AGENDA
Department of Business and Professional Regulation
Drug Wholesale Distributor Advisory Council
Homewood Suites
2987 Apalachee Parkway
Tallahassee, FL 32301
850-402.9400

Conference Call Number 888-670-3525
Conference Code 9259887749

February 15, 2018
9:30 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, MD, Physician

DBPR Staff:
Drew Winters, Division Director
Jonathan Zachem, Secretary
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. December 7, 2017 Meeting Transcript (informational only)

TAB 2: Division Director's Report – Drew Winters

a. DDC Rules Report

b. Discussion of potential rule workshop on “Virtual Manufacturers” & “Prescription Drug Wholesale Distributor-Broker Only”.

c. Discussion of potential rule workshop on definition of “administrative services”.

TAB 3: Other Business
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: February 15, 2018, 9:30 a.m.
Conference Call Number: 1(888)670-3525, Conference Code: 9259887749
PLACE: Homewood Suites, 2987 Apalachee Parkway, Tallahassee, FL 32301, (850)402-9400
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.
TAB 1: Chair's Report – Steve Mays, Chair

a. December 7, 2017 Meeting Transcript (informational only)
STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL

COUNCIL MEETING
(Via Telephone Conference)
TRANSCRIPT OF PROCEEDINGS

DATE: December 7, 2017
TIME: 9:30 a.m. - 10:27 a.m.

Stenographically reported by:
Deborah Alff, RPR

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

DBPR STAFF ATTENDING:
Drew Winters, Division Director
Jonathan Zachem, Secretary
Andrew Pifer, Deputy Secretary
Renee Alsobrook, Compliance Manager
Dinah Greene, Government Operations Consultant
Rebecca Burnett, Regulatory Supervisor

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PROCEEDINGS

(Whereupon, the meeting was called to order at 9:30 a.m.)

CHAIRMAN MAYS: Good morning, everyone.

This is Steve Mays. I'd like to call this meeting of the Drug Wholesale Distributor Advisory Council to order.

I would want to remind everyone to identify yourself before you speak so the court reporter will know who's speaking, and make sure you give your last name.

For anyone that's on the phone, which everybody is on the phone, so please mute your line when you're not speaking, especially if you're on a mobile or a room full of noise. And whatever you do, please don't put us on hold so we don't have to listen to any hold music or a company advertisement.

Ms. Greene, I think we're ready for a roll call.

MS. GREENE: Yes, sir.

Jeenu Phillips?

(No response.)

MS. GREENE: Brian Files?

(No response.)

MS. GREENE: Michael Mone?
MR. MONE: Present.

MS. GREENE: Scott Brock?

MR. BROCK: Here.

MS. GREENE: Arlene Elliott?

MS. ELLIOTT: Present.

MS. GREENE: Dean Ellis?

MR. ELLIS: Here.

MS. GREENE: Jeff Tuller?

(No response.)

MS. GREENE: Patrick Barnes?

MR. BARNES: Here.

MS. GREENE: Peter Hart?

MR. HART: Here.

MS. GREENE: Jennifer Goldman?

MS. GOLDMAN: Here.

MS. GREENE: Mr. Chair, you have a quorum.

CHAIRMAN MAYES: Okay. Great. Thank you, Ms. Greene.

I want to start the meeting off, as usual, by reading the goals of the council as stated in Chapter 499 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 the
prescription drugs and public health, make
recommendations to improve coordination with
other states' regulatory agencies and the
federal government concerning the wholesale
distribution of drugs, and make recommendations
to minimize the impact of regulation of the
wholesale drug industry, while ensuring
protection of the public health."

Okay. We have no items. If you'll notice,
there's no agenda items on the Chair's report
today, so I will just take this opportunity to urge
all the council members to submit agenda topics in
the future. That would help the Council fulfill
our purpose.

At this point, I will turn it over to
Mr. Winters for a division director's report,
which you will find under Tab 2.

MR. WINTERS: Good morning, Council Members.
Again, Drew Winters, Division Director for the
Division of Drugs, Devices and Cosmetics.

If you will turn to Tab 2, as indicated by
the Chair, we will start with our rules report
and kind of a run down that. Dinah has put this
together for us, in looking at the applications for us.

Currently, we've got multiple applications that have been noticed for development. Currently, the ones that are under development and just in their fledgling stages of development, where we are moving to start the process revising those applications and making sure they're streamlined and have the most up-to-date information, are the device manufacturer application, limited prescription drug veterinary wholesaler, the prescription drug wholesale distributor broker-only permit.

However, I will note, on the -- for the prescription drug wholesale distributor broker-only permit, currently that permit application is defined in our out-of-state and in-state prescription drug wholesale distributor permits. So the application itself is available in that particular realm, so we have done quite a bit of work on that.

We also have the prescription drug distributor charitable organization, the prescriptive institutional research, and retail pharmacy wholesale distributor, the third-party
logistics provider, the veterinary prescription
drug retail establishment, and the application
for the veterinary drug and prescription drug
wholesale distributor. Those are currently in
their fledgling stages. Again, we will be working
on those. Currently, I believe, matter of fact, I
saw Rebecca was working on several of those just
yesterday to start those.

Now, currently we have gone through, and ones
that have been noticed for development and we have
been working on the finalized draft and will be
working with the council on, are ones that are
located in the darker brown color, which are the
application for restricted drug distributor and
blood establishment permit. Again, we have a draft
of that and are circulating that around
completion. The same is in the works for our
destruction permits and the governmental programs
and the health care entity permit, as well as the
reverse distributor.

In addition, I want to put a big thanks,
though, to Rebecca Burnett, our processing manager
and (inaudible) --

If you'll note on the bottom of the
applications, there are several applications that
we have noted here that are being created for the purpose of assisting our individual licensees and permit holders to streamline and be able to provide certain changes. Those are the applications for change of mailing address, the name change application, the change in physical location and the application for certificate of free sale.

And I've got -- Rebecca kind of took the lead on that and identified a situation where we needed to put out official applications (inaudible) -- and those are in the process now. They have been drafted to pass around currently for review, so we're moving along with that. And so we will be providing or can provide those documents to the council members once we complete our internal review and move forward in the process, so we look forward to getting those to council members for any input you have.

The one application that we currently have at the very end of the rules reports is for the certified designated representative. That's an application in its initial development and draft. We did file a notice of development on November 7, 2017, to have an application that is ready for review which (inaudible) -- set forth today, though
we expect to be routing that around, as well, for
rulemaking and development, and to file a notice of
proposed rule.

But, with that, at the previous council
meeting, we had been asked to address some
information regarding the designated
representative. So what I will do is go ahead and
complete, at this point in time, the rules for --
only to note, if you look on the last portion of
that, we have a list of those applications in green
we have completed the full process on. And they
are good to go and they have been published and
completed, and they are on our website at this
point in time.

So what I'm going to do is just go ahead
and officially close the rule meeting or the
rule-noticed portion of our report, so that we can
transition to a further discussion of the next
item, which is the related application for
the CDR.

Does anybody have any questions or concerns or
other items regarding the -- just the rule portion
itself, about where we stand on the rules and the
development process, to address right now just as
an administrative process? Then we'll get more
into the CDR application.

(No response.)

MR. WINTERS: Hearing none, I'm going to go ahead and close on just the rulemaking report and move to the second item, which is just behind the rules report, which is our application for Certified Designated Representative, which is DBPR-DDC-226 is our form number.

We have gone through the application and tried to make some significant improvements in several areas. One, and this is probably one of the big ones that I think that we are moving forward and wanted to get the -- I reached out to some members of the council individually, but I wanted to bring it to the council's attention of what we'd like to move forward with.

