Call to Order: Steve Mays, Chair

TAB 1: Chair's Report – Steve Mays, Chair
   a. August 16, 2018 Meeting Transcript (informational only)
   b. Nominations of Chair and Vice Chair

TAB 2: Division Director's Report – Drew Winters
   a. DDC Rules Report
   b. Certified Designated Representative

TAB 3: Other Business
Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Drugs, Devices and Cosmetics

The Division of Drugs, Devices and Cosmetics announces a telephone conference call to which all persons are invited.

DATE AND TIME: December 13, 2018
9:30 a.m.

PLACE: Conference Call Number 888-670-3525
Conference Code 9259887749

GENERAL SUBJECT MATTER TO BE CONSIDERED: General Business

A copy of the agenda may be obtained by contacting: Dinah Greene, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, FL 32399-1047, (850)717-1800, Dinah.greene@myfloridalicense.com.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Dinah Greene, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, FL 32399-1047, (850)717-1800, Dinah.greene@myfloridalicense.com. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Dinah Greene, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, FL 32399-1047, (850)717-1800, Dinah.greene@myfloridalicense.com.
STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL

COUNCIL MEETING
(Via Telephone Conference)
TRANSCRIPT OF PROCEEDINGS
DATE: August 16, 2018
TIME: 9:30 a.m. - 10:12 a.m.
Stenographically reported by:
Deborah Alff, RPR

COUNCIL MEMBERS ATTENDING:
Steve Mays, Chair, Prescription Drug Wholesalers
Jeenu Phillips, Vice Chair, Board of Pharmacy
Joseph Lavino, CVS Health, Retail Pharmacy
Michael Mone, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Dean Ellis, Secondary Prescription Drug Wholesalers
Jeffrey Tuller, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Peter Hart, Medical Gas
Jennifer Goldman, Physician

DBPR STAFF ATTENDING:
Drew Winters, Division Director
Dinah Greene, Government Operations Consultant

ALSO PRESENT:
D. Ty Jackson, GrayRobinson, P.A.
Shannon B. Hartsfield, Holland & Knight, LLP

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(Whereupon, the meeting was called to order at approximately 9:33 a.m.)

CHAIRMAN MAYS: Good morning, everybody. My name is Steve Mays. I would like to call this meeting of the Drug Wholesale Distributor Advisory Council to order.

I just want to remind everyone that we do have a court reporter on the line, and that you need to identify yourself each time before you speak so the court reporter will know who is speaking for the record. If you don't, I may interrupt you to remind you to identify yourself, or she may.

For anyone who's on the phone -- which everyone is on the phone today -- to please mute your line when you're not speaking and that will cut down a lot on some of the background noise that we hear often. And also, please, do not put us on hold so we don't have to listen to anyone's paid commercial announcement or music.

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

MS. GREENE: Yes, sir.

Jeenu Philip?

DR. PHILIP: Present.
MS. GREENE: Joseph Lavino?

MR. LAVINO: Present.

MS. GREENE: Michael Mone?

MR. MONE: Present.

MS. GREENE: Scott Brock?

MR. BROCK: I'm here.

MS. GREENE: Arlene Elliott?

(No response.)

MS. GREENE: Dean Ellis?

MR. ELLIS: Here.

MS. GREENE: Jeffrey Tuller? Jeffrey Tuller?

(No response.)

MS. GREENE: Patrick Barnes?

MR. BARNES: Here.

MS. GREENE: Peter Hart?

MR. HART: Present.

MS. GREENE: Jennifer Goldman?

DR. GOLDMAN: Present.

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

CHAIRMAN MAY: Okay. Thank you, Dinah.

I want to start the meeting off as usual by reading the goals of council as stated in Chapter 499, Florida Statutes, 499.01211, Drug Wholesale Distributor Advisory Council.

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

So having said that, we do have a few items on the Chair's Report today. The first order of business is to officially welcome Joseph Lavino as our new council member representing retail pharmacy. Joseph is currently employed by CVS Health as legal counsel for pharmacy regulatory affairs. He's also a Pharm.D. and a J.D.

So, Joseph, would you like to tell us a little bit more about yourself, or do you have any words for the council?

MR. LAVINO: Sure, Steve. Thanks for the
introduction. And hello, everybody. Thanks for having me. I really look forward to contributing to this council. As Steve had mentioned, I am in-house counsel for CVS -- (Telephone interference.)

MR. LAVINO: I'm a licensed pharmacist in both Florida and in Massachusetts. I currently reside in Massachusetts. In my day-to-day capacity as legal counsel for CVS, I advise the corporation on various aspects of pharmacy practice, including implementation of the TFCSA across the enterprise, which was a major contributing factor to my interest in serving on this council.

So, again, thanks for having me. I look forward to working with all of you.

CHAIRMAN MAYS: Joe, we certainly welcome you to the council. Anyone else, anyone have any questions for Joe before we move on?

MR. MONE: This is just Michael. Hi, Joe.

CHAIRMAN MAYS: The next thing on the agenda is the CDR exam review. So I think we had the group come in and speak to us at the last council meeting about asking for our assistance in reviewing the exam to see if there's any improvements that could be made to it. And I know
Michael Mone had volunteered to lead that task. And I had accompanied him to Tallahassee, I think it was about a month or so ago, maybe it was last month, and went through the review.

And, Michael, I'd like for you, if you would, to provide everybody a little bit of an overview of what took place.

MR. MONE: This is Michael Mone.

Council members and to all staff and guests, Steve and I sat down with the testing folks and looked through a representative sample of examination questions, and also looked at some examination questions that whose performance in the past had been difficult for candidates to determine whether or not the exam development process in the item bank was an accurate reflection of what is necessary to be known by candidates taking the examination, as well as whether the examination was designed appropriately for the level of the candidates.

And what we came away with after going through several hours of exam items review, as well as looking at the blueprint that the candidates would study from, and the statutes in the areas that were necessary, we came away with the conclusion that
the exam is properly developed; it is properly sourced; it is accurately representative of what a candidate should know. And, in fact, this could be other opportunities to write new items for the examination to bring us to having a more robust item bank so that items would not necessarily be over-used.

We looked at the statistics. We looked at everything you could possibly look at, and came away with the conclusion that the examination is an appropriate examination. There's things with every examination that could be done. The most important thing would be to get new items into the item bank.

MR. WINTERS: Mr. Chair, this is Drew Winters, Division Director. I just want to take a moment and kind of speak a little bit to that because I wanted to, one, thank Michael and yourself for taking that opportunity to review and having that outside information brought to us so we could do that. And I think that the review that we did was an outstanding one and, again, is something that we welcome the input the council through Mr. Mone to take the time and do that.

I also wanted to mention that I think that...
after having the review and the information
provided, that again it was -- it was something
that did show, and I wanted to take a moment to
just thank our staff. I know that Chief Dixon and
our enforcement chief, Renee Alsobrook, and some of
our team spent a lot of time trying to work on that
exam, so I wanted to recognize them for their
efforts to do that, and to also, with the input on
some of our questions, that we can take that back
and, again, make sure that the test is commensurate
with what we'd expect out of our CDR. So it was a
good review and a good opportunity to get that
input, and I wanted to thank you for that.

And again, just to put out there that we again
will continue, as we do, to monitor the test, that
we continue to ensure that that test is overseen by
our Bureau of Education testing as they monitor
those statistics and will continue to do so. So,
thank you.

CHAIRMAN MAYS: Thank you, Drew.

This is Steve Mays. I want to just add that
I was just overly impressed with the staff, the
testing team and the testing staff and the
development staff. I was just really going through
the review of the different questions and the
exam. I was really blown away with how well it's put together. And I can tell there's been a lot of thought put into it, so I applaud the department for putting together a good exam.

Is there any questions, any questions from council members?

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

CHAIRMAN MAYS: Go ahead, Mr. Barnes.

MR. BARNES: Just -- I'm trying to think back. One of the reasons why, correct me if I'm wrong, why we looked at this is because potentially we felt that the exam was too difficult, is that -- does my memory serve me correctly?

