AGENDA
Department of Business and Professional Regulation
Drug Wholesale Distributor Advisory Council

Florida Department of Business and Professional Regulation
2601 Blair Stone Road, Bldg. B
Tallahassee, FL 32399

Conference Call Number: 1-888-585-9008
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September 12, 2019
9:30 a.m.

Council Members:
Steve Mays, Chair, Prescription Drug Wholesalers
Jeenu Philip, Vice Chair, Board of Pharmacy
Joseph Lavino, CVS Health, Retail Pharmacy
Michael Mone, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Ariene 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:
Walter Copeland, Division Director
Halsey Beshears, Secretary
Tim Page, Deputy Secretary
Renee Alsobrook, Compliance Manager
Stephanie Prine, Government Operations Consultant
Rebecca Burnett, Regulatory Supervisor

Call to Order: Steve Mays, Chair

TAB 1: Chair's Report – Steve Mays, Chair
  a. June 13, 2019 Meeting Transcript (information only) – pg. 1
  b. 499.01211, F. S. – Drug Wholesale Distributor Advisory Council – pg. 9

TAB 2: Division Director's Report – Walter Copeland
  a. Legislative Update
     a. HB-19 (Laws of Florida 2019-99 provided) – pg. 10
  b. Safe Importation Action Plan – pg. 37
  c. Shop Smarter for Dental Supplies – pg. 41
  d. Disciplinary Information
     a. Compliance and Enforcement Unit Report – pg. 78

TAB 3: Other Business

*Page numbers in RED correspond with the page numbers in the lower right corner on page documents NOT the computer page number.
MR. MONE: That is close enough. Present.
MS. PRINE: Scott Brock.
MR. BROCK: Here.
MS. PRINE: Arlene Elliott.
MS. ELLIOTT: Present.
MS. PRINE: Dean Ellis.
MR. ELLIS: Present.
MS. PRINE: Jeffrey Tuller.
MR. TULLER: Present.
MS. PRINE: Patrick Barnes.
MR. BARNES: Present.
MS. PRINE: Peter Hart. Peter Hart.

Jennifer Goldman.

CHIEF ALSOBROOK: Dr. Goldman.

MS. PRINE: All right, and staff in
Tallahassee, we have myself, Stephanie Prine,
Renee Alsbrook, Rebecca Burnett, Curt Bender,
Kathryn Price and Director Walter Copeland.

CHAIRMAN MAYS: All right, thank you.
MS. PRINE: And you have a quorum, so we
can get started.

CHAIRMAN MAYS: Okay, great, thanks.
Okay, I want to start the meeting off as usual
by reading the goals of council as stated in
Chapter 499.01211 of Florida Statutes. The
council shall review the (inaudible) 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
agency and the federal government concerning
the wholesale distribution of drugs. Make
recommendations to minimize the impact of
regulation of the wholesale distribution
industry while ensuring protection of the
public health.

So for the Chairs' report today I want to
first welcome the new Division Director Walter
Copeland and the new government operations
consultant Stephanie Prine to the council.

As you all no Drew and Dina have moved on
to another department. So Mr. Copeland, would
you like to give the council a brief
introduction, tell us a little about yourself?

DIRECTOR COPELAND: Absolutely, and glad
to meet all of y'all over the phone. I think
I have corresponded by e-mail. But I am going
on the six-week here in the role,

And to give you a little quick blurb on my
past, prior to joining — joining DDC here, I
served as the Chief Financial Officer with the
Madison, Florida School District. And prior to
that spent my career in the private sector as a
CFO with some convenient store chains, a
consulting and CPA firm, and I have spent some
time right when all the stuff hit the fan in
banking, I was a bank President with the
Wachovia Bank.

Again, I am going on my six weeks here,
it is a great team. They have instructed me
well, I am trying to get up to speed on some
of the details I need to get up to speed on,
and I appreciate all the acceptance and however
I can help or find help, always reach out to me
and I will work to do that,

CHAIRMAN MAYS: Okay, Mr. Prine, would
you like to say anything?

MS. PRINE: Good morning, I am, well I
have been with DDC since January, I came from
a 15-year career with a Department of Health,
So I am glad to be here, glad to learn new

things and just continue, continue my growth
here with the division.

CHAIRMAN MAYS: Great, Thank you guys,
and welcome to the council.
Secondly under the Chair’s report and
under tab one you will find a transcript of our
last meeting conducted on March 10th for
informational purposes. So do we have any
questions from council members or interested
parties on the line?

All right. We will now turn it over to
Mr. Copeland for the Division Director’s report
under tab two.

DIRECTOR COPELAND: Absolutely, Some of
these items being new on board, I am going to
defer to Chief Alsobrook. I am going to let
her handle A and I will handle B, and if you
don’t mind.