If you look at the general information on number one, it goes to the examination information. At the previous drug advisory council meeting, we discussed the CDR and how we wanted to transition the CDR to where we only had one necessary for licensure purposes because we felt that was most in compliance with the law, and also provided more of a clear picture to us at the regulatory end.
As part of that discussion, the council members had asked if we could provide some research and ideas regarding items to help streamline that CDR process, so, in the event that somebody did need to switch a CDR, get a new CDR in place, some of the items that we could do to help make that process more complete and more efficient.

One of the items that we looked at was the application process and to see if there was something that was causing a delay. One of the items that we noted was that, currently, we only allow six months from the date that you apply and get approval to take the examination to complete that examination.

In reviewing that, what happens is after six months, if you haven't passed the examination, you go back through the entire application process again. You're required to re-apply. In reviewing that, it appears that because there's no other items -- more formality and can cause a delay for somebody trying to finish that application process, we felt that it would be prudent to push that out, give more time for somebody to complete that application or, sorry, not the application but the examination. At this point in time we're
recommending an 18-month time period, which adds an
additional 12 months to the current time frame.

And so that means that somebody would have the
time to take the exam, if they don't pass it the
first time, that, again, they can have that
additional time without having to go through again
that process of applying.

It also will help our processors focus their
time more on other applications as opposed to this,
and so we put that in there.

And what I'd like is just some comments or any
concerns that anybody has regarding that particular
item, at this point in time, regarding our move to,
again, push that to 18 months.

I think it's in compliance with our general
charge to only -- to regulate fairly and
efficiently and only keep those items that would
be appropriate to provide additional safeguards.

So I think that 18-month works for that, so, but
any comments from the council would be welcome.

MR. PHILLIPS: Hey, Drew. This is Jeenu
Phillips. I just wanted to the let you know that
I'm on the call. I joined about five minutes ago.

I would support the recommended change to add
the 18 months. I think it decreases burden on the
staff, as well as allows for the person to -- if
they fail it, to go ahead and retake it without the
concern of having to re-apply, so I would agree
with that.

MR. WINTERS: Okay, Mr. Phillips. And welcome
to the call. We're glad you're here.

Is there anybody else that had comments on the
18 month or are otherwise concerned about it?

MR. MONE: Drew, this is Michael Mone. I do
agree with Mr. Phillips' comments with regard to
the 18 months. I think it's reasonable. I think
it balances the interests that we are (inaudible)
bound to look toward and I would support it.

MR. ELLIS: This is Dean Ellis. I agree with
that.

CHAIRMAN MAY: And Mr. Winters, this is
Steve Mays. I agree, also. I think that it's a
good step in the right direction. I really
applaud the effort to extend the date. I know it's
a struggle, I know, for our company sometimes to
get people, you know, through that examination, in
that, you know, a lot of them have their regular
job to do and sometimes it just takes a lot of
hours of their time and then, you know, having to
get -- you know, study or pass an exam in a short
period of time. I know it has been a struggle, so I think this is great. It sounds like we've got a fairly unanimous agreement with this.

MR. WINTERS: Thank you, Council Members. I appreciate that. We will move forward with that, again, as part of our application advisory review process and make that revision.

Some of the other items that we looked at in order for the application, itself, is that we tried to look at the work experience and some of the things that we were seeing when people were applying, that they were having a little bit of difficulty with our previous application.

And understanding what we were looking for, if you'll note on page 4 of 23 of that application, we tried to streamline that a little bit to give some additional direction and let everybody understand it.

When we look for the two years, one, it doesn't have to be all one employer; two, that when you do that, if you will help adequately identify that -- for each employer you can submit multiple sheets, but to check one of the three boxes that would apply, that are required under the statute. Then to certify that that is the type of activity
that they were engaged in, the permit or the state of issuance for the difference, the wholesalers or their military experience.

And so we provide that and also provided just a more streamlined approach to it, something that they can use one sheet at a time to really take that and provide the work experience. It's also going to help our processors review this a little bit quicker for purposes of ensuring compliance with that.

And so that was part of the other items that we looked at when addressing work experience and personal information, and that was just for your review. If you see anything or have concerns, by all means, please let us know and we'll certainly look at that, but I think that's going to be very helpful to, again, direct them to what we're looking for in each one of those elements.

The other information, again, the personal information statement, which is now included as part of the application itself, is contained starting on page nine.

Again, this -- we did check and move through this application. While we know it does have some difficult information as far as putting it all
together, we did maintain the information as well. We went through each step on the requirements for
the application process under 499.012, and made
sure we didn't have anything in there that was not
part of the statutory requirement, so that was
placed in there.

And we, like I said, that is something that is
also meeting the same requirements as would be also
on the distributor application. So we feel like
that is clear, and it's clear it is allowed under
the statute, so please review that and let us know
if you have any concern or comment.

One of the other items in looking at that was,
beyond the application, what we also tried to do is
to look to the examination itself, and make some
inquires with the division's Bureau of Education
and Testing.

And so we actually met with the Bureau of
Education and Testing, including its director,
Mr. Andy Janesek, and their head of examination,
Alex Bosque, and a few other representatives of the
bureau, to really touch base with them.

And I believe it was Council Member Mone,
you had inquired about development of the
examination and whether or not we could have
council members be part of that. And in talking
with them and from the support of the division,
when we start the review process we are going to
reach out to council.

And actually, at this point in time, I may
ask the council (background noise) -- I believe
it's appropriate, Mr. Chair, that we could
designate at least one person off the council that
we might be able to use as our initial contact for
reviewing items for the examination, such as, the
candidate information booklet and other items that
we are developing here, just a streamlining
process (inaudible) -- update.

And then, also, that would be the person that
initially we would look to when we start to
identify subject matter experts and develop the
test overhaul, which we do approximately once every
three to four years, that we would be able to
contact them, because I do want the council to have
input into the development of the examination.

So what I will do, Mr. Chair, is just turn
it over to you, just kind of as a discussion item
for the council to discuss, having somebody
involved in the exam development. See if there
is possibly a nomination of somebody that might
be able to be our singular point of contact in
initial matters.

We recognize that certain matters we will
bring back to the council that will -- for a full
inquiry, but just to have somebody that we can use
off the council to be kind of a starting point
would be a big help to the department.

CHAIRMAN MAYS: Thank you, Mr. Winters.

This is Steve Mays. I really -- and I don't want
to voluntell anybody, but Michael Mone would be a
great person to take this effort on, if he's
willing to, or if anybody else would like to
volunteer to be that, you know, that point person.

MR. MONE: Mr. Chairman, this is Michael Mone.

I'll be more than happy to do it. As you are well
aware and any other folks are, I've been writing
and participating in the exam development of the
MPJE, which all the pharmacy students in the
country take for the last 22 years, so I might know
a little bit about this.

CHAIRMAN MAYS: I know you do, and it might be
appropriate just to see what the rest of the
council thinks about that. All in favor, everybody
in favor, say aye.

(Chorus of ayes.)
CHAIRMAN MAYS: Anyone opposed?

(No response.)

CHAIRMAN MAYS: Thank you, Mr. Mone, for taking this point role.

MR. WINTERS: We'll note that as a resolution of the council to nominate and elect Mr. Mone just as our contact person.

And what I'll do is, Council Member Mone, we'll reach out to you after the meeting and kind of give you an update on what where we're looking at and -- we will start setting some (inaudible) -- meetings -- and go over --

(Telephone interference.)

