tr>
<tr>
<td>61N-2.025</td>
<td>Application for Retail Pharmacy Drug Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.026</td>
<td>Application for Third Party Logistics Provider Permit</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Proposed filed 3/29/18</td>
<td>DDC responding to letter from JAPC</td>
</tr>
<tr>
<td>61N-2.027</td>
<td>Application for Veterinary Prescription Drug Retail Establishment</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.028</td>
<td>Application for Veterinary Prescription Drug Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.029</td>
<td>Application for Change of Mailing Address</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Proposed filed 1/22/18</td>
<td>Division has submitted the rule for adoption.</td>
</tr>
<tr>
<td>61N-2.030</td>
<td>Application for Name Change</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Proposed filed 1/22/18</td>
<td>Division has submitted the rule for adoption.</td>
</tr>
<tr>
<td>61N-2.031</td>
<td>Application for Change of Physical Location</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Proposed filed 2/1/18</td>
<td>Division has submitted the rule for adoption.</td>
</tr>
<tr>
<td>1N-2.032</td>
<td>Application for Certificate of Free Sale</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Effective 4/12/18</td>
<td>The rule has been adopted and is effective.</td>
</tr>
<tr>
<td>61N-2.033</td>
<td>Application for Certification as a Designated Representative</td>
<td>To adopt and incorporate the division's permitting application forms into rule</td>
<td>Effective 4/12/18</td>
<td>The rule has been adopted and is effective.</td>
</tr>
</tbody>
</table>

Notice of development filed, but no initial draft of the rule has been completed.
Revised rule has been drafted and is being reviewed by division staff.
Rule published for proposed: division is awaiting & responding to public comment.
The rule is being routed for adoption approval.
The rule has been adopted and is effective.
The rule has been adopted and is effective.

<table>
<thead>
<tr>
<th>Rule #</th>
<th>Title</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>61N-1.016</td>
<td>Product Registration</td>
<td>11/2/17</td>
</tr>
<tr>
<td>61N-1.017</td>
<td>Certificates of Free Sale</td>
<td>10/24/17</td>
</tr>
<tr>
<td>61N-1.018</td>
<td>FEES</td>
<td>11/2/17</td>
</tr>
<tr>
<td>61N-1.028</td>
<td>Product Tracking and Tracing-Definitions</td>
<td>5/16/16</td>
</tr>
<tr>
<td>61N-1.029</td>
<td>Product Tracking and Tracing- Manufacturer Requirements</td>
<td>5/11/16</td>
</tr>
<tr>
<td>61N-1.030</td>
<td>Product Tracking and Tracing- Wholesale Distributor Requirements</td>
<td>5/11/16</td>
</tr>
<tr>
<td>61N-1.031</td>
<td>Product Tracking and Tracing-Dispenser Requirements</td>
<td>5/11/16</td>
</tr>
<tr>
<td>61N-1.032</td>
<td>Product Tracking and Tracing - Repackager Requirements</td>
<td>5/11/16</td>
</tr>
<tr>
<td>61N-1.0245</td>
<td>Notice of Non Compliance- Minor Violations</td>
<td>11/2/17</td>
</tr>
<tr>
<td>61N-2.001</td>
<td>Application for Complimentary Drug Distributor Permit</td>
<td>6/9/16</td>
</tr>
<tr>
<td>61N-2.002</td>
<td>Application for Cosmetic Manufacturer Permit</td>
<td>10/24/17</td>
</tr>
<tr>
<td>61N-2.005</td>
<td>Application for Freight Forwarder Permit</td>
<td>6/9/16</td>
</tr>
<tr>
<td>61N-2.006</td>
<td>Application for Health Care Clinic Establishment Permit</td>
<td>6/9/16</td>
</tr>
<tr>
<td>61N-2.008</td>
<td>Application for Medical Gas Manufacturer Permit</td>
<td>6/9/16</td>
</tr>
<tr>
<td>61N-2.009</td>
<td>Application for Medical Gas Wholesale Distributor Permit</td>
<td>6/9/16</td>
</tr>
<tr>
<td>61N-2.010</td>
<td>Application for Medical Oxygen Retail Establishment Permit</td>
<td>6/9/16</td>
</tr>
<tr>
<td>61N-2.011</td>
<td>Application for Nonresident Prescription Drug Manufacturer Permit</td>
<td>5/11/17</td>
</tr>
<tr>
<td>61N-2.0111</td>
<td>Application for Nonresident Prescription Drug Manufacturer-Virtual Permit</td>
<td>1/11/17</td>
</tr>
<tr>
<td>61N-2.012</td>
<td>Application for Out-of-State Prescription Drug Wholesale Distributor Permit</td>
<td>7/11/17</td>
</tr>
<tr>
<td>61N-2.013</td>
<td>Application for Over-the-counter Drug Manufacturer Permit</td>
<td>6/9/16</td>
</tr>
<tr>
<td>61N-2.014</td>
<td>Application for Prescription Drug Manufacturer Permit</td>
<td>6/9/16</td>
</tr>
<tr>
<td>61N-2.015</td>
<td>Application for Prescription Drug Repackager Permit</td>
<td>5/11/17</td>
</tr>
<tr>
<td>Application ID</td>
<td>Description</td>
<td>Date</td>
</tr>
<tr>
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</tr>
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<td>Application for Prescription Drug Wholesale Distributor Permit</td>
<td>7/11/17</td>
</tr>
<tr>
<td>61N-2.0141</td>
<td>Application for Prescription Drug Manufacturer- Virtual Permit</td>
<td>1/11/17</td>
</tr>
<tr>
<td>61N-2.0151</td>
<td>Application for Nonresident Prescription Drug Repackager Permit</td>
<td>1/11/17</td>
</tr>
</tbody>
</table>
TAB 2: Division Director's Report – Drew Winters