CHIEF ALSOBROOK: Good morning everybody,

CHAIRMAN MAYS: Good morning.

CHIEF ALSOBROOK: The CDR report is under
tab two, I just wanted to give everybody an
update of the effectiveness of the work that we
have done at your request on the CDR exam,
As you know last year we worked on those

revisions to the candidate booklet, providing a
little additional information as to the areas
where the exam would test.

Mr. Mone worked with the Board of Testing
to review the questions, giving us some input
on that kind of information. The effectiveness
of the test, the work, excuse me, does appear
to have paid off as the testing rate has
increased, and we have included that
information in the materials for you, also,
The test rate appears to have increased
from the 30 percentiles to the 50 percentile
tile. So we are very pleased at that, that
testing rate has increased and we wanted to
make sure that you were aware of that.

So if you have any questions concerning
the CDR exam and the SLA, please let me know,
And again, thank you for those who participated
in assisting us with — with these revisions.

CHAIRMAN MAYS: Okay, Thanks for that
update. Any questions from the council members
or anyone else on the line? Okay.

DIRECTOR COPELAND: Okay, I am going to
give you a broadbrush overview of House Bill
19 which is the foreign prescription drug

importation program that were signed in the law
I believe Monday, and I want to go through a
broadbrush overview of that, if you have any
specific questions I will try to answer or
Chief Alsobrook or Kathryn, Ms. Price in legal,

But basically what the Bill does is it
allows Florida or directs us to put into play
two different foreign prescription drug
importation program.

The first one is the Canadian program, and
that program is led by AHCA. And so we are
working with them diligently in assisting,
There is a lot of common areas between the
Canadian program that AHCA oversees and the
international program that falls under DPBR.
Even though the Bill is effective July
1st, ‘19, but those programs under the Bill
require approval by the federal government and
the United States, HHS. We are in the
progress now of building our proposals under
the international prescription drug side of it,
and in doing that, the Bill directs here at
DDC, we are work with the Department of Health
on the international program to develop the
proposal or HHS approval. We are working
They have been a great deal of help and we
have got a pretty short timeline on this thing.
We had an initial projection, projected
timeline for the first draft of our proposal of
August 31st. I think that is going to be moved
up closer to August the 1st now.
And again, I will let Chief Alsobrook get
into any of the details that you all may have,
but I will tell you that we are working
diligently on the proposal. It is the biggest
ting thing we have going on, and we are
collaborating well with Department of Health
and with the Agency for Health Care
Administration to work together on this.

So that is kind of the broadbrush
overview, I was expecting some hard questions,
CHAIRMAN MAYS: I guess are you expecting
to do some rulemaking at some point?
CHIEF ALSOBROOK: Chairman Mays, this is
Renee, We will not do any rulemaking until the
Health and Human Services approves the proposal
submitted by the Department. Assuming that
there is approval of the proposal, then there
would be rulemaking.

CHAIRMAN MAYS: Makes sense.
DIRECTOR COPELAND: And Chair, when we
developed our implementation plan, we broke it
down into two segments. The first one is the
necessary tasks to build the proposal with the
detail that we needed, and then as you referred
to rulemaking, implementation of the permit and
the registration required by the Bill, we would
put into play after the approval.
But what we have done is we have already
reached out to every other division and portion
that would have a part of building the
implementation. So as soon as we get the
approval and/or the go ahead from leadership,
we are ready to run with actually putting the
program together and into play.
CHAIRMAN MAYS: Thanks. Thanks for that.
CHIEF ALSOBROOK: Chair, Chairman Mays, I
can tell you that in our meetings with the
Department of Health, the Board of Pharmacy at
its June meeting, I believe June 18th, next
week we will be reviewing House Bill 19. I don’t
know if the Florida law number for this Bill,
but will be reviewing provision of the Bill
that creates the international export pharmacy
permit. And they probably will be considering
it for rulemaking purposes.

So, you know, because it is a collegial
body and they have to act only when they are
meeting, that will be taking place,
Conversations about that will be taking place
in June.

But again, their ability to act as an
exporter would be contingent upon the approval
of the plan as I read the Bill now. Now, I
don’t think how the Board or the Board’s
counsel will read that Bill, but to be, you
know, not misread the council or leave out
information, I did want to make sure that you
were aware that they have agendaed this topic
at the Board meeting next week.

CHAIRMAN MAYS: Yes.
CHIEF ALSOBROOK: If you have the Bill,
that is on line 390. It is section two, it
starts on line 388 of the Bill within your
material. That is the international permit.
And that falls under this agenda, excuse me,
falls under the authority and it goes on for
two pages. I am sorry, I didn’t hear you.

A VOICE: Yes, just to kind of jump on

what Ms. Alsobrook said. So the Board next
week will be looking at doing a few things.
One is amending 64B-16.28100 which is the
pharmacy permit rule. And so we are looking at
adding a new permit type and application for --
for this dubious statutory change.