CHAIRMAN MAYS: This is Steve. I think, part of one of the reasons we looked at it is, I think they actually asked for our assistance. And also, I think the fail rate was pretty high and that was one of the reasons that we wanted to look at it. And Drew and Michael, correct me if I'm mistaken, but I think that was probably the driving force behind it.

MR. MONE: Mr. Chairman, this is Michael Mone. If that was Drew that was going to talk, I'll let him talk first.

MR. WINTERS: This is Director Winters. Yes,
the information that we had is that we did want to provide an update on the CDR exam because we did, we do look to the council to provide some industry input that is available.

We did bring our Bureau of Education's director, and our exam development director with him. And I think that, as the Chairman said, that is exactly what we anticipated; one, just an opportunity to get some input and, two, when we reviewed the exam there was concerns.

And obviously there's a little bit lower passage rate on this particular exam, so we were concerned to make sure that there was not an issue that the exam was testing on material that was not representative of what a CDR would need to be able to know about.

And I think that was just an effort by the council members and coordination with the department to review that, and I think we had a good review and found, so far, that the exam does exactly what we expected.

And with that, we'll continue to monitor it and see what we can do about providing additional information out there, maybe making a more robust test prep pack, but also just to get the word out.
to our candidates that are going to be sitting for it, they do need to prep for that exam. Ind I think that was basically what I took out of the exam review.

And I'll turn it over to Council Member Mone to provide any additional comments.

MR. MONE: This is Michael Mone. I would agree a hundred percent with what Drew just said, except that I would point out one other aspect.

When we looked at it -- and I think there was a concern that we had expressed as a council, over a long period of time, about the pass rate. And the conclusion that I drew was that the pass rate is not a function of the examination itself, but a function of the candidate's preparation for the exam.

It is a -- a prudent examinee who studies for that examination should pass that on the first time. There is no reason, based upon the items that are in there, the test design or the instructions of what is to be covered, that they should not be able -- if they study, that they should not be able to pass that exam.

And Drew made a very good point that you --

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prep materials to them, so that they are more
focused on what is necessary to do their jobs. And
it's not designed to help them pass the exam. It's
designed to help them understand the information
that they need to study to be able to pass the exam.

CHAIRMAN MAYS: And this is Steve. I totally
agree. I mean, that's kind of what I came away
from the review process also, is that it really
comes down to preparation. So I think, in my
opinion, a lot of folks take this exam probably
too lightly and, you know, that they think they
can just show up and answer it on their common
sense and not prepare to, you know, understand
the Florida statutes and rules. So I think
that's probably, you know, that seems to be the
bottom line is it really is all about
preparation.

So, you know, obviously there's some things
that we thought we might could tweak, very minor
things with some of the questions, but other than
that, I think it's a very fair exam and it just
requires some preparation.

Any other questions from council members?

MR. TULLER: Yeah. Hey, good morning. It's
Jeff Tuller. I apologize for being late.
I just wanted to concur with most of the prior comments. Having taken the CDR exam myself, I did exactly what Steve said. I thought that because of my experience that I'd get through it on the first time, but the first sitting I did not pass. So it did do exactly what Mr. Mone said. You have to prepare for this exam. And I've consequently, maybe by a little luck, got through the second then in time.

So the questions themselves, I have two things I'd like to bring up here. One is having a system to go back and reevaluate the questions to make sure we are covering the categories that we think is appropriate to -- and is a good process. But the exam preparation piece is where, I think, a lot of people are left in the dark and left in the cold, so we could, I believe, get a lot better at that.

And I know, for example, California, before you take their DR exam, they have specific companies that you have to, that you engage with, and they will take you through a multitude of classes in various sections of business. So there's options to look at, but I concur with the test itself, I can, with the example -- thinking I
could have gotten through it on the first time and did not, and then realized that the -- you really have to get through it. And it does take some study time, which is what we want, so I think it's important, so I just wanted to be the living example of what you've just spoken about. Thank you.

CHAIRMAN MAYS: Thanks, Mr. Tuller.

Any other questions from council members or any questions from any other interested parties on the line before we move on?

(No response.)

CHAIRMAN MAYS: Okay. All right. The next item on the agenda is nominations for chair and vice-chair. So the -- I think we're a little past due on it, but, the chair and vice-chair terms are for one year, as I recall.

Now, although I have, you know, reapplied to stay on the council for another term, I want to make sure that we open it up for nominations for a new chair and vice-chair.

And what we'll do is we'll take those nominations at our next call, which I believe is in December. So this will give everyone time to be thinking about anyone that they would like to
nominate. And if there's any questions or anything like that, feel free to reach out to Dinah. She can give you some advice on that.

So, anyway, I just want to make that announcement, so be thinking about that, and then we'll take those nominations and select a different chair and a vice-chair at our next scheduled call. Any questions from any council members on that, or other parties?

(No response.)

CHAIRMAN MAYS: Okay. Last thing on the Chair's Report is just to call out that the meeting transcript from our last meeting is in there for informational purposes for your review.

So at this point, if there's not any other questions from council members or interested parties, I'll turn it over to Mr. Winters for the Division Director's Report under tab two.

MR. WINTERS: Thank you, Mr. Chair. I do appreciate it and I'll move right now just to start with our rules report as the first agenda item under my tab.

Just kind walking through this, we've got, as many of you are aware, our goal has been to make sure that we have adopted all the applications via
rule in the Florida Administrative Code at the request of the joint administrative procedures committee for many years and we are continuing that process.

One is a big thanks to Dinah for all of her efforts going through that. Many of you don't realize the background to that, but she does a lot of work to make sure those rules and applications as we create them are moved through the rule process.

The first item on our rules report is the application for a device manufacturer purpose, or permit, excuse me. That one has been noticed for development, but we have not finalized the action on that.

The next two items, I'm going to just mention briefly because I want to spend a little more time which will be on my second agenda item under my tab, what is rule 61N-1.001, which is, we have noticed for development for the solely administrative services definitions, and did hold the -- an initial rule hearing on that, a rule workshop to provide an opportunity for people to put comments in on that.

And then also the next rule underneath that,
which is 61N-1.0155, which is a new rule, but that
will be to adopt the establishment, security, and
storage exemptions for virtual manufacturers, both
in-state and out-of-state and the broker-only. And
that we'll talk about under my second tab for
today, but, just moving forward, we are going to
move through that.

Currently, we are in the process of the next
applications, which is 61N-2.007, which is the
application for limited prescription drug
veterinary wholesale distributor; 61N-2.021, which
is the application which is the restricted
health care prescription drug distributor
government programs permit; the 61N-2.022, which
again is the restricted health care entity permit;
and 2.023 of 61, which is the institutional
research permit; the 61N-2.025, the retail pharmacy
drug wholesale distributor permit; 61N-2.027, the
application for a veterinary prescription drug
retail establishment; and 61N-2.028, which is the
application for the veterinary prescription drug
wholesale distributor permit.

Those applications have all been finalized and
we are noticing them for proposed rulemaking.
We're routing those sort of internally and we'll
expect to notice those here shortly, once they've
gone through internal processes.

As has been our standard protocol, once we do
notice that for rulemaking, we will bring that to
the next council meeting to provide copies of those
applications for people to review and to provide
any input they have regarding those, but we will
notice those for proposed rulemaking shortly. I
believe that they have finished through most of our
internal processes and we'll move those through
shortly. So with that, that's our base rule
reports.

As you'll see, the finalized rules on the
other side that are listed in green, those are ones
that we've already completed rule development for.
And again, we will continue that process for the
current ones that are going to be adopted. Again,
those are aimed specifically at adopting our forms
via rule so that they are officially adopted and
have the effect of law, and so we have that out
there.

With that general report, if there's any
questions generally about our rules report, you can
let me know now. But otherwise, I think that most
of our general questions are going to come

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regarding the second and third rules that I mentioned, which are our solely administrative services, and our establishment, security and storage exemptions, which I'll address now if there's not any initial questions.

Okay. Hearing no initial questions, I'll go forward with that, if you'll again move to the second item on our agenda. This is a draft rule of 61N-1.0155, which is going to be our establishment, security and storage exemptions for virtual manufacturers and broker-only distributors.