House Bill 675
An act relating to pharmacies; amending s. 465.003, F.S.; revising and providing definitions; amending s. 465.004, F.S.; revising the membership of the Board of Pharmacy; amending s. 465.019, F.S.; establishing Class III institutional pharmacies; providing requirements for such pharmacies; conforming provisions to changes made by the act; amending s. 465.0252, F.S.; revising notice requirements to conform to changes made by the act; amending s. 499.003, F.S.; providing and revising definitions; amending s. 499.01, F.S.; authorizing the distribution of medicinal drugs and prepackaged drug products without a specified permit under certain conditions; deleting a provision exempting certain drug repackagers from specified permit requirements; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (7) and (13) of section 465.003, Florida Statutes, are amended, and subsections (21) and (22) are added to that section, to read:

465.003 Definitions.—As used in this chapter, the term:
(7) "Institutional formulary system" means a method
whereby the medical staff evaluates, appraises, and selects
those medicinal drugs or proprietary preparations which in the
medical staff's clinical judgment are most useful in patient
care, and which are available for dispensing by a practicing
pharmacist in a Class II or Class III institutional pharmacy.

(13) "Practice of the profession of pharmacy" includes
compounding, dispensing, and consulting concerning contents,
therapeutic values, and uses of any medicinal drug; consulting
concerning therapeutic values and interactions of patent or
proprietary preparations, whether pursuant to prescriptions or
in the absence and entirely independent of such prescriptions or
orders; and conducting other pharmaceutical services. For
purposes of this subsection, "other pharmaceutical services"
means the monitoring of the patient's drug therapy and assisting
the patient in the management of his or her drug therapy, and
includes review of the patient's drug therapy and communication
with the patient's prescribing health care provider as licensed
under chapter 458, chapter 459, chapter 461, or chapter 466, or
similar statutory provision in another jurisdiction, or such
provider's agent or such other persons as specifically
authorized by the patient, regarding the drug therapy. However,
nothing in this subsection may be interpreted to permit an
alteration of a prescriber's directions, the diagnosis or
treatment of any disease, the initiation of any drug therapy,
the practice of medicine, or the practice of osteopathic
medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189 and the preparation of prepackaged drug products in facilities holding Class III institutional pharmacy permits.

(21) "Central distribution facility" means a facility under common control with a hospital holding a Class III institutional pharmacy permit that may dispense, distribute, compound, or fill prescriptions for medicinal drugs; prepare prepackaged drug products; and conduct other pharmaceutical services.

(22) "Common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.

Section 2. Subsection (2) of section 465.004, Florida Statutes, is amended to read:

465.004 Board of Pharmacy.—
(2) Seven members of the board must be licensed pharmacists who are residents of this state and who have been engaged in the practice of the profession of pharmacy in this state for at least 4 years and, to the extent practicable, represent the various pharmacy practice settings. Of the pharmacist members, two must be currently engaged in the practice of pharmacy in a community pharmacy, two must be currently engaged in the practice of pharmacy in a Class II, institutional pharmacy or a Modified Class II, or Class III institutional pharmacy, and three must be pharmacists licensed in this state irrespective of practice setting. The remaining two members must be residents of the state who have never been licensed as pharmacists and who are in no way connected with the practice of the profession of pharmacy. No person may be appointed as a consumer member who is in any way connected with a drug manufacturer or wholesaler. At least one member of the board must be 60 years of age or older. The Governor shall appoint members to the board in accordance with this subsection as members' terms expire or as a vacancy occurs until the composition of the board complies with the requirements of this subsection.