In addition to that, we will be looking at
developing some disciplinary guidelines for the
international export pharmacy permit. So they
are requiring that the Board of Pharmacy do it
from a rulemaking process standpoint.

CHAIRMAN MAYS: Thanks. Any other
questions from council members?

MR. PHILIP: Yes, this is Jeenu again. I
guess I understand that the -- that
the Canadian program is I guess is intended for
like jails and other the state run facilities
for patients. And then the international
program is I guess intended for, you know,
everyone else.

So maybe a question for Ms. Alsobrook. So
it is my understanding that AHCA or the
Department will be looking at creating a
listing of drugs for the Canadian program. Do
you remember if any -- if there is any such
requirement for the international export pharmacy program, or is it, you know all drugs?

CHIEF ALSOBKROOK: This is Renee again. There are prohibitions against certain drugs that cannot be brought into the states. I am trying to find that citation for you. Give me just one minute, I did bring it. If you look at lines 1046, No, that is not it.

CHAIRMAN MAY: Maybe start 201 maybe.

MR. PHILIP: Yes, it is 1039, prescription drugs.

CHIEF ALSOBKROOK: Yes. Those are the drugs. What I am doing is I have had our pharmacists go through a list of drugs that I got through the Department of Management Services, because one of the things we want to look at is potential cost savings, and the list that I got from the Department of Management Services is a list of drugs that you know, we have in our pharmacy benefit plan and that is a pretty extensive list of drugs.

To try and go through and give me an idea of what type of drugs are excluded, because I am not a pharmacist, so I don’t know. I mean, I know what a controlled substance is, but I don’t know these others. So they’re trying to give me an idea what kind of drugs would be excluded.

But the idea is to present a couple of options, the Director wants me to come up with a couple of options. If we had a limited list of drugs that would save you, know, the most money for the State of Florida and are fairly safe drugs, and then if we had a more expanded list of drugs that would be allowed to be imported.

So there are a couple of options that would possibly be presented as a program to the United States Health and Human Services. So that final decision hasn’t been made by the Division Director and the Secretary asked, too, whether all drugs would be allowed to come in that are not specifically excluded by the legislation or if it would be a more limited list initially.

DIRECTOR COPELAND: This is Walter. And if I can interject real quick, I think Chief Alsobrook and I in looking at different options, we are, you know, we are trying to see around corners and you don’t have much to reference in what obviously HHS is looking for. But even if we did have a compromise list of the drugs that would qualify under the Bill, we also want to take into account maybe even though there is some drugs that qualify, maybe there is some that would give HHS heartburn otherwise.

So we are trying to think of the best presentation that would be more likely to give us a yes. So that is what we are working through the details right now. And absolutely to start with we want the comprehensive list and when we make — we are eliminating some, is that correct?

CHIEF ALSOBKROOK: That is absolutely correct. Okay, we want to be able to assure in our proposal to the extent that we can, that we can avoid adulteration, counterfeit, expired drugs, and the more you get away from higher priced drugs, the more likely you are to be able to eliminate those types of issues that obviously are concerns of all regulators.

So that is the assessment that the Director and the Secretary will have to make. And at this stage of drafting the proposal we just are still gathering information to know how we are going to present that. I mean, it is a big — it is a big decision. It is a lot of ideas circulating.

Now, the Canadian proposal, obviously they are have already information from the central pharmacy at Department of Health as to the drugs that are being provided to Department of Corrections.

They already have information on drugs that are being provided wards of the state, the term that I also use by the way. So they already have an idea of the types of drugs they’re going to ask the United States Health and Human Services to allow them to import from Canada, because they have that data already in existence.

But we obviously do not have necessarily that population to — we may not have those drugs or want those drugs, you know. We are not necessarily going to be treating tuberculosis in the prisons to the general population. So we may not want to include those types of drugs as an example,

MR. PHILIP: The other question I had was
around (inaudible). So the international wholesale distributors and I guess exporters in general and importers need to follow the U.S. track and trace law.

CHIEF ALSOBROOK: Yes, sir. Well, the provisions will obtain a license would require that they comply with that law. If they won’t agree to do that, then they won’t get a permit.

We understand that as a foreign entity that necessarily they would not have to comply with the tracking and tracing requirements, but to obtain the Florida permit then they would have to agree to comply with those provisions of tracking and tracing, as well as the federal labeling requirements which means that the drugs are going to have to be in English because that is what the FDA requires.

So we know that there is going to be the international wholesale distributor is going to have to comply substantially with the same requirements that a current wholesale distributor located in the United States has to comply with, including having a CER, bonds, etcetera, that are required as well as inspections. Now, can they be inspected as

often as the U.S. based wholesale distributor, we are going to have to figure out that. The Director would talk to you about they only give us $3,000 to conduct those inspections. And the last time I tried to buy a plane ticket out of the country, $3,000 barely paid for it.