I wanted to bring this to the council. I know that this is a little bit different than our normal process, because normally I would go ahead and notice this for rulemaking, but I felt that based on how we've proceeded with this, and the related rule which is under 61N-1.001 for the definition of solely administrative services, I felt that this would be a good opportunity for me to present this to the council members, just for any comments or other items that we would like to take care of beforehand, and also just an opportunity for those in the interested parties and the public to have an opportunity to see that rule.

Again, what we went through is, based on the
language in the statutes, it says specifically that
for virtual manufacturers and for the broker-only,
as well, that we can waive certain storage,
security, and establishment requirements. The way
that I've read that in the statute, I believe
that it does limit us to the first three elements
and so we focused on those specifically.

I have had a question when we initially
addressed that, which is, an application of the
4 through 15 of the remaining sections of 499.0121,
that how would those read out? I think, if you'll
note, I put some language in here that makes clear.

I hope that, in the event that those are not
applicable to the business model, i.e., you don't
have anything that would be effectuated by those,
4 through 15, but again, the division recognizes
that in some of those instances, because you are a
virtual, they would not be applicable. But going
through there, again, we looked at that as part of
our development. I think that we've got a pretty
good rule here and would like to provide any
opportunity for anyone to make a comment.

Again, with the establishment requirements, we
basically would waive all those requirements for
virtual and out-of-state virtuals and broker-only
permit holders. The only thing that they would be
required to maintain in those sections is to be of
suitable size in construction to facilitate proper
operation, and that they have to be maintained in
orderly condition. And they have to maintain the
written policies and procedures regarding the
receipt of prescription drugs, and to ensure that
those policies and procedures are adequately
addressed in the event that an inadvertent delivery
or attempted delivery were to occur at that
establishment. That would be the only requirement
to be maintained, and otherwise the establishment
would not be required to maintain those
requirements in subsection one.

We did make sure to put clarifying language
that, again, that relieving of the establishment
requirements did not otherwise take out the
necessity to maintain compliance with the other
provisions of 499, and applicable fair law
regarding authorized trading partners and the other
specific requirements, and especially the due
diligence requirements.

On the security requirements, again, we did
waive those, except that they need to make sure
that the outside control for the facility was well
established, and that they ensure that their recordkeeping computer systems were appropriately protected to ensure the integrity of any records and electronic records being transmitted from the facility. And again, as far as the storage requirements go, we did waive those in their entirety based on the information.

So with that, that is the presentation of the draft rule. If there are any comments or questions that people would like to provide initially, I did want to make sure that everybody did understand that this is, again, just an additional opportunity for comment. Once we do propose it again, everybody will have the same ability and authority through the rulemaking process they would have. This was just an additional courtesy and step that we decided to put in, to make sure we did have a good rule.

So with that, I will turn it over to any of the council members and the chairman to receive comments on the draft and go from there.

CHAIRMAN MAYS: Any comments or questions from council members?

(No response.)

CHAIRMAN MAYS: How about from interested
parties on the line?
(No response.)

CHAIRMAN MAYS: Okay. Mr. Winters, it doesn't seem like there's any comments at this point.

MR. WINTERS: Well, I generally take this as a positive, that overall the rule does what we want it to do, and we'll move forward.

Again, we will notice it through the normal rulemaking process, which will again give additional time to comment, as well, but, hopefully, that means we've got a good rule here.

CHAIRMAN: Great. Mr. Winters, do you have any other business you want to --

MR. WINTERS: The only other item I wanted to mention is that I did mention 61N-1.001, the soley administrative services definition. We continue to strive to find a good definition regarding that. We've got a working draft, but, again, I don't think it's in a position now that we're ready to bring it out and to notice it. We're being very cautious and diligent in that rule to make sure that what we attempt to do is going to be good for both the regulatory portion under the division, but also that it's cognizant in recognizing the circumstances of the industry, and that we --
don't roll out a rule that's going to cause more problems than it would good to resolve those issues.

    Again, a thank you to many of the representatives out in the industry that have provided those comments. They have been very helpful and continue to provide some assistance to us, as we try to develop an appropriate language. And I hope to have that closer when we get to the December meeting, hopefully have something to provide to the council, but, again, we are going to strive to continue that. And I think we've gotten some good resolutions to policy items and concerns, and we're just trying to figure out how to formulate that into the best rule possible. Again, I will continue to strive for that.

    If anybody has any questions or comments, of course, I'm always here to try and take those, and we'll try to address them as we go forward through the rulemaking process.

    CHAIRMAN MAYS: Thank you, Mr. Winters.

    MR. WINTERS: And that concludes my report otherwise.

    CHAIRMAN MAYS: Okay. Great. One question of Dinah. What is the date of our -- do we have a date set for the December meeting call?
MS. GREENE: Yes.

CHAIRMAN MAYS: It's going to be a call, right?

MS. GREENE: Yes, it will be a conference call on December 6.

CHAIRMAN MAYS: December 6. Okay. This is just as a reminder to everyone, that will be our next meeting and it will also be a call.

So is there any other business from the council?

(No response.)

CHAIRMAN MAYS: Hearing none, do we have a motion to adjourn?

MR. WINTERS: We've got a tab three.

CHAIRMAN MAYS: Uh-oh, did I miss something here?

MR. WINTERS: We've got a tab three for Dr. Philip to provide information on NABP update.

CHAIRMAN MAYS: I'm so sorry, Dr. Philip. I totally missed that. I apologize.

DR. PHILIP: No worries. Thank you. Thank you, Chair Mays. So, and I guess, Mr. Mone, I know Mr. Mone is on the call.

Michael, if you have anything to add, you may be familiar with this if you've been involved with it at all, but this is, this is really just a brief FOR THE RECORD REPORTING, INC. TALLAHASSEE, FLORIDA 850-222-5491
recap of a call that I had with Josh Bolin, who's
the Associate Executive Director at NABP, regarding
two pieces. One is the definition of "suspicious
orders," and the second is the central reporting
system where NABP acts as a repository. And this
was mentioned at the NABP annual meeting, and so I
subsequently followed up with Mr. Bolin at NABP to
get a little more information with regard to what
the status is on this.

So my understanding is that NABP has met with
certain regulators and industry folks to really
understand where they are when it comes down to the
definition of suspicious orders. So they wanted to
facilitate some discussion on some meaningful
information, including looking at the different
data elements that will be useful for regulators.
So I think that discussion is going to continue.
It's just a matter of looking to get some consensus.

Ideally, they want to be able to, you know,
provide a definition that can eventually be rolled
into the NABP model act. Also that they're looking
at, in terms of the reporting system, they're
looking to, you know, reduce or eliminate multiple
reporting, and so, so the concept here is that NABP
can act as that repository and hopefully eliminate
some of the unneeded multiple reporting. So you're looking at having all the information reported from, you know, the information reported to a singular place versus multiple places.

So my understanding is, in Jersey, California and Ohio, specifically, you're looking at more useful regulations. And there seems to be some consensus that a central reporting system makes sense.

There is a task force schedule to meet on August 29 and 30 this year. It's going to be attended by NABP, a DEA regulatory industry, really for the purpose of looking for some consensus on, you know, on the definition of suspicious orders.

My understanding is that there are regulators from Indiana, Michigan, Ohio, Illinois and Tennessee that are going to be in attendance. The goal here is to try and provide better tools for all the regulators. They will have a report that's going to be created after the meeting, and so, I can look to report back on the next call after this task force meets to see what the outcome of the meeting will be.

I don't have much more to add, but I can, I'll take any questions. And Mr. Mone, I don't know if
you have anything else to add on top of this, what
I just said, or if you can correct me if I said
anything incorrectly.

MR. MONE: Mr. Chairman, this is Michael Mone.
Everything that Jeenu said is correct, as always.
And that the only point that I will make is that
it's an effort to drive efficiencies in the
reporting system by providing that single
repository, with a single set of definitions, to
create the uniformity that is necessary, so that
regulatory agencies can timely act on that
information. And that's the real genesis of this.

CHAIRMAN MAYS: Okay. And this is Steve.
I actually can add a little bit of color to
this. I was invited to attend this meeting at
the end of August. They've invited, I know,
representatives, I believe, from McKesson,
Cardinal, AmerisourceBergan and HD Smith. I'm
not sure who else.