Section 3. Subsections (4) and (6) of section 465.019, Florida Statutes, are amended, and paragraph (d) is added to subsection (2) of that section, to read:

465.019 Institutional pharmacies; permits.—
(2) The following classes of institutional pharmacies are established:

   (d)1. "Class III institutional pharmacies" are those institutional pharmacies, including central distribution facilities, affiliated with a hospital that provide the same services that are authorized by a Class II institutional pharmacy permit. Class III institutional pharmacies may also:

   a. Dispense, distribute, compound, and fill prescriptions for medicinal drugs.

   b. Prepare prepackaged drug products.

   c. Conduct other pharmaceutical services for the affiliated hospital and for entities under common control that are each permitted under this chapter to possess medicinal drugs.

   d. Provide the services in sub-subparagraphs a.-c. to an entity under common control which holds an active health care clinic establishment permit as required under s. 499.01(2)(r).

  2. A Class III institutional pharmacy shall maintain policies and procedures addressing:

   a. The consultant pharmacist responsible for pharmaceutical services.

   b. Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products.

   c. Recordkeeping to monitor the movement, distribution,
and transportation of medicinal drugs and prepackaged drug products.

d. Recordkeeping of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products.

e. Medicinal drugs and prepackaged drug products that may not be safely distributed among Class III institutional pharmacies.

(4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II or Class III institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the
patient with a prescription for such drug for use after the
initial 24-hour period. The board may adopt rules necessary to
carry out the provisions of this subsection.

(6) In a Class II or Class III institutional pharmacy, an
institutional formulary system may be adopted with approval of
the medical staff for the purpose of identifying those medicinal
drugs, proprietary preparations, biologics, biosimilars, and
biosimilar interchangeables that may be dispensed by the
pharmacists employed in such institution. A facility with a
Class II or Class III institutional pharmacy permit which is
operating under the formulary system shall establish policies
and procedures for the development of the system in accordance
with the joint standards of the American Hospital Association
and American Society of Hospital Pharmacists for the utilization
of a hospital formulary system, which formulary shall be
approved by the medical staff.

Section 4. Subsection (3) of section 465.0252, Florida
Statutes, is amended to read:

465.0252 Substitution of interchangeable biosimilar
products.—

(3) A pharmacist who practices in a Class II, or Modified
Class II, or Class III institutional pharmacy shall comply with
the notification provisions of paragraph (2)(c) by entering the
substitution in the institution's written medical record system
or electronic medical record system.
Section 5. Subsection (39) of section 499.003, Florida Statutes, is amended, and paragraphs (w) and (x) are added to subsection (48) of that section, to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(39) "Prepackaged drug product" means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing or by a facility holding a Class III institutional pharmacy permit in the establishment in which the prepackaging occurred.

(48) "Wholesale distribution" means the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, but does not include:

(w) A hospital covered by s. 340B of the Public Health Service Act, 42 U.S.C. s. 256b, that arranges for a prescription drug wholesale distributor to distribute prescription drugs covered under that act directly to a contract pharmacy. Such hospital is exempt from obtaining a restricted prescription drug distributor permit under s. 499.01(2)(h).

(x) The dispensing or distribution of a medicinal drug by a Class III institutional pharmacy pursuant to s. 465.019.

Section 6. Paragraphs (b) and (h) of subsection (2) and
subsection (5) of section 499.01, Florida Statutes, are amended
to read:

499.01 Permits.—

(2) The following permits are established:

(b) Prescription drug repacker permit.—A prescription
drug repacker permit is required for any person that
repackages a prescription drug in this state.

1. A person that operates an establishment permitted as a
prescription drug repacker may engage in distribution of
prescription drugs repackaged at that establishment and must
comply with all of the provisions of this part and the rules
adopted under this part that apply to a prescription drug
manufacturer.

2. A prescription drug repacker must comply with all
appropriate state and federal good manufacturing practices.

3. A prescription drug repacker permit is not required
for distributing medicinal drugs or prepackaged drug products
between entities under common control which each hold either an
active Class III institutional pharmacy permit under chapter 465
or an active health care clinic establishment permit under
paragraph (2)(r). For purposes of this subparagraph, the term
"common control" has the same meaning as in s. 499.003(48)(a)3.