REPORTER: I'm getting some feedback, if you could repeat your last sentence? I'm not sure where the feedback is coming from.

MR. WINTERS: This is Drew Winters.

REPORTER: It was an echo.

MR. WINTERS: Is that better?

REPORTER: Yes.

MR. WINTERS: Thank you. And please let us know if you do need me to repeat anything and we'll be happy to kind of take a moment. You know, technology is a wonderful thing until it stops working.

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So we will do that and we'll go forward again
with just reaching out to Council Member Mone to
provide some informational items as additional
points.

So the other items that we've looked at, and
just to kind of give you some background information
is that I did, as part of the reach-out to the
Bureau of Education and Testing, we first started
with a query question regarding the exam itself,
how it's administered and some of the points, to
see if there was an access issue that might be for
our candidates, i.e., they were having to travel
too long to locations, they were not able to access
the test on a regular basis, or they were having
difficulty with any type of assistance in getting
it scheduled.

The information that we've received so far has
been very positive. That information is that
because Pearson VUE is a computer-based testing
facility, they have testing facilities all over the
world, multiple facilities in states and in
Florida, and other states remote to Florida, so it
is one where we do appear to have a very good
amount of access to testing centers.

The other information was that the test
itself is available, I believe, six to seven days a week at these testing centers, and can't be scheduled where -- it's not one like we have where it's like the bar exam or the construction exam where they can only take it once or twice a year. This test is available on pretty much any given day. And Pearson VUE has that available, too.

The scheduling seems to be very good, and we have not received a large number of complaints regarding scheduling. Every so often, we will have a reach-out regarding potentially rescheduling exams, and Pearson VUE seems to be handling those very well.

The other benefit we have, and this is more if we do have individuals that are further out in the country or they are actually international, we do have -- I know there may be individuals who are located currently in another country. Pearson VUE does have the ability, as well, to schedule and get outside testing centers to be able to administer those exams, and they have access to military bases.

In fact, we found out and they were able to provide information, they were actually able to administer testing to individuals on an aircraft
carrier through a testing center that was available there, so, again, we're seeing a lot of positives on that.

I am going to -- at our February meeting to be held here in Tallahassee, I'm going to have personnel from the Bureau of Education and Testing and Pearson VUE available for the council, to give a small presentation and any questions that you may have that they can answer directly.

If anybody has any general questions regarding our testing protocols and how we set that up with our vendor, I can take those now. And if I can't answer them, certainly we'll relay those questions to the Bureau of Education and Testing for answers and also for more details at the presentation at our February meeting so they can have personnel here in place to answer questions in person.

Are there any questions regarding the testing procedure?

(No response.)

MR. WINTERS: Hearing none, I'll go ahead and move on.

The last part of the research that we looked at, and this kind of trails back to why I asked to have a council member that might be available to
help us in the development arena, we are -- I did pull the last three months of test scores.

And those test scores, the pass-fail rates, excuse me, I don't have the scores themselves, but I do have the pass-fail rate. They widely varied depending on the month, but averaged out, it's about a 50-percent pass-fail rate, which means that we do have a somewhat difficult test. Because of the subject matter, that's probably not inappropriate, but it does lead to the conclusion that this is a very important test but a difficult one.

We did not -- we looked at a correlation between first-time takers versus second-time takers. Oddly enough, in the few months we saw where the first-time takers were passing more than the second-time takers, and in the middle month we actually saw where it flipped. So there doesn't seem to be a large correlation, but that would be something that we can offer at Pearson VUE, to provide more statistical data available to us in regards to that.

So, with that, one of the things we will look at is we look to move towards the test overhaul, or not "overhaul," but the updates. We will look at
those and see if they are still relevant.

I do know that Pearson VUE does use sound psychometrics, which means that they do look to the correlation of the test. I know Mr. Mone will have much more expertise on this, but they ensure that the testing does appear to be relevant, that they don't have test questions that do not appear to correlate with the pass-fail rate, and so they do look at those on testing.

We do also allow for candidates to review their test and exam for questions that they missed, to help them with future exams.

So with that, is there any other questions that anybody has on the CDR examination process?

CHAIRMAN MAYS: Mr. Winters, this is Steve Mays. I guess I would be curious, and maybe that's something that we can get a little more information on if there's a -- if there's a pattern or some data on, you know, the categories of questions that seem to be missed more than others, you know, maybe as it relates specifically to a statute or a specific type.

And again, not having taken the exam myself, I'm not really sure how the questions are laid out on the exam, whether they're categorized in a
certain area or not. I was just wondering, you know, if there's any way to look at the data and see if there's maybe some questions that might just be confusing to the test-taker, does that make sense?

MR. WINTERS: It does. And I appreciate the question. It's something that over the years that I've been dealing with examinations, both here with the division and with the other boards and entities, it is something that we do need to check.

I think it's probably best, and that's one of the reasons why I've just provided some general information, that we will be able to have Pearson VUE address those issues directly.

Of course, as many of you know, part of the concern and always the give-and-take when trying to make sure on examinations is to ensure that, while we discuss them and look at generalities, we make sure that we keep the security of the exam by not releasing any information that would otherwise undermine the ability to have a solid, secure exam, and know that the individuals, when they take it and pass it, that they are actually taking and passing it from a good psychometric standpoint, that we're not seeing any people being able to buy
the test and not have to actually have the
knowledge, but we will definitely have that
available. And we'll also work with Council
Member Mone to, again, work with us initially as
we -- (voice breaking up) -- the February
meeting.

MR. BARNES: Mr. Chairman, this is
Patrick Barnes.

CHAIRMAN MAYS: Yes, sir. Go right ahead.

MR. BARNES: Patrick Barnes. Do others -- and
just pardon my ignorance. Do other states have a
CDR for their wholesalers, and is there a -- I'm
just curious, is there a standard test that's out
there?

MR. WINTERS: This is Drew Winters.
Actually, Mr. Chairman, go ahead.

CHAIRMAN MAYS: No, go ahead.

MR. WINTERS: As far as, Council Member Barnes,
the -- there is no standardized test, I can tell
you that, for CDRs. And the designation in any
particular state, we would need to do a little more
research to identify those states that do use a
certified designated representative for something
that correlates to -- I'm sure the nomenclature
that we use here in Florida may not be carried
across other states, but we can certainly look at
that, that issue.

MR. BARNES: I was just curious. Thank you.

CHAIRMAN MAYS: And Mr. Barnes, this is
Steve Mays. I mean, from my understanding, there
are not many states that -- and Michael Mone might
be able to add on to this, but I don't -- I think
most states, you know, have a designated
representative requirement or a certified
representative requirement. And typically they
don't require an exam to be taken, so, I mean, it's
kind of one thing I applaud Florida for doing
because the -- I'm not sure in some of those states
that there's any validation that a designated rep
actually understands, you know, the laws and
regulations of the state.

So, I think, probably Florida is a little
more stringent than most other states, if not all.
I know, like California has an exempree type
requirement, where I think their statutes actually
require pharmacists or an exempree to be on duty,
and they have to just -- I think, and somebody
correct me. Michael, you might know more than I
do, it sounds like. I think they require a certain
amount of experience and probably some documentation
that they've been trained in distribution of
wholesale drugs.

So, again, I don't know of any other states
that actually require the passing of an exam, I
guess, is the bottom line.

MR. MONE: Mr. Chairman, this is Michael.
You are correct.

CHAIRMAN MAYS: I feel better now. I wasn't
sure. I hope that answers your questions,
Mr. Barnes.

MR. BARNES: Yes, thank you.