I have accepted and plan to attend. They're
calling it the meeting of the suspicious orders
workgroup. It's taking place August 29 and 30.
So they -- and again, the way Jeenu has spelled
it out is the way it was kind of described to me
as far as what that meeting will be.
And I would like to also confirm that there are a lot of states looking at the various different suspicious order reporting requirements, and it kind of reminds me of the old pedigree days where we started running into, you know, 50 states with 50 different requirements. And we're starting to see that now with suspicious order reporting.

I know California has one now that they wanted all these suspicious order reports and now they're asking, you know, the companies that are reporting the orders to also give them the reasons why for each one. So it's getting a little more complicated, the deeper we get into it. So, I think, the more that we can standardize that whole process is going to be for the betterment of the industry and the regulators.

Any questions from the council for Mr. Philip?
(No response.)

CHAIRMAN MAYS: And again, I apologize, Jeenu, for skipping tab three and jumping right to the end.

DR. PHILIP: Of course.

CHAIRMAN MAYS: All right. Are there any questions from any other interested parties about the NABP update?
(No response.)
CHAIRMAN MAYS: Okay. Is there any other business?
(No response.)
CHAIRMAN MAYS: So we'll try this again. Okay. Hearing none, do we have a motion to adjourn?
MR. BARNES: Motion to adjourn. This is Patrick Barnes.
DR. PHILIP: And I will second it. This is Jeenu Philip.
CHAIRMAN MAYS: Okay. Thanks for the second. All in favor, say "aye."
(Chorus of "Ayes.")
CHAIRMAN MAYS: Any opposed?
(No response.)
CHAIRMAN MAYS: Okay. The meeting is adjourned. Thank you. And we'll talk to everyone in December.
(Whereupon, the meeting was adjourned at approximately 10:12 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
council meeting, and that the transcript, pages
1 through 32, contains a true and complete record
of my stenographic notes and recordings thereof.

Dated this 30th day of August, 2018, at
Tallahassee, Leon County, Florida.

__________________________
DEBORAH ALFF, COURT REPORTER

FOR THE RECORD REPORTING, INC.
TALLAHASSEE, FLORIDA  850-222-5491
To: Drug Wholesale Distributor Advisory Council  
From: Drew Winters, Director  
Date: December 13, 2018  
Re: Division Rulemaking (rev.12/14/18)

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

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<thead>
<tr>
<th>Rule #</th>
<th>Title</th>
<th>Purpose</th>
<th>Status</th>
<th>Next Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>61N-2.003</td>
<td>Application for Device Manufacturer Permit</td>
<td>To adopt and incorporate the division's permitting application forms into rule</td>
<td>Notice of Development filed 2/26/16;</td>
<td></td>
</tr>
<tr>
<td>61N-1.001</td>
<td>General Regulations - Definitions</td>
<td>Adoption of a definition of &quot;solely administrative services&quot; as set forth in s. 499.003(48)(t), F.S., and applicable to Rule Chapters 61N-1 and 61N-2, F.A.C.</td>
<td>Notice of Development filed 4/5/18; 5/10/18 - Rule Hearing</td>
<td>Finalize the rule and publish a Notice of Proposed Rule</td>
</tr>
<tr>
<td>61N-1.0155</td>
<td>Establishment, Security, Storage Exemptions for Virtual Manufacturers and Broker-Only Distributors</td>
<td>Create a new rule establishing exemptions from establishment, security and storage requirements under s. 499.0121, F.S., for prescription drug manufacturer-virtual, non-resident prescription drug manufacturer-virtual, and prescription drug wholesale distributor-broker only permit holders pursuant to s. 499.01(2)(a),(c), and (e), F.S.</td>
<td>Notice of Development filed 4/5/18; 5/10/18 - Rule Hearing</td>
<td>Finalize the rule and publish a Notice of Proposed Rule</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 proposed rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.021</td>
<td>Application for Restricted Rx Drug Distributor - Government Programs Permit</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of proposed rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.022</td>
<td>Application for Restricted Rx Drug Distributor - Health Care Entity Permit</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of proposed rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.023</td>
<td>Application for Restricted Rx Drug Distributor – Institutional Research Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of proposed rulemaking for rule and application.</td>
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<tr>
<td>61N-2.025</td>
<td>Application for Retail Pharmacy Drug Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of proposed rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.027</td>
<td>Application for Veterinary Prescription Drug Retail Establishment</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of proposed rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.028</td>
<td>Application for Veterinary Prescription Drug Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of proposed rulemaking for rule and application.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Rule #</th>
<th>Title</th>
<th>Effective Date</th>
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<tbody>
<tr>
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<td>Product Registration</td>
<td>11/2/17</td>
</tr>
<tr>
<td>61N-1.017</td>
<td>Certificates of Free Sale</td>
<td>10/24/17</td>
</tr>
<tr>
<td>61N-1.018</td>
<td>FEES</td>
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<tr>
<td>61N-1.028</td>
<td>Product Tracking and Tracing-Definitions</td>
<td>5/16/16</td>
</tr>
<tr>
<td>61N-1.029</td>
<td>Product Tracking and Tracing- Manufacturer Requirements</td>
<td>5/11/16</td>
</tr>
<tr>
<td>61N-1.030</td>
<td>Product Tracking and Tracing- Wholesale Distributor</td>
<td>5/11/16</td>
</tr>
<tr>
<td></td>
<td>Requirements</td>
<td></td>
</tr>
<tr>
<td>61N-1.031</td>
<td>Product Tracking and Tracing-Dispenser Requirements</td>
<td>5/11/16</td>
</tr>
<tr>
<td>61N-1.032</td>
<td>Product Tracking and Tracing- Repackager Requirements</td>
<td>5/11/16</td>
</tr>
<tr>
<td>61N-1.0245</td>
<td>Notice of Non Compliance- Minor Violations</td>
<td>11/2/17</td>
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<tr>
<td>61N-2.001</td>
<td>Application for Complimentary Drug Distributor Permit</td>
<td>6/9/16</td>
</tr>
<tr>
<td>61N-2.002</td>
<td>Application for Cosmetic Manufacturer Permit</td>
<td>10/24/17</td>
</tr>
<tr>
<td>61N-2.005</td>
<td>Application for Freight Forwarder Permit</td>
<td>6/9/16</td>
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<tr>
<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>
<td>6/9/16</td>
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<td>61N-2.009</td>
<td>Application for Medical Gas Wholesale Distributor Permit</td>
<td>6/9/16</td>
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<td>61N-2.010</td>
<td>Application for Medical Oxygen Retail Establishment Permit</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>
<td>1/11/17</td>
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<td>61N-2.012</td>
<td>Application for Out-of-State Prescription Drug Wholesale Distributor Permit</td>
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<td>61N-2.013</td>
<td>Application for Over-the-counter Drug Manufacturer Permit</td>
<td>6/9/16</td>
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<td>61N-2.014</td>
<td>Application for Prescription Drug Manufacturer Permit</td>
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<tr>
<td>61N-2.016</td>
<td>Application for Prescription Drug Wholesale Distributor Permit</td>
<td>7/11/17</td>
</tr>
<tr>
<td>61N-2.018</td>
<td>Application for Restricted Rx Drug Distributor – Blood Establishment Permit</td>
<td>5/8/18</td>
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<tr>
<td>61N-2.019</td>
<td>Application for Restricted Rx Drug Distributor – Charitable Organization Permit</td>
<td>6/5/18</td>
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<tr>
<td>61N-2.020</td>
<td>Application for Restricted RX Drug Distributor- Destruction Permit</td>
<td>6/5/18</td>
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<tr>
<td>61N-2.024</td>
<td>Application for Restricted Rx Drug distributor – Reverse Distributor</td>
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</tr>
<tr>
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<td>5/8/18</td>
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<tr>
<td>61N-2.030</td>
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</tr>
<tr>
<td>61N-2.0151</td>
<td>Application for Nonresident Prescription Drug Repackager Permit</td>
<td>1/11/17</td>
</tr>
</tbody>
</table>
The renewal deadline for licenses issued by the Division of Drugs, Devices & Cosmetics with October expiration dates has been extended from October 31, 2018 to November 30, 2018 at 11:59pm due to Hurricane Michael. Licenses will not be placed in a delinquent status for non-renewal, and delinquency fees will not be assessed until that time. Continuing Education credits will continue to be accepted for this renewal cycle during this period.