(h) Restricted prescription drug distributor permit.—

1. A restricted prescription drug distributor permit is
required for:
a. Any person located in this state who engages in the
distribution of a prescription drug, which distribution is not
considered "wholesale distribution" under s. 499.003(48)(a).
b. Any person located in this state who engages in the
receipt or distribution of a prescription drug in this state for
the purpose of processing its return or its destruction if such
person is not the person initiating the return, the prescription
drug wholesale supplier of the person initiating the return, or
the manufacturer of the drug.
c. A blood establishment located in this state which
collects blood and blood components only from volunteer donors
as defined in s. 381.06014 or pursuant to an authorized
practitioner’s order for medical treatment or therapy and
engages in the wholesale distribution of a prescription drug not
described in s. 499.003(48)(j) to a health care entity. A mobile
blood unit operated by a blood establishment permitted under
this sub-subparagraph is not required to be separately
permitted. The health care entity receiving a prescription drug
distributed under this sub-subparagraph must be licensed as a
closed pharmacy or provide health care services at that
establishment. The blood establishment must operate in
accordance with s. 381.06014 and may distribute only:
(I) Prescription drugs indicated for a bleeding or
clotting disorder or anemia;
(II) Blood-collection containers approved under s. 505 of
the federal act;
(III) Drugs that are blood derivatives, or a recombinant
or synthetic form of a blood derivative;
(IV) Prescription drugs that are identified in rules
adopted by the department and that are essential to services
performed or provided by blood establishments and authorized for
distribution by blood establishments under federal law; or
(V) To the extent authorized by federal law, drugs
necessary to collect blood or blood components from volunteer
blood donors; for blood establishment personnel to perform
therapeutic procedures under the direction and supervision of a
licensed physician; and to diagnose, treat, manage, and prevent
any reaction of a volunteer blood donor or a patient undergoing
a therapeutic procedure performed under the direction and
supervision of a licensed physician,
as long as all of the health care services provided by the blood
establishment are related to its activities as a registered
blood establishment or the health care services consist of
collecting, processing, storing, or administering human
hematopoietic stem cells or progenitor cells or performing
diagnostic testing of specimens if such specimens are tested
together with specimens undergoing routine donor testing. The
blood establishment may purchase and possess the drugs described
in this sub-subparagraph without a health care clinic

CODING: Words striken are deletions; words underlined are additions.
establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

5. A restricted prescription drug distributor permit is not required for distributions between pharmacies that each hold an active permit under chapter 465, have a common ownership, and are operating in a freestanding end-stage renal dialysis clinic, if such distributions are made to meet the immediate emergency medical needs of specifically identified patients and do not occur with such frequency as to amount to the regular and systematic supplying of that drug between the pharmacies. The department shall adopt rules establishing when the distribution
of a prescription drug under this subparagraph amounts to the
regular and systematic supplying of that drug.

6. A restricted prescription drug distributor permit is
not required for distributing medicinal drugs or prepackaged
drug products between entities under common control that each
hold either an active Class III institutional pharmacy permit
under chapter 465 or an active health care clinic establishment
permit under paragraph (2)(r). For purposes of this
subparagraph, the term "common control" has the same meaning as
in s. 499.003(48)(a)3.

(5) A prescription drug re-packer permit issued under
this part is not required for a restricted prescription drug
distributor permit holder that is a health care entity to
re-package prescription drugs in this state for its own use or
for distribution to hospitals or other health care entities in
the state for their own use, pursuant to s. 499.003(48)(a)3.,

(a) The prescription drug distributor notifies the
department, in writing, of its intention to engage in
re-packing under this exemption, 30 days before engaging in the
re-packing of prescription drugs at the permitted
establishment;

(b) The prescription drug distributor is under common
control with the hospitals or other health care entities to
which the prescription drug distributor is distributing
prescription drugs. As used in this paragraph, "common control"
means the power to direct or cause the direction of the
management and policies of a person or an organization, whether
by ownership of stock, voting rights, contract, or otherwise;

(c) The prescription drug distributor repackages the
prescription drugs in accordance with current state and federal
good manufacturing practices; and

(d) The prescription drug distributor labels the
prescription drug it repackages in accordance with state and
federal laws and rules.

The prescription drug distributor is exempt from the product
registration requirements of s. 499.015 with regard to the
prescription drugs that it repackages and distributes under this
subsection. A prescription drug distributor that repackages and
distributes prescription drugs under this subsection to a not-
for-profit rural hospital, as defined in s. 395.602, is not
required to comply with paragraph (c) or paragraph (d), but must
provide to each health care entity for which it repackages, for
each prescription drug that is repackaged and distributed, the
information required by department rule for labeling
prescription drugs. The department shall adopt rules to ensure
the safety and integrity of prescription drugs repackaged and
distributed under this subsection, including rules regarding
prescription drug manufacturing and labeling requirements.
Section 7. This act shall take effect July 1, 2018.