MR. WINTERS: This is Drew Winters. I
thought I heard possibly another comment come
through. Whoever was going to make a comment,
please, please do so.

(No response.)

MR. WINTERS: Not hearing anything else, I'll
just go ahead and just close on that CDR
application and just kind of the underlying
information available for it. So if anybody does
think of anything after the meeting and you want to
reach out to us, please feel free to do so.

CHAIRMAN MAYS: Also, this is Steve Mays
again. I just want to open it up, also, if
there's -- are there any questions from any other
interested parties on the line, other than council members?

(No response.)

CHAIRMAN MAYS: Anything else, Mr. Winters?

MR. WINTERS: Not on that particular item, but we will move to item number C, which is the controlled substance reporting.

As the council is aware, we have been in the process of trying to update our controlled substance reporting system, which mirrors and uses basically the ARCOS data that's on the ARCOS system out of the federal government.

We have completed the primary development of that system. And I'm happy to say that we have been able to move to the beta testing process, and we were able to get five or six industry reps that were able to come in and provide beta testing to our system through a secure site with us, and to provide and use both mock data and test data to see how the system would operate within and outside of the agency.

That beta testing was very good as far as getting information. It showed that, again, some of the positives that we have. And with the interface itself, it's more user-friendly. It's
going to be improvements that was universal
across beta testers, that the install of the new
system and the new interface was much more
user-friendly.

The functionality was going to be much, much
extended from what the current system, which is,
again, the current system is up and operating and
being updated on a monthly basis, that the system
itself, with the upgrades, is going to be an
improvement. However, of course, with every beta
testing, it identifies several items that were
critical to be able to resolve before we would be
able to roll that system out.

The beta testers, again, I won't name them by
name, but I will tell you that they're
representatives from major portions of the industry
and they were very, very helpful. They also
provided suggestions as far as formatting on the
documentation and other items available to CDR
submitters, excuse me, CSR submitters.

What we're doing right now is we're taking
that beta testing information and moving back to
development to correct and resolve the issues that
we've recognized that as we -- again, as with most
systems, internally they function well, but when
we try and interface them outside of the agency, that interface does cause a different response in many respects. And so we were able to identify those before we would actually make the system go live.

So we were very happy that, again, that the feedback was positive regarding interface, identifying those items that would be an issue for our developers once we launch the system, so we're going to continue the updates in development.

I will tell you that our primary developer in this case has actually taken another position, but we have a new developer that is on task, that was able to take a little bit of time with that developer. And she is coming online now, and so it may slow us down a few weeks, but, hopefully, crossing our fingers, she comes very highly recommended, so we will continue that process again to update the CSR system.

Once we're able to get some of the major issues resolved, I hope to be able to provide a demonstration of that system, but, again, we don't want to provide that until we have adequately resolved the functionality.

And the new system will have an e-query
ability that the current system does not. We want to make sure that's functioning correctly. Once we do that, we'll be able to provide a better demonstration and we look forward to doing that very soon.

So we will keep the council members posted regarding that development, and let you know as we (inaudible) this, obviously an arduous process.

One of the things -- the people I want to recognize right now is Dinah Greene. Not only does she keep the office running, but she's also one of my primary people that has done a lot to look at that CSR system and has really made a lot of efforts, and noted a lot of items that we've corrected and used personnel to make sure that once we do get to roll that out, she's going to have a very large stamp of her knowledge and help on that so -- kind of (voice breaking up) -- look to see that.

And I, also, while he's not here, I wanted to recognize for the record Terence Blakely. He is our current data steward and he has been working feverishly to again move this forward.

Unfortunately, for the council members, if any of you have had an opportunity to deal with
Terence, unfortunately he will be taking a -- he's received a promotion over with the Department of Juvenile Justice and will be actually moving on to a new location.

We're very sad to see him go because he is part of the family and has done a lot of great works. So, but, if any of you do know Terence, feel free to send him an email and touch base with him.

But, otherwise, I know it's just a general report, but I wanted to let you guys know where we're at and to give you the positive notes. We have moved into that external testing of the system for input from the industry as per our beta testers.

So, with that, I'll turn it over to Steve and council members for questions or comments on the controlled substance reporting.

CHAIRMAN MAYS: Mr. Winters, this is Steve Mays. Can you give us just like a very, maybe a brief overview of how that information is being used by the department that's shared with different agencies? How do you guys basically take that data and use it, can you just kind of give us an overview of that?
MR. WINTERS: We can. Again, mostly what we're looking at is just the reporting in the system to us. There is, as many of you are aware, the prescription drug monitoring program. The program is the PDMP, and it is with Department of Health. That program is, again, for the dispensers and the physicians. And we have -- our system is for, obviously, the distributors and the manufacturers for their -- their distributions of controlled substances into the state.

Currently, those distributions are reported to us on a monthly basis, and they are in our system so that we can review them to see if we have an appropriate amount of distribution to a given entity.

So as far as, is that data is available, that data is available by statute to the Florida Department of Law Enforcement. In addition, through requests for documentation, it may be available to other law enforcement entities. And we do try to coordinate the information that we have with that, for other agencies that have oversight of that same item.

I know that we have also been working our process to again work with the prescription drug
monitoring program system with the Department of Health, to try and correlate that data so that we can better identify distribution would not be in -- would not be in sync with what we're seeing as far as dispensing in any given period, where we can identify inappropriate distribution -- (voice breaking up) -- so we do look to those when we try and identify the items that would be inappropriate distribution.

Currently, of course, under the statute, anything over 7500 units dispensed in any, any given month is considered a suspect distribution of any given substance, so that is one of the standards that we've got.

But we are, again, always looking at this program to try and develop it into (inaudible) -- I know, in regard to compliance, I have been reviewing this to look at it with particular drugs that we think are of significant interest, and try and pull the information out of the system -- distribution to identify --

REPORTER: You're fading off again.

MR. WINTERS: I don't know if it's me or if it's the phones. Generally, I don't have a problem with people saying they can hear me,
but the --

The current system that we have, we are clearing that. Renee and I have been again working on updating our protocols to better identify items, look at drugs of concern, and also to better coordinate that information with distributions or, excuse me, dispensings in the state.

And we have reached out to the PDMP program to, again, match those up to, as the statute says, try and identify those distributions that are inappropriate or would point to items that would be of concern to the agency.

MR. BARNES: Mr. Chairman, this is Patrick Barnes.

CHAIRMAN MAYS: Go ahead, Mr. Barnes.

MR. BARNES: Just for clarification, I'm assuming we're talking about distributions from the wholesaler to individual pharmacies, and that is what's being looked at, is that correct?

MR. WINTERS: We are looking at any distribution, whether it be from one distributor to the next, or from a distributor to a dispensing entity. So we look at all the distributions. It doesn't matter, and again, it depends on if it is a distribution. So we do look at all of those, and
it would not be limited simply to a distribution but to an end dispenser.

So we do look at all the reporting. And it does match the same basic reporting format that you would see in the ARCOS data, the federal government and our system data about the controlled substances listed under 893 of the Florida Statutes, so that is what we measure our requirements against.

So it is for any, any person that makes a distribution, whether it be a manufacturer or a wholesale distributor. And so those, it is, again, not limited just to (inaudible) --

MR. BARNES: Patrick Barnes again.

So is there any way to factor in, where if you're looking at two pharmacies or dispensaries, where one may have five times the volume as the other one, is that somehow factored in, meaning, they just fill more prescriptions than the other one?