Division of Drugs, Devices and Cosmetics

The Division of Drugs, Devices and Cosmetics safeguards the health, safety, and welfare of the citizens of the state of Florida from injury due to the use of adulterated, contaminated, misbranded drugs, drug ingredients and cosmetics by administering the provisions of the Florida Drug and Cosmetic Act (Chapter 499, F.S.). The Program carries out its responsibilities through three bureaus: Compliance & Enforcement, Licensing and Legal.

Do I Need License?

Are You Moving?

Quick Links

Need Help?

- FAQs
DIVISION OF DRUGS, DEVICES AND COSMETICS – CERTIFIED DESIGNATED REPRESENTATIVE

Certified Designated Representative

All prescription drug wholesale distributor and out-of-state prescription drug wholesale distributor permittees and applicants must designate in writing at least one natural person to serve as the designated representative for a given establishment. Such person must have an active certification from the department (a "certified designated representative" or "CDR").

Requirements:

Application: Individuals applying for this certification must complete the Department’s application. Mail or deliver the application and all required attachments to:

Florida Department of Business and Professional Regulation
Division of Drugs, Devices and Cosmetics
2601 Blair Stone Road
Tallahassee, FL 32399-1047

Certification Criteria: All CDR’s and CDR applicants must:

- Be at least 18 years of age.
- Have not less than 2 years of verifiable full-time work experience in a pharmacy licensed in this state or another state, where the person’s responsibilities included, but were not limited to, recordkeeping for prescription drugs, or have not less than 2 years of verifiable full-time managerial experience with a prescription drug wholesale distributor licensed in this state or in another state.
- Provide a personal information statement, including a set of fingerprints for a criminal background check, to the department as part of the application process. Refer to Form DH 2125, "Personal Information Statement" effective January 2004.
- Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing the distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs (the "CDR examination").
- An application is not complete until the applicant has received a passing score on the CDR examination. The applicant will be notified by regular mail at the applicant’s home mailing address of the applicant’s eligibility to schedule the examination.
- If the applicant has not passed the CDR examination within eighteen (18) months of the eligibility notification, the department may deny the application.

Operational Requirements: All CDR’s and CDR applicants must:

- Be employed in a managerial position by the wholesale distributor, and actively involved in and aware of actual daily operations.
- Be physically present at the establishment during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence.
- May serve as a designated representative for only one wholesale distributor at any one time.

Examination Information
Certified Designated Representative Examinations

Applicants for licensure as a Certified Designated Representative (COR) must take and pass a written examination regarding federal and state laws and rules governing distribution of prescription drugs.

For more information about licensing and application requirements, please click here to visit the Division of Drugs, Devices & Cosmetics license information webpage.
Certified Designated Representative Examinations

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For more information about licensing and application requirements, please click here to visit the Division of Drugs, Devices & Cosmetics license information webpage.

- Scheduling a Computer-Based Examination
- Examination Content
- Preparing for the Examination

- The Department of Business and Professional Regulation’s Candidate Information Booklet (CIB) provides additional information to prepare candidates to take their professional licensure examinations. Click this link to view and download Candidate Information Booklets.
- A printable law booklet is available for download that includes current versions of Chapter 499, Florida Statutes, Chapter 61J-1, Florida Administrative Code, Code of Federal Regulation, Title 21, and United States Code, Title 21. These references are available to assist candidates in preparing for the Certified Designated Representative examination. Click this link to view and download the printable law booklet.
Candidate Information Booklet
for the
Certified Designated Representative
Laws and Rules Examination

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Certified Designated Representative Examinations

Applicants for licensure as a Certified Designated Representative (CDR) must take and pass a written examination regarding federal and state laws and rules governing distribution of prescription drugs.

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- Scheduling a Computer-Based Examination
- Examination Consent
- Preparing for the Examination

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Florida Certified Designated Representative Law Book

Chapter 499, Florida Statutes

Chapter 61N-1, Florida Administrative Code

Code of Federal Regulations, Title 21

United States Code, Title 21

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Certified Designated Representative Examinations

Applicants for licensure as a Certified Designated Representative (CDR) must take and pass a written examination regarding federal and state laws and rules governing distribution of prescription drugs.

For more information about licensing and application requirements, please click here to visit the Division of Drugs, Devices & Cosmetics license information webpage.

Examination Content Outline
- Product Integrity - 27.5%
- Records - 25%
- Inspections - 15%
- Authorized Recipients - 10%
- Lawful/Unlawful Products - 10%
- Permits and Renewals - 10%
- CDR Requirements - 5%

Preparing for the Examination
Candidate Information Booklet
for the
Certified Designated Representative
Laws and Rules Examination
Candidate Information Booklet for the Certified Designated Representative Laws and Rules Examination
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Statement of Nondiscriminatory Policy

The Department of Business and Professional Regulation does not discriminate among candidates on the basis of age, sex, race, religion, national origin, handicap, or marital status.

Please save this document for future reference.

1. Introduction

This Candidate Information Booklet (CIB) is designed to introduce Computer Based Testing and provide candidate information for this examination. The Department of Business and Professional Regulation has retained the services of Pearson VUE to schedule, administer, score, and report the results for computer-based testing. Pearson VUE is a leading provider of assessment services to regulatory agencies and national associations and offers licensing and credentialing support services to associations, state agencies, and private industry.

Your examination(s) will be administered on an electronic testing system. The testing system eliminates the use of paper, pencil, and answer sheets. Candidates input their responses by entering the answer of their choice (A, B, C or D). Before you begin the examination, you will have an opportunity to go through a tutorial on the computer. The computer is very simple to operate; it should only take you a few minutes to learn to use it.

The screen features a variety of function buttons to help candidates navigate through the examination. The function buttons are located in the same position throughout the test. Candidates can mark a question for review, move forward or backward one question at a time, or move to a specific question. The summary screen, which can be accessed at any time during the examination, shows candidates the following:

- Number of questions answered
- Number of questions unanswered and/or skipped
- Time remaining for the examination

II. Testing Locations and Reservations

To locate a Pearson VUE Test Center near you, as well as to check that site’s availability, use this link to view the vendor web site for more details: https://home.pearsonvue.com/fl/dbpr.

Making your Test Reservations

Candidates that already know their candidate identification number are reminded that they do not have to wait for a “Confirmation” “Authorization” letter to make their reservation.

Telephone or Internet Reservations

Call 1.888.204.6239 and a Pearson VUE Customer Care Associate will help you to select a convenient examination date and location and answer any questions you may have. The best times to call for a reservation are: Monday – Friday (8am – 11pm), Saturday (8am – 5pm), and Sunday (10am – 4pm). You may register as far in advance as you would like to test based on seat availability. However, it is strongly recommended that you call at least five (5) business days before the examination date desired since reservations are made on a first-come, first-served basis.

Candidates may register via the Internet. You may submit a request via the Internet to Pearson VUE website at http://www.PearsonVUE.com twenty-four (24) hours a day, seven (7) days a week, provided you include a credit card number, electronic check or voucher, and valid email address. A reservation confirmation will be returned to you via email. Examination reservations may be canceled or changed via the Internet.

Please have the following information when you call to make an examination reservation:

- Your authorization notice
- Candidate identification number listed on your authorization notice
• Your full name, address and a daytime telephone number
• The location of the test center you desire
• The name of the examination you will be taking
• Credit card number, check, or voucher

III. The Examination

Content Overview

This is a closed book examination. Reference materials and/or the Candidate Information Booklet will not be allowed in the test room at the time of the examination. No written material other than that issued at the time of testing will be permitted.

Candidates must submit an application and fee to the Department to be authorized to sit for the examination. You will be given ninety (90) minutes (1½ hours) to complete the examination. This time does not include the thirty (30) minutes for the tutorial. The examination consists of forty (40) scored multiple-choice questions.

Content Outline

<table>
<thead>
<tr>
<th>Content Area</th>
<th>Percentage of Exam</th>
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<tbody>
<tr>
<td>Product Integrity:</td>
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<tr>
<td>A. General</td>
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<td>B. Storage</td>
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<tr>
<td>C. Recalls</td>
<td>27.5%</td>
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<tr>
<td>D. Quarantine</td>
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<tr>
<td>E. Returns</td>
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<td>F. Security</td>
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<td>Records</td>
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<td>Inspections</td>
<td>12.5%</td>
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<td>Authorized Recipients</td>
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<td>Lawful/Unlawful Products</td>
<td>10%</td>
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<td>Permits and Renewals</td>
<td>10%</td>
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<tr>
<td>CDR Requirements</td>
<td>5%</td>
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</tbody>
</table>

References

I. Chapter 499 Florida Statutes - All sections relating to prescription drugs
   Chapter 499 Florida Drug and Cosmetic Act

II. Chapter 61N-1, Florida Administrative Code - All sections relating to prescription drugs
   Rule Chapter: 61N-1 Regulations for Drugs, Devices and Cosmetics

III. Code of Federal Regulations (CFR)
    Title 21 Code of Federal Regulations (CFR) Food and Drug
    A. Part 205.2
    B. Part 205.3
    C. Part 205.4
    D. Part 205.50
Sample Questions
(The correct answers are bold and italicized.)

1. Which activity is not authorized under a prescription drug wholesale distributor permit?

   A. distribution of complimentary drug samples
   B. selling to a licensed ship captain
   C. selling to a permitted charitable organization
   D. sending returns to a wholesale supplier

2. The safety of a drug returned to a prescription drug wholesale distributor is doubted by the certified designated representative. Which option is NOT available to the certified designated representative?

   A. destroy the drug
   B. return the drug to stock
   C. return the product to its manufacturer
   D. test the product

3. What type of agreement must a purchasing wholesale drug distributor and a selling wholesale drug distributor enter into before a wholesale transaction occurs?

   A. confidentiality
   B. cooperative
   C. fixed-price
   D. indemnity

4. Why must the outside perimeter of an establishment used for wholesale drug distribution be well-lighted?

   A. for the protection of personnel working at the establishment
   B. in case the establishment takes delivery of prescription drugs after dark
   C. to aid local law enforcement officials
   D. to help secure the establishment from unauthorized entry

Pilot Testing

The Examination may contain a small number of experimental or “pilot test” questions. The purpose of including pilot test questions within the examination is to expand and improve the bank of questions from which
future examinations will be drawn. This is a common practice used by many national and state examination programs and is a critical step in ensuring the continued reliability and validity of these examinations.

In the event that pilot test questions are included within the examination, these questions will NOT be counted when computing scores. Additional time will be given for answering the pilot test questions. The time allowed for testing has been evaluated to ensure there is adequate time for completing test questions and pilot questions.

Pilot questions are NOT identified. If the pilot questions were identified, many of the candidates would skip them, and the results would not be valid. The development of a good examination requires accurate candidate response information for the pilot questions.

Test Taking Advice

The advice offered here is presented primarily to help you demonstrate knowledge and maximize your chances of passing the examination.

• Read all instructions carefully.

• For best results, pace yourself by periodically checking your progress. This will allow you to make any necessary adjustments.

• Be sure to record an answer for each question, even the items about which you are not completely sure. You can note the questions you wish to reconsider on the computer testing system and return to them later.

• Alert a Proctor or Test Center Manager to any problems that may occur during the examination. Do not wait until the examination is over to inform someone about a problem.

Supplies

It is expressly understood by each candidate that the State of Florida, and/or the Department of Business and Professional Regulation, and the Department’s staff hereby assume absolutely no liability of any nature whatsoever for any items of the candidate’s personal property which may have been brought to, left at, or left outside the examination site.

It is further understood that the candidate’s admission to the examination shall hereby constitute the candidate’s full, knowing, and complete waiver of any and all such claims against the State of Florida, and/or the Department of Business and Professional Regulation, and the Department’s staff.

What to Bring

All candidates will be required to bring the following items to the testing center on the day of the examination:

• Personal items are not permitted in the examination room. Any personal items such as toiletries, snacks, etc must be encased in a clear plastic bag, no larger than 8” X 11” in size and kept in the locker provided by the vendor.

• Two forms of valid signature identification, one of which is government issued: driver’s license, state identification card, passport or military identification card. Student or employment I.D. cards and photo bearing credit cards are not acceptable as picture bearing identification. Candidates will not
be admitted without showing proper identification. Your name and address must match what was submitted on your application.

• Calculators are permitted if they are silent, hand-held, battery-operated, non-printing, and without an alphabetic keypad. Solar calculators are not recommended

• To better serve our “English as a second language” candidates, the Bureau of Education and Testing is permitting the use of foreign language translation dictionaries during the examination. Translation dictionaries shall contain word-for-word or phrase translations ONLY. Dictionaries that contain definitions of words, explanations of words, or handwritten notes may NOT be used.

• Electronic translation dictionaries are NOT recommended as most will have more than word-for-word or phrase translations. An alphabetic keypad, have mathematical formulas and stored memory capabilities. Should these electronic translation devices have these capabilities; these devices WILL be rejected by the Proctor or Test Center Manager in NOT being suitable for the test site environment.

• Testing Center staff will inspect and approve each dictionary before it can be used during the examination. In order to maintain security and to ensure fairness to all candidates, candidates are limited to the use of a single dictionary.

• If you have any questions concerning acceptable translation dictionaries, please contact the Bureau of Education and Testing at 850.487.1395

What not to Bring

Unauthorized supplies, those not listed in this Candidate Information Booklet, will be subject to removal by the Department’s representative at the examination site.

The following items are NOT allowed in the examination room:

• Cameras, tape recorders, or computers

• Pagers, electronic transmitting devices, or telephones (watches with alarms or beepers should be set so that they will NOT sound or go off during the examination administration)

• Any bound or loose leaf reference materials and notes

• Dictionary, thesaurus, or other spelling aids

• Canisters of mace, pepper spray, or other personal defense items

• Purses, briefcases, portfolios, fanny packs, or backpacks

IV. Administrative Policies

Change and Cancellation Policies

If you wish to cancel your exam, you must contact Pearson VUE 2 DAYS prior to your scheduled appointment. Cancelling an exam less than 2 DAYS prior to your appointment or missing your exam may result in forfeiting your exam fees.
Absence Policy

If you are unable to attend the examination for which you were scheduled, you may be excused for the following reasons:

- Your illness or that of an immediate family member
- Death in the immediate family
- Disabling traffic accident
- Court appearance or jury duty
- Military duty

All candidates seeking excused absences must submit written verification and supporting documentation of the situation to Pearson VUE no later than four days after the original examination date. Documentation of medical absences must have the original signature of the medical practitioner. Stamped signatures will NOT be accepted. You will be required to pay your examination in full, and possibly reapply to DBPR, if you do not show up for your exam appointment.

Admission to the Examination

When registering at the test center, you will be required to have the following items:

- Two forms of valid signature identification, one of which is government issued: driver’s license, state identification card, passport or military identification card. **Student or employment I.D. cards and photo bearing credit cards are not acceptable as picture bearing identification.** Candidates will not be admitted without showing proper identification. Your name and address must match what was submitted on your application.

Admission Procedures

- Please report to the test center thirty (30) minutes prior to your scheduled examination. As part of the checking-in process, a photo will be taken of the candidate prior to taking the exam. This photo will be visible on the candidate’s exam result report. The Test Center Manager will assign you a seat and assist you with the computer. You may take up to fifteen (15) minutes to complete the tutorial and the Test Center Manager will answer any questions you may have about the computer testing unit at this time.

- The time you spend on the tutorial will NOT reduce the time allotted for taking your examination. When you feel comfortable with the computer testing unit, you may begin your examination. The time of the examination begins the moment you look at the first question on your examination.

- Your specific reporting time will be given to you when you make your examination reservation. Please allow yourself sufficient time to find the test center. Make sure you have all necessary documentation before you report for registration.

- At the completion of the examination, your score report will provide instructions on the next step of the licensure process.

Late Arrivals

Test Center Managers will review the daily schedule for that day to determine if the candidate can be accommodated due to tardiness. If the tardiness was caused by an emergency (i.e., car trouble, traffic accident, etc) the candidate must provide documentation of the event. If the candidate cannot be accommodated due to unex-
Rules for the Examination

• The examination materials, documents, or memoranda of any kind are not to be taken from the examination room.