MS. ALSOBROOK: Mr. Barnes, this is Renee Alsobrook. When we get data that appears to be suspicious, meaning that there seems to be a large volume, that's where the expertise of our drug inspectors assigned to those local areas becomes critical because they know the actual
area and they would know, for example, if that is
a high-volume pharmacy, or if that pharmacy is next
to a hospital that treats a lot of cancer patients,
and that that pharmacy would then, for example,
come off the list as a suspicious pharmacy because
high volume would be justifiable.

MR. BARNES: Thank you.

MS. ALSOBROOK: And we found that, does that
make sense?

MR. BARNES: Yes. Yes, it does. Thank you.

MS. ALSOBROOK: Yes, sir.

CHAIRMAN MAYS: This is Steve Mays.

I mean, you can probably tell, this is, you
know, a reporting, you know, given the whole opioid
epidemic in the country, there's been, you know,
from a national wholesale distributor's
perspective, I mean, that every -- many, many
states now are requiring different types of state
reporting and, you know, our format is that, you
know, we try to be consistent.

And I think the format that you're using in
Florida, I think, is -- it's the type of format
that we're trying to use, you know, because we
want to try to have some uniform reporting across
the country, to, you know, all the states that
require.

And then unfortunately there's states that pass statutes that require reporting and then they really don't -- can't handle the data or don't know what to do with it, so that kind of was part of my question is, you know, it's good to know that you guys are getting the data and making use of it and trying to identify where the problems are.

MR. WINTERS: And we are aware. We're currently, you know, always trying to look at that to try and use the data better. So, and that's really one of the focuses, as you indicated, with the current opioid epidemic, to look at our system and see if we can (inaudible) -- so that's what we're doing.

CHAIRMAN MAYES: All right. Thank you.

MR. BARNES: Mr. Chairman, Patrick Barnes, again.

CHAIRMAN MAYES: Yes, sir.

MR. BARNES: And I was just wondering if -- it would be good if this system that we have could actually, for the dispensers, give you a percentage of the volume that they're doing that's controlled drugs. I think that would really be a telling point, where if one dispenser's percentage was 15
percent and another one was 50 percent, that could
guide you in further investigation. And I don't
know the capabilities of the system, but I was
just -- I'll just throw that out there.

CHAIRMAN MAYS: This is Steve Mays. I mean,
I think the challenge with that is, you would
basically have to have all the prescription drug
data to be able to kind of, you know, to be able
to determine that percentage. That would be
the -- that would be, I guess, the tough part for
the department. They would have to have all the
data --

MR. WINTERS: And again, that's what -- as
with any system, we look to improvements in the
future. And like I said, we're working on those
right now. And as we can develop more and, you
know, I'll just make a general statement and kind
of close. We are working to try and improve that
system and, again, gain more, more reporting in
functionality as we can.

Again, as the Chairman said, sometimes we are
limited to what information is available, but
again, we are also reaching out to additional
resources that are in sister agencies and other
states that would be helpful to us. We're really
trying to focus on improving that portion of our
program and we'll continue to do that.

CHAIRMAN MAYS: Okay. All right. Thank you,
Mr. Winters.

This is Steve Mays with one last comment.
I think one of the things that the distributors
struggle with is, we only have knowledge of what
we distribute to a given pharmacy. And we don't
know, in just about every case, we don't know how
much of these drugs that that pharmacy may be
purchasing from wholesaler B and wholesaler C and
maybe D. And sometimes that totality may look
large and we may not even be aware of how much, you
know, they may be purchasing from other suppliers.
So that's always a struggle for us as a
distributor, to, you know, identify that.

And you know, of course, DEA has that data.
And I suppose in this system you would have all
that data, so you would know how many different
suppliers are supplying a given pharmacy.

Or sometimes each one, each distributor on its
own may not be distributing a suspicious quantity,
but when you look at the total purchases of that
pharmacy from all the distributors, it could look
pretty bad for the pharmacy. Does that make sense?
MR. WINTERS: Yes, Chairman, it does.

MS. ELLIOTT: This is Arlene Elliott. I just have a quick question. Is this information internal for your department only, or is this public information or shared with any other agencies or departments?

MR. WINTERS: It depends. Under the statute, the Florida Division of Law Enforcement is permitted access to this information, but beyond that, again, it depends on the requests and the access and what items you're asking for out of the system that may be protected or may be trade secrets, so we do, we do have to look at that.

And so each individual request for information out of the -- any system inside of the agency or including the controlled substance reporting system is evaluated based on its individual request to determine if it can be filled and the ability to access the system, so I can only give you that general answer.

MS. ELLIOTT: Okay. That's great.

Thank you.

CHAIRMAN MAYS: Any other questions from council members or from other interested parties on the line, any other questions?
(No response.)

CHAIRMAN MAYS: Do you have anything else, Mr. Winters?

MR. WINTERS: At this point in time, that really concludes my report.

I did want to -- again, I hate to always do it, but I love the soapbox to stand on, to kind of recognize some more people.

I may be the voice in the room, but, again, Chief Alsobrook is here. She's been a great help to me. And again, I did not mention her in the application process review. Her and Dinah have both been great resources and provided a lot of help with that, and I want to recognize them both, Renee Alsobrook and Dinah Greene.

And then also, I wanted to recognize, in the room I have Andrew and also Shena (phonetic) from our Office of General Counsel. They've been our newest attorneys. And again, I said this at the last meeting, but I'll say it again. They have come on strong and have caught on very quickly and they have been a great help. So, again, it's great having them. They've been a great help.

Other than that, I will turn it back over to you, Mr. Chair, for any other items that we need
to address on the agenda. Thank you.

CHAIRMAN MAYS: Just the only thing I would mention is the -- under Tab 3, you'll find the meeting transcript from our August 17 in-person meeting for informational purposes, so, if you want to go through that.

Also, I guess, my last question, is there any other business from the council members?

MR. ELLIS: Mr. Chairman, this is Dean Ellis. I wanted to get on the soapbox with Drew because this past year so much has been accomplished. I know we went over a lot of things in our last in-person meeting, but I just wanted to say, the department has done a fantastic job this past year in closing a lot of things.

Of course, we call it "closing" in sales, but I'm not sure what we call it in the government arena, but they've done an excellent job in getting things done.

My company received our first two-year permit which was a cause for celebration. So I just wanted to give you kudos. You guys have done a great job and you've been there for us. Thank you.

CHAIRMAN MAYS: I will echo those comments myself. This is Steve Mays.
Any other business, Council Members?
(No response.)

CHAIRMAN MAYS: Okay. Well, we've been able
to use up a better part of an hour today, so it's
been, I think, a very productive meeting. So
hearing no other business, do we have a motion to
adjourn?

MR. BARNES: This is Patrick Barnes.
So moved.

CHAIRMAN MAYS: Do we have a second?


CHAIRMAN MAYS: All in favor, say aye.
(Chorus of ayes.)

CHAIRMAN MAYS: Any opposed?
(No response.)

CHAIRMAN MAYS: Okay. The meeting is
adjourned. Thank you very much.
(Whereupon, the telephonic meeting was
concluded at approximately 10:27 a.m.)
CERTIFICATE OF REPORTER

COUNTY OF LEON )

STATE OF FLORIDA )

I, DEBORAH ALFF, do hereby certify that I was authorized to and did report the foregoing proceedings via telephone conference, and that the transcript, pages 1 through 46, contains a true and complete record of my stenographic notes and digital recordings thereof.

Dated this 2nd day of January, 2018, at Tallahassee, Leon County, Florida.