• Listen carefully to the instructions given by the Test Center Manager and read all directions thoroughly. Test Center Managers are NOT qualified or authorized to answer questions concerning examination content. However, if you have any procedural questions, they will do their best to assist you.

• If you have a concern about the content of an examination question, please request a “Candidate Comment Form.”

• You must have the Test Center Manager’s permission to leave the examination room. You will NOT be allowed additional time to make up for time lost.

• Smoking will not be permitted in an examination room or in the restrooms, based on the October 1985 Florida Clean Indoor Air Act.

• Do not bring food into an examination room. If applicable, a lunch break will be provided. Drinks are allowed in spill proof containers. Children and visitors are NOT allowed in the test center.

• You are NOT permitted to take personal belongings such as briefcases, large bags, study materials, extra books, or papers into the testing room. Any such materials brought into the testing room will be collected and returned to you when you have completed the test. Pearson VUE and the Department are NOT responsible for lost or misplaced items.

• Under NO circumstances will you be permitted to work beyond the time allotted for the examination. Time limits are generous; you should have ample time to answer all questions and check all work.

Apparel

Please dress comfortably, but appropriately, for the examination. The examination room is usually climate controlled. However, it is not always possible to maintain a temperature suitable to each candidate, and from time to time there are maintenance problems beyond the Department’s or Pearson VUE’s control. It is suggested that you bring a sweater or jacket in case the temperature is cooler than your individual preference.

Change of Address

If an address change occurs after your examination administration, please make corrections at http://www.My-FloridaLicense.com or by completing the change of address form provided at the end of this booklet.

Change or Correction of Name

If you have a name change or correction, please send a copy of notarized legal documentation to the Central Take Unit-License Maintenance immediately.
Special Testing Accommodations

The Department of Business and Professional Regulation certifies that it will comply with the provisions of the Americans with Disabilities Act (42 USC Section 12101, et seq.) and Title VII of the Civil Rights Act, as amended (42 U.S.C.2000e, et seq.), in accommodating candidates who, because of a disability, need special arrangements to enable them to take an examination.

All applicants for an examination or a reexamination who desire special testing accommodations due to a disability must submit an application to the Special Testing Coordinator prior to each exam. The application can be found at: http://www.myfloridalicense.com/dbpr/servop/testing/documents/ada_applic.pdf?x40199.

The application for accommodation must be completed and returned to the Bureau of Education and Testing at:

Department of Business and Professional Regulation
Bureau of Education and Testing
Special Testing Coordinator
2601 Blair Stone Road
Tallahassee, Florida 32399-0791

For more information regarding special testing accommodations, please our visit webpage at: http://www.myfloridalicense.com/DBPR/examination-information/special-testing-accommodations/

V. Scoring Information and Grade Notification

Scoring Procedures

All questions are equally weighted. Examination scores are reported as percentage scores. The minimum percentage score needed to pass has been set at seventy-five percent (75%).

Notification of Results

All candidates will receive an official photo-bearing exam result report immediately following completion of their examination. Please verify that all information is correct on your exam result report prior to leaving the test center.

Examination Review and Fees

Candidates who fail an examination are entitled to review the questions they answered incorrectly, under such terms and conditions as may be prescribed by the Department of Business and Professional Regulation. Candidates are entitled to review only their most recent examination. The candidate shall be permitted to review only those questions the candidate answered incorrectly.

The request to review must be made within 21 days from the date of the examination and can be scheduled by going online to: http://www.PearsonVUE.com or by calling 1.888.204.6230. The same security requirements observed at the examination will be followed during the review session. Reviews will be held at a Pearson VUE testing center.

The fees associated with reviewing a Computer Based Testing examination are included in the following link: http://www.myfloridalicense.com/dbpr/servop/testing/documents/cbt_exam_admin_Fee_2016.pdf.
Review Session

The review session is considered to be an extension of the examination administration. Only the candidate may attend the review session. Proper identification is required to obtain entry. There will be no talking or note taking of any kind. Candidates are usually given one-half of the exam administration time. For example, a 2 hour and 30 minute examination will only receive 1 hour and 15 minutes to review. Candidate will not be able to see their original exam book since it is not retained, after the exam.

Challenge Process

Written challenges are accepted for DBPR developed examinations. Candidates are given an opportunity during the review session to note in writing, on the computer, any objections they have to questions answered incorrectly. The challenges are forwarded to the Bureau of Education and Testing for review by a Psychometrician and subject matter experts to determine if there is any merit to the candidate’s objection.

The response time to challenges, on average, is approximately 21 days. Due to the confidential nature of the examinations, the only response you will receive is “credit” or “no credit” for each challenged question. Credit will only apply to the candidate who reviewed and challenged. Per Rule 61-11.017(g) the candidate’s challenges must be submitted in writing during the scheduled review. Any challenges or supporting documentation submitted after the candidate has left the review room shall not be accepted.

For informal review and formal hearing procedures visit: http://www.myfloridalicense.com/DBPR/examination-information/examination-reviews-and-hearings/.

Reexamination Information

Beginning in April, a candidate who fails to achieve the required passing score on the examination must wait 30 days before retaking the examination. A candidate will have 18 months, from the date they are authorized to test, to pass the examination. After 18 months the candidate must reapply to the Department. Pertinent reexamination information is provided to all affected candidates along with the original grade report.
VI. Appendix

Points of Contact

Please contact the appropriate office for questions regarding the following:

Application Policies and Fees

Customer Contact Center
2601 Blair Stone Road
Tallahassee, Florida 32399-0791
850.487.1395

Scheduling, Grade Notification, and Reviews

Pearson VUE, Inc.
Customer Care at 1.888.204.6230
Website: www.PearsonVUE.com
Fax-Back System at 1.800.274.8920

Formal Hearings

Department of Business and Professional Regulation
Bureau of Education and Testing
2601 Blair Stone Road
Tallahassee, Florida 32399-0791
850.487.1395

Requests for Special Testing Accommodations

Department of Business and Professional Regulation
Bureau of Education and Testing
Special Testing Coordinator
2601 Blair Stone Road
Tallahassee, Florida 32399-0791
BETSTesting@myfloridalicense.com

For information regarding hotels or directions to the examination site, contact the chamber of commerce in the city where your examination has been scheduled.

Visit our website at:
http://www.MyFloridaLicense.com/DBPR
Please fill out the change of address form below and return to:

Florida Department of Business and Professional Regulation
Central Intake Unit – License Maintenance
601 Blair Stone Road
Tallahassee, Florida 32399-0791
Fax: 850.487.9529

Address Change Form

Please type or print in the appropriate spaces below if you have a change of address correction.

NAME: ________________________________

*SOCIAL SECURITY #: __________________

EXAMINATION DATE: __________________

CANDIDATE NUMBER: __________________

PHONE NUMBERS: __________________

Area Code/Home Number        Area Code/Work Number

OLD ADDRESS: _________________________

NEW ADDRESS: _________________________

SIGNATURE: _________________________

NOTE: If your name has changed, please use your prior name on this form and contact the Central Intake Unit for name change information.