DEBORAH ALFF, COURT REPORTER

FOR THE RECORD REPORTING, INC.
TALLAHASSEE, FLORIDA 850-222-5491
TAB 2: Division Director's Report – Drew Winters

a. DDC Rules Report

b. Discussion of potential rule workshop on “Virtual Manufacturers” & “Prescription Drug Wholesale Distributor-Broker Only”.

c. Discussion of potential rule workshop on definition of “administrative services”.
RULES REPORT

To: Drug Wholesale Distributor Advisory Council
From: Drew Winters, Director
Date: January 24, 2018
Re: Division Rulemaking (rev.1/24/18)

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>
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</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>
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<tr>
<td>61N-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 is awaiting &amp; responding to public comment.</td>
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<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 Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of proposed rulemaking for rule and application.</td>
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<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 of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of proposed rulemaking for rule and application.</td>
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<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>
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<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>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 Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of proposed rulemaking for rule and application.</td>
<td></td>
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<tr>
<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>
<td></td>
</tr>
<tr>
<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 Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of rulemaking for rule and application.</td>
<td></td>
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<tr>
<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>
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<tr>
<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>
<td></td>
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<tr>
<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 is awaiting &amp; responding to public comment</td>
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<tr>
<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 is awaiting &amp; responding to public comment</td>
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<tr>
<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 will be filed 1/31/18</td>
<td>File Notice of rulemaking</td>
<td></td>
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<tr>
<td>Application for Certificate of Free Sale</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 is awaiting &amp; responding to public comment</td>
<td></td>
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<tr>
<td>Application for Certification as a Designated Representative</td>
<td>To adopt and incorporate the division's permitting application forms into rule</td>
<td>Notice of Proposed filed 1/5/18</td>
<td>Division is awaiting &amp; responding to public comment</td>
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</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 is being published; division is awaiting & responding to public comment.

The rule has been adopted and is effective.
The rule has been adopted and is effective.

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<td>61N-1.016</td>
<td>Product Registration</td>
<td>11/2/17</td>
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<td>61N-1.017</td>
<td>Certificates of Free Sale</td>
<td>10/24/17</td>
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<td>61N-1.018</td>
<td>FEES</td>
<td>11/2/17</td>
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<td>61N-1.028</td>
<td>Product Tracking and Tracing-Definitions</td>
<td>5/16/16</td>
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<td>61N-1.029</td>
<td>Product Tracking and Tracing- Manufacturer Requirements</td>
<td>5/11/16</td>
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<td>61N-1.030</td>
<td>Product Tracking and Tracing- Wholesale Distributor Requirements</td>
<td>5/11/16</td>
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<td>61N-1.031</td>
<td>Product Tracking and Tracing-Dispenser Requirements</td>
<td>5/11/16</td>
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<td>61N-1.032</td>
<td>Product Tracking and Tracing - Repacker Requirements</td>
<td>5/11/16</td>
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<td>61N-1.0245</td>
<td>Notice of Non Compliance- Minor Violations</td>
<td>11/2/17</td>
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<td>61N-2.001</td>
<td>Application for Complimentary Drug Distributor Permit</td>
<td>6/9/16</td>
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<td>61N-2.002</td>
<td>Application for Cosmetic Manufacturer Permit</td>
<td>10/24/17</td>
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<td>61N-2.005</td>
<td>Application for Freight Forwarder Permit</td>
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<td>61N-2.006</td>
<td>Application for Health Care Clinic Establishment Permit</td>
<td>6/9/16</td>
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<td>61N-2.008</td>
<td>Application for Medical Gas Manufacturer Permit</td>
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<td>61N-2.009</td>
<td>Application for Medical Gas Wholesale Distributor Permit</td>
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<td>61N-2.010</td>
<td>Application for Medical Oxygen Retail Establishment Permit</td>
<td>6/9/16</td>
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<td>61N-2.011</td>
<td>Application for Nonresident Prescription Drug Manufacturer Permit</td>
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<td>61N-2.0111</td>
<td>Application for Nonresident Prescription Drug Manufacturer-Virtual Permit</td>
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<td>Application for Out-of-State Prescription Drug Wholesale Distributor Permit</td>
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<td>Application for Over-the-counter Drug Manufacturer Permit</td>
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<td>61N-2.014</td>
<td>Application for Prescription Drug Manufacturer Permit</td>
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<td>61N-2.015</td>
<td>Application for Prescription Drug Repacker Permit</td>
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<td>61N-2.016</td>
<td>Application for Prescription Drug Wholesale Distributor Permit</td>
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499.01 Permits.—
(1) Before operating, a permit is required for each person and establishment that intends to operate as:
(a) A prescription drug manufacturer;
(b) A prescription drug repackager;
(c) A nonresident prescription drug manufacturer;
(d) A nonresident prescription drug repackager;
(e) A prescription drug wholesale distributor;
(f) An out-of-state prescription drug wholesale distributor;
(g) A retail pharmacy drug wholesale distributor;
(h) A restricted prescription drug distributor;
(i) A complimentary drug distributor;
(j) A freight forwarder;
(k) A veterinary prescription drug retail establishment;
(l) A veterinary prescription drug wholesale distributor;
(m) A limited prescription drug veterinary wholesale distributor;
(n) An over-the-counter drug manufacturer;
(o) A device manufacturer;
(p) A cosmetic manufacturer;
(q) A third party logistics provider; or
(r) A health care clinic establishment.
(2) The following permits are established:
(a) Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.
1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in distribution of prescription drugs for which the person is the manufacturer and must comply with s. 499.0121 and all other provisions of this part and rules adopted under this part. The department shall adopt rules for issuing a virtual prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.
2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.
3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(48)(j) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.
(b) Prescription drug repackager permit.—A prescription drug repackager 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 repackager 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 repackager must comply with all appropriate state and federal good manufacturing practices.
(c) Nonresident prescription drug manufacturer permit.—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of
the provisions required of a prescription drug manufacturer under this part. The department shall adopt rules for issuing a virtual nonresident prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual nonresident manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the distribution of such prescription drugs when required by this part. This subparagraph does not apply to a manufacturer that distributes prescription drugs only for the manufacturer of the prescription drugs where both manufacturers are affiliates.

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any prescription drug distributed into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

(d) Nonresident prescription drug repackager permit.—A nonresident prescription drug repackager permit is required for any person located outside of this state, but within the United States or its territories, that repackages prescription drugs and engages in the distribution of such prescription drugs into this state.

1. A nonresident prescription drug repackager must comply with all of the provisions of this section and the rules adopted under this section that apply to a prescription drug manufacturer.

2. A nonresident prescription drug repackager must be permitted by the department and comply with all appropriate state and federal good manufacturing practices.

3. A nonresident prescription drug repackager must be registered as a drug establishment with the United States Food and Drug Administration.

(e) Prescription drug wholesale distributor permit.—A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that wholesale distributes such prescription drugs in this state. The department may adopt rules for issuing a prescription drug wholesale distributor-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(f) Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories, which engages in the wholesale distribution of prescription drugs into this state. The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

(g) Retail pharmacy drug wholesale distributor permit.—A retail pharmacy drug wholesale distributor is a retail pharmacy engaged in wholesale distribution of prescription drugs within this state under the following conditions:

1. The pharmacy must obtain a retail pharmacy drug wholesale distributor permit pursuant to this part and rules adopted under this part.