*Under the Federal Privacy Act, disclosure of Social Security Numbers is voluntary, unless specifically required by Federal Statutes. In this instance, Social Security Numbers are mandatory pursuant to Title 42, United States Code, Sections 653 and 654; and Sections 455.203(9), 409.2577, and 409.2598, Florida Statutes. Social Security Numbers are used to allow efficient screening of applicants and licensees by a Title IV-D child support agency to assure compliance with child support obligations. Social Security Numbers must also be recorded on all professional and occupational license applications, and will be used for licensee identification pursuant to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Welfare Reform Act), 104 Pub.L. 193, Sec. 317.
# Common Abbreviations and Definitions

<table>
<thead>
<tr>
<th>Abbreviations</th>
<th>Definitions</th>
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<tbody>
<tr>
<td>DBPR</td>
<td>Department of Business and Professional Regulation</td>
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<tr>
<td>F.S.</td>
<td>Florida Statute</td>
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<tr>
<td>F.A.C.</td>
<td>Florida Administrative Code</td>
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<tr>
<td>BET</td>
<td>Bureau of Education &amp; Testing</td>
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<tr>
<td>ADA</td>
<td>Americans with Disability Act</td>
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<tr>
<td>CBT</td>
<td>Computer Based Testing</td>
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<tr>
<td>CE</td>
<td>Continuing Education</td>
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<tr>
<td>CIB</td>
<td>Candidate Information Booklet</td>
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<tr>
<td>BCAIB</td>
<td>Building Code Administrators and Inspectors Board</td>
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<tr>
<td>ICC</td>
<td>International Code Council</td>
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<tr>
<td>FBC</td>
<td>Florida Building Commission</td>
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<tr>
<td>CILB</td>
<td>Construction Industry Licensing Board</td>
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<tr>
<td>ECLB</td>
<td>Electrical Contractors’ Licensing Board</td>
</tr>
<tr>
<td>FAQ</td>
<td>Frequently Asked Questions</td>
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# Content Outline

<table>
<thead>
<tr>
<th>Content Areas</th>
<th>Percentage of Exam</th>
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<tbody>
<tr>
<td><strong>I. Product Integrity:</strong></td>
<td></td>
</tr>
<tr>
<td>A. General</td>
<td></td>
</tr>
<tr>
<td>B. Storage</td>
<td></td>
</tr>
<tr>
<td>C. Recalls</td>
<td>27.5%</td>
</tr>
<tr>
<td>D. Quarantine</td>
<td></td>
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<tr>
<td>E. Returns</td>
<td></td>
</tr>
<tr>
<td>F. Security</td>
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<tr>
<td><strong>II. Records</strong></td>
<td>25%</td>
</tr>
<tr>
<td><strong>III. Inspections</strong></td>
<td>12.5%</td>
</tr>
<tr>
<td><strong>IV. Authorized Recipients</strong></td>
<td>10%</td>
</tr>
<tr>
<td>**V. Lawful/Unlawful Products</td>
<td>10%</td>
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<tr>
<td><strong>VI. Permits and Renewals</strong></td>
<td>10%</td>
</tr>
<tr>
<td><strong>VII. CDR Requirements</strong></td>
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</tr>
</tbody>
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# References

I. **Chapter 499 Florida Statutes** - All sections relating to prescription drugs
   Chapter 499 Florida Drug and Cosmetic Act

II. **Chapter 61N-1, Florida Administrative Code** - All sections relating to prescription drugs
    Rule Chapter: 61N-1 Regulations for Drugs, Devices and Cosmetics

III. **Code of Federal Regulations (CFR)**
    Title 21 Code of Federal Regulations (CFR) Food and Drug
    A. Part 205.2
    B. Part 205.3
    C. Part 205.4
    D. Part 205.50
    E. Part 205.6
    F. Part 205.8
    G. Part 1301.71 and 72
IV. United States Code (USC)
Title 21 United States Code Food and Drugs
A. Chapter 9 Subchapter II Section 321
B. Chapter 9 Subchapter III Section 331
C. Chapter 9 Subchapter III Section 333
D. Chapter 9 Subchapter V Section 351
E. Chapter 9 Subchapter V Section 352
F. Chapter 9 Subchapter V Section 353
G. Chapter 9 Subchapter V Section 360eee
H. Chapter 9 Subchapter V Section 360eee-1
I. Chapter 9 Subchapter V Section 360eee-2

Content Description
The following content descriptions provide candidates helpful information and general guidance regarding items that may be tested on the examination. The content descriptions are not an exhaustive list of items that may be included on the examination. Candidates should be familiar with all reference materials indicated above and the Division reserves the right to test on any items contained in those specific references.

Product Integrity:
Candidates should be familiar with the definitions found in section 499.003, Florida Statutes (hereinafter FS), storage, handling and recordkeeping set forth in section 499.0121, FS, and adulterated and misbranded drugs or devices set forth in sections 499.006 through 499.007, FS. In addition, candidates will see examination questions regarding prohibited acts as set forth in section 499.005, FS. Candidates should know the application requirements for establishments set forth in section 499.012, FS, including specific issues regarding establishments in residences. Candidates should be familiar with drug samples and their permissibility as set forth in section 499.028, FS. Maintenance of records as set forth in Rule 61N-1.012, Florida Administrative Code (hereinafter FAC), will also be tested on the exam. Questions regarding the receipt, storage and security of prescription drugs in Rule 61N-1.013, FAC, will be included on the examination. Candidates should familiarize themselves with the definitions and wholesale distributor requirements of product tracking and tracing in Rules 61N-1.028 and 61N-1.030, FAC. Finally, sections of Rules 61N-1.023 and 61N-1.0301, FAC, and Title 21 CFR 205.50 will be tested.

Records:
Candidates should be aware of the definitions covered under Rule 61N-1.001, FAC. Records of drugs, cosmetics and devices from Rule 61N-1.012, FAC, will be covered under this section, as well as the appropriate time to notify the Department of a security threat as found in Rule 61N-1.013, FAC. Candidates will be tested on: the prohibited acts from sections 499.005, FS, inspections and investigations from section 499.0051, FS, recordkeeping, prescription drug purchase list, and written policies and procedures under section 499.0121, FS. Candidates should expect examination questions inspections and investigations from section 499.051, FS. Parts of 21 CFR 205.50 will also be tested during the examination. Finally, the definitions and wholesale distributor requirements for product tracking and tracing as covered in Rules 61N-1.028 and
61N-1.030, FAC and 21 USC sections 360eee through 360eee-2 will also be tested in this section of the examination.

**Inspections:**
Inspections and investigations as well as imminent dangers from sections 499.051 and 499.065, FS, and Rule 61N-1.019, FAC, will be covered under this section. Candidates should also expect to see questions that cover compliance with federal, state and local law in section 499.0121, FS, and be familiar with the Department’s role in enforcing and administering parts of section 499.002, FS. Finally, candidates should review and have a general familiarity with Rule 61N-1.015, FAC and section 499.012, FS.

**Authorized Recipients:**
This section covers definitions from section 499.003, FS, and Rule 61N-1.001, FAC. The examination will contain questions on prohibited acts such as the sale or transfer of a prescription drugs to unauthorized person in section 499.005, FS, and possession of certain drugs without lawful prescriptions and exceptions thereto pursuant to section 499.03, FS. Candidates should also be familiar with the differing types of permits and their scopes of work set forth in section 499.01, FS. Candidates should be ready to answer questions on exceptions and specific distributions authorized for wholesale distribution of prescription drugs set forth in Rule 61N-1.011, FAC. Restricted prescription drug distributor permits and related provisions in Rule 61N-1.023, FAC, will be included on the exam. Finally, parts of sections 499.0121 and 499.055, FS, and Rules 61N-1.012, 61N-1.015, 61N-1.028 and 61N-1.031, FAC, should be reviewed.

**Lawful and Unlawful Products:**
The areas covered under this section will include definitions under section 499.003, FS, prohibited acts under section 499.005, FS, and adulterated and misbranded drugs or devices in sections 499.006 through 499.007, FS. Candidates will see items covering the sale, manufacture, repackaging and distribution of new drugs in section 499.023, FS. In addition, examination questions regarding ephedrine from sections 499.033, FS, the seizure and condemnation of drugs, devices, or cosmetics under section 499.062, FS, and the imminent danger arising from inspections under section 499.065, FS, will be included on the examination. Finally, candidates should be familiar with the penalties associated with selling or purchasing contraband prescription drugs under section 499.0051, FS.

**Permits and Renewals:**
Candidates should be aware of the definitions covered under section 499.003, FS, and Rule 61N-1.001, FAC. In addition, candidates will be tested on permit and application requirements set forth in sections 499.01 and 499.012, FS, and Rule 61N-1.015, FAC. Finally, candidates will be tested on sections 499.005, 499.028 and 499.067, FS.

**CDR Requirements:**
This section will cover permit application requirements set forth in section 499.012, FS. Candidates will also be tested on cease and desist orders and the removal of certain persons set forth in section 499.0661, FS. Finally, examination questions regarding definitions, licensing, permitting and application requirements from Rules 61N-1.001 and 61N-1.015, FAC will be included on the examination.