2. The wholesale distribution activity does not exceed 30 percent of the total annual purchases of prescription drugs. If the wholesale distribution activity exceeds the 30-
percent maximum, the pharmacy must obtain a prescription drug wholesale distributor permit.
3. The transfer of prescription drugs that appear in any schedule contained in chapter 893 is subject to chapter 893 and the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.
4. The transfer is between a retail pharmacy and another retail pharmacy, or a Modified Class II institutional pharmacy, or a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs.
5. All records of sales of prescription drugs subject to this section must be maintained separate and distinct from other records and comply with the recordkeeping requirements of this part.
(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 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.

(i) Complimentary drug distributor permit.—A complimentary drug distributor permit is required for any person that engages in the distribution of a complimentary drug, subject to the requirements of s. 499.028.

(j) Freight forwarder permit.—A freight forwarder permit is required for any person that engages in the distribution of a prescription drug as a freight forwarder unless the person is a common carrier. The storage, handling, and recordkeeping of such distributions must comply with the requirements for wholesale distributors under s. 499.0121. A freight forwarder must provide the source of the prescription drugs with a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.

(k) Veterinary prescription drug retail establishment permit.—A veterinary prescription drug retail establishment permit is required for any person that sells veterinary prescription drugs to the public but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2. Veterinary prescription drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary prescription drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5. A veterinary prescription drug retail establishment must sell a veterinary prescription drug in the original, sealed manufacturer’s container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary prescription drug.

6. A veterinary prescription drug retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

7. Prescription drugs sold by a veterinary prescription drug retail establishment pursuant to a practitioner’s order may not be returned into the retail establishment’s inventory.

(I) Veterinary prescription drug wholesale distributor permit.—A veterinary prescription drug wholesale distributor permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesale distributor that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a limited prescription drug veterinary wholesale distributor in lieu of the veterinary prescription drug wholesale distributor permit. A veterinary prescription drug wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121.
(m) Limited prescription drug veterinary wholesale distributor permit.—Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale distributor, or out-of-state prescription drug wholesale distributor, a limited prescription drug veterinary wholesale distributor permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act under the following conditions:

1. The person is engaged in the business of wholesaling prescription and veterinary prescription drugs to persons:
   a. Licensed as veterinarians practicing on a full-time basis;
   b. Regularly and lawfully engaged in instruction in veterinary medicine;
   c. Regularly and lawfully engaged in law enforcement activities;
   d. For use in research not involving clinical use; or
   e. For use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing.

2. No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3. The person does not distribute in any jurisdiction prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4. A limited prescription drug veterinary wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee’s license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

5. A limited prescription drug veterinary wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6. A limited prescription drug veterinary wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121.

7. A limited prescription drug veterinary wholesale distributor may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8. A limited prescription drug veterinary wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesale distributor in this state if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(6) must be followed for this transaction.

(n) Over-the-counter drug manufacturer permit.—An over-the-counter drug manufacturer permit is required for any person that engages in the manufacture or repackaging of an over-the-counter drug.
1. An over-the-counter drug manufacturer may not possess or purchase prescription drugs.

2. A pharmacy is exempt from obtaining an over-the-counter drug manufacturer permit if it is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

3. An over-the-counter drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

   (o) Device manufacturer permit.—
   
   1. A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if:
      
      a. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner’s order for a specific patient; or
      
      b. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8).

   2. A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

3. The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of medical devices for human use.

   (p) Cosmetic manufacturer permit.—A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph.

   (q) Third party logistics provider permit.—A third party logistics provider permit is required for any person that contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer, wholesale distributor, or dispenser, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. A third party logistics provider located outside of this state must be licensed in the state or territory from which the prescription drug is distributed by the third party logistics provider. If the state or territory from which the third party logistics provider originates does not require a license to operate as a third party logistics provider, the third party logistics provider must be licensed as a third party logistics provider as required by the federal act. Each third party logistics provider permittee shall comply with s. 499.0121 and other rules that the department requires.

   (r) Health care clinic establishment permit.— A health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the term “qualifying practitioner” means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

   1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the
qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license.

(3) A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state intended for research and development and not for resale or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subsection and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6). The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; if available, the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(3).

(a) The immediate package or container of a prescription drug active pharmaceutical ingredient distributed into the state that is intended for research and development under this subsection shall bear a label prominently displaying the statement: "Caution: Research and Development Only—Not for Manufacturing, Compounding, or Resale."

(b) A prescription drug manufacturer that obtains a prescription drug active pharmaceutical ingredient under this subsection for use in clinical trials and or biostudies authorized and regulated by federal law must create and maintain records detailing the specific clinical trials or biostudies for which the prescription drug active pharmaceutical ingredient was obtained.

(4)(a) A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is
distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6).

(b) A permit issued under this part is not required to distribute a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3. Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6).

4. The immediate package or container of any active pharmaceutical ingredient distributed into the state that is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: “Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale.”

(c) An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(6) must be followed for such transactions.

(d) Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file:

1. A record of the FDA establishment registration number, if any;
2. The resident state or federal license, registration, or permit that authorizes the source to distribute prescription drugs; and
3. A copy of the most recent resident state or FDA inspection report, for all distributors and establishments from whom they purchase or receive prescription drugs under this subsection.

(e) All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs within or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f) A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or
state or federal good manufacturing practices for identity, purity, potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g) The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(3).

(h) This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permit holder that is a health care entity to repack the 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., if:

(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging 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.


Note.—Subsection (2) intro. former s. 499.012(2) intro.; paragraph (2)(c) former s. 499.012(2)(e); paragraph (2)(d) former s. 499.012(2)(a); paragraph (2)(e) former s. 499.012(2)(c); paragraph (2)(f) former s. 499.012(2)(d); paragraph (2)(g) former s. 499.014; paragraph (2)(i) former s. 499.012(2)(f); paragraph (2)(k) former s. 499.012(2)(g); paragraph (2)(l) former s. 499.012(2)(h); paragraph (2)(n) former s. 499.012(2)(b); paragraph (2)(o) former s. 499.013(2)(c); paragraph (2)(p) former s. 499.013(2)(b); paragraph (2)(q) former s. 499.013(2)(d); paragraph (2)(r) former s. 499.013(2)(e).
61N-1.028 Product Tracking and Tracing – Definitions.

The following definitions apply to the product tracking and tracing requirements set forth in Rules 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.

(1) “AFFILIATE” means a business entity that has a relationship with a second business entity if, directly or indirectly:
(a) One business entity controls, or has the power to control, the other business entity; or
(b) A third party controls, or has the power to control, both of the business entities.

(2) “AUTHORIZED” means:
(a) A manufacturer or repacker, registered as a drug establishment with the FDA;
(b) A wholesale distributor, having a valid license under Florida law or federal law, and complying with the licensure reporting requirements under 21 U.S.C. s. 353(e), as of 12/1/15 which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06713;
(c) A third-party logistics provider, having a valid license under Florida law or federal law, and complying with the licensure reporting requirements under 21 U.S.C. s. 360eee-3(b) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06714; and,
(d) A dispenser, having a valid license under Florida law.

(3) “DISPENSER” means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor. Dispenser does not include a person who dispenses only products to be used in animals when the product is dispensed on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship.

(4) “DISPOSITION” means, with respect to a product within the possession or control of an entity, the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other handling or actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

(5) “DISTRIBUTE” or “DISTRIBUTION” means to sell, purchase, trade, deliver, handle, store, or receive a product. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.

(6) “EXCLUSIVE DISTRIBUTOR” means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer’s product to a subsequent repackager, wholesale distributor, or dispenser.

(7) “GRANDFATHERED” means, with respect to a product, a product that is not labeled with a product identifier and that entered the pharmaceutical distribution supply chain on or before March 1, 2016.

(8) “HOMOGENEOUS CASE” means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

(9) “ILLEGITIMATE PRODUCT” means a product that:
(a) Is counterfeit, diverted, or stolen;
(b) Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
(c) Is the subject of a fraudulent transaction; or
(d) Appears unfit for distribution such that the product would likely result in serious adverse health consequences or death to humans.

(10) “LICENSED” means having a valid license in accordance with Florida law. For the purposes of Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C., a dispenser is considered “licensed” if the dispenser has a valid license under Florida law.

(11) “MANUFACTURER” means:
(a) A person that holds an application approved under 21 U.S.C. 355 (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06715, or a license issued under section 351 of the Public Health Service Act (42 U.S.C. s. 262) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06716, for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;
(b) A co-licensed partner or affiliate of a person described in paragraph 61N-1.028(11)(a), F.A.C., that obtains the product directly from a person described in this paragraph or paragraph 61N-1.028(11)(a) or 61N-1.028(11)(c), F.A.C.; or

(c) An affiliate of a person described in paragraph 61N-1.028(11)(a) or 61N-1.028(11)(b), F.A.C., that receives the product directly from a person described in this paragraph or paragraph 61N-1.028(11)(a) or 61N-1.028(11)(b), F.A.C.

(12) “MEDICAL CONVENIENCE KIT” means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2) (as of 12/1/15) which is incorporated by reference herein, http://www.frules.org/Gateway/reference.asp?No=Ref-06712. A “medical convenience kit” is considered an “exempt medical convenience kit” if it is a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user, and:

(a) The kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with 21 U.S.C. s. 360(b)(2) (as of 12/1/15) which is incorporated by reference herein, http://www.frules.org/Gateway/reference.asp?No=Ref-06717;


(c) If the kit includes a product:

1. The person that manufacturers the kit purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer and did not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and,

2. The product is:
   a. An intravenous solution intended for the replenishment of fluids and electrolytes;
   b. A product intended to maintain the equilibrium of water and minerals in the body;
   c. A product intended for irrigation or reconstitution;
   d. An anesthetic;
   e. An anticoagulant;
   f. A vasopressor; or
   g. A sympathomimetic.

(13) “PACKAGE” means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product. For purposes of this paragraph, an “individual saleable unit” is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.


(15) “PRODUCT IDENTIFIER” means a standardized graphic that includes, in both human readable form and on a machine-readable data carrier, the standardized numerical identifier, lot number, and expiration date of the product. Unless authorized by the department, the applicable data shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon a package and homogeneous case.

(16) “QUARANTINE” means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use.
(17) “REPACKAGER” means a person who owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without a further transaction.

(18) “RETURN” means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

(19) “RETURNS PROCESSOR or REVERSE LOGISTICS PROVIDER” means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

(20) “SPECIFIC PATIENT NEED” refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

(21) “STANDARDIZED NUMERICAL IDENTIFIER” means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

(22) “SUSPECT PRODUCT” means a product for which there is reason to believe that such product:

(a) Is potentially counterfeit, diverted, or stolen;
(b) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
(c) Is potentially the subject of a fraudulent transaction; or
(d) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(23) “THIRD PARTY LOGISTICS PROVIDER” means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

(24) “TRADING PARTNER” means:

(a) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

(b) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

(25) “TRANSACTION”.

(a) The term “transaction” means the transfer of product between persons in which a change of ownership occurs.

(b) EXEMPTIONS. The term “transaction” does not include:

1. Intracompany distribution of any product between members of an affiliate or within a manufacturer;
2. The distribution of a product among hospitals or other health care entities that are under common control;
3. The distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act (42 U.S.C. s. 247d) (as of 12/1/15) which is incorporated by reference herein, http://www.frlrules.org/Gateway/reference.asp?No=Ref-06724, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
5. The distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with 21 U.S.C. s. 353(d) (as of 12/1/15) which is incorporated by reference herein, http://www.frlrules.org/Gateway/reference.asp?No=Ref-06726.
6. The distribution of blood or blood components intended for transfusion;
7. The distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;
8. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. s. 501(c)(3) (Internal Revenue Code) (as of 12/1/15) which is incorporated by reference herein, http://www.frlrules.org/Gateway/reference.asp?No=Ref-06727, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
9. The distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;


11. Products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. s. 2011) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06720.

   a. A product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
   b. 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or
   c. 2 or more finished medical devices plus one or more drug or biological products that are packaged together in a “medical convenience kit”;

13. The distribution of an “exempt medical convenience kit” as set forth in subsection 61N-1.028(12), F.A.C.;

14. The distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

15. The distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

16. The distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

17. The distribution of a medical gas (as defined in 21 U.S.C. s. 360dd) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06721; or


(26) “TRANSACTION HISTORY” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. The transaction history for a grandfathered product begins with the owner of the product on January 1, 2015.

(27) “TRANSACTION INFORMATION” means:
   (a) The proprietary or established name or names of the product;
   (b) The strength and dosage form of the product;
   (c) The National Drug Code number of the product;
   (d) The container size;
   (e) The number of containers;
   (f) The lot number of the product;
   (g) The date of the transaction;
   (h) The date of the shipment, if more than 24 hours after the date of the transaction;
   (i) The business name and address of the person from whom ownership is being transferred; and,
   (j) The business name and address of the person to whom ownership is being transferred.

(28) “TRANSACTION STATEMENT” means a statement, in paper or electronic form, that the entity transferring ownership in a transaction:
   (a) Is authorized as required under this chapter;
   (b) Received the product from a person that is authorized as defined in subsection 61N-1.028(2), F.A.C.;
(c) Received transaction information and a transaction statement from the prior owner of the product, as required under Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.;

(d) Did not knowingly ship a suspect or illegitimate product;

(e) Had systems and processes in place to comply with verification requirements under Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.;

(f) Did not knowingly provide false transaction information; and,

(g) Did not knowingly alter the transaction history.

The owner of a grandfathered product is exempt from asserting receipt of transaction information and transaction statement from the prior owner.

(29) “VERIFICATION” or “VERIFY” means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager.

(30) “WHOLESALE DISTRIBUTION” means the distribution of a drug subject to 21 U.S.C. s. 335(b) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06723, to a person other than a consumer or patient, or receipt of a drug subject to 21 U.S.C. s. 335(b) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06723, by a person other than the consumer or patient, but does not include:

(a) Intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(b) The distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(c) The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to 42 U.S.C. s. 247d (section 319 of the Public Health Service Act) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06724, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;


(e) The distribution of minimal quantities of drug by a licensed community pharmacy that is a retail pharmacy to a licensed practitioner for office use;

(f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(g) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(h) The distribution of a drug by the manufacturer of such drug;

(i) The receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(j) A common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(k) The distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with 21 U.S.C. s. 360eee-1(e) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06732.

(l) Saleable drug returns when conducted by a dispenser;

(m) The distribution of an “exempt medical convenience kit” as set forth in subsection 61N-1.028(12), F.A.C.;

(n) The distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(o) The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(p) The distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;


(r) Facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or
(5) The transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repacker described in 21 U.S.C. s. 360eee(16)(B) (as of 12/1/15) which is incorporated by reference herein, http://www.firules.org/Gateway/reference.asp?No=Ref-06732, and registered under 21 U.S.C. s. 360 (as of 12/1/15) which is incorporated by reference herein, http://www.firules.org/Gateway/reference.asp?No=Ref-06731, for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

(31) "WHOLESALE DISTRIBUTOR" means a person (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider, or repacker) engaged in wholesale distribution.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History—New 5-16-16.