So you know, that may be an issue. But the requirement for compliance with U.S. law are written into the Bill and would be applicable to these international wholesale distributors.

CHAIRMAN MAYES: Ms. Alsobrook, the definition of importer in the Bill, the wholesale distributor pharmacy or pharmacist import a prescription drugs into the state under the program.

CHIEF ALSOBROOK: Yes, sir.

CHAIRMAN MAYES: In the pilot program do you believe that that would be part of the pilot program also, to include all entities?

CHIEF ALSOBROOK: Yes, sir. I know I looked at that myself and thought a pharmacist has never been a distributor in my entire career, but the Legislature can make decisions that they don’t ask me for permission to make.

So I find it intriguing, I wonder about errors and omission insurance, but that is up to the pharmacist.

CHAIRMAN MAYES: I appreciate the information.

CHIEF ALSOBROOK: And for international line 1011, that is the definition of importer.

CHAIRMAN MAYES: Ms. Alsobrook, this is Steve Mays. And I assume the requirement that they comply with the DSCS requirements, like, you know, that they’re labeling also includes the serialization requirements that are being implemented?

CHIEF ALSOBROOK: Yes, sir. They specifically reference the Drug Quality Security Act, 21 USC 351 S Sequel, et al. And they reference the Federal Act that define it under 301 on line 999. It is defined as the Federal Act.

So it would appear to me that they have to put everything including product identifiers their product.

CHAIRMAN MAYES: Thank you. Any other questions from council members? Any other interested parties on the line have any questions? Okay, Mr. Copeland,

DIRECTOR COPELAND: On the 7073 and Chief Alsobrook, you drop in anytime if I miscalculate on anything. But basically setting – setting the fees related to the international prescription drug distributor, and I think it sets the maximum at 800 per the permit,

And also addresses the fees for on-site inspection related to these four distributors, and the maximum there would be $3,000. So as you are aware we are looking at a lot of – a lot of moving parts and not a lot of inflow.

So that is the gist, that is basically the gist of that Bill.

A VOICE: (Inaudible). There are several options that we have to weigh that the Department wants to choose to get it before HHS, but some of the options are adversarial in nature and we don’t want end up in a position where we are on the opposite side of HHS. So we know who is going to win that one.

CHIEF ALSOBROOK: That was Ms. Prime.

A VOICE: I spoke out of turn.

CHAIRMAN MAYES: I am sorry, go ahead.

CHIEF ALSOBROOK: We are just going to
say, we got a long, hot summer coming.

CHAIRMAN MAYES: Ms. Alsobrook, this is Steve. One question. I just kind of had a thought. Would there be any possibility of requiring those Canadians or international distributors since you have kind of limited resources to be able to do an inspection, to possibly work with NABP to do some sort of like a broad inspection or what would require them to be accredited somehow? That way they would pay the cost of the inspection.

CHIEF ALSOBROOK: That is certainly something we will consider as part of our rule. Because it does, the statute does allow us to utilize, I believe other inspections or consider other inspections.

CHAIRMAN MAYES: Yes.

CHIEF ALSOBROOK: You know, the session this year, committee starts September and they go and the Legislature starts in January. And if that is something that we need to look at, that might be a good time to tweak the Bill follow allow that if we get approval for the plan, because that is something, you know, one of the things that is obvious is if this is going to cost more than it saves, then what is the point.

So if -- if having the importers, excuse me, the exporter, also the distributor, have their own inspection, that is not going to cost the State of Florida, therefore, it is going to save the State of Florida money, that might be an argument to have the Legislature add that as a possibility to the Bill. So that was a very significant suggestion, I appreciate that.

Chair Mays.

CHAIRMAN MAYES: You are welcome. I just think our biggest, as yours is I know, you know, our biggest priority is the safety of the drugs, and you know, you can't -- if you can't be sure that they are getting adequately inspected for compliance with -- with the requirements, you know, it makes it a little challenging, a little scary.

CHIEF ALSOBROOK: Well, and that agency does have a good reputation for performing those inspections and making good decisions regarding entities that they in inspect, I think they are credible.

MR. FLYNN: Mr. Chairman, this is David Flynn, counsel for the Board of Pharmacy. If I may be recognized for one moment, please.

CHAIRMAN MAYES: Sure, go ahead.

MR. FLYNN: This is David Flynn, and I will be working on House Bill 19 on behalf of the pharmacy. I just wanted to state at least for the international export pharmacy permit, there is when it comes to inspections, and an approving of inspection entities, we had to do this in 2014, and the legislation is similar to 2014 legislation. 

So the Board will have the opportunity at least for the international export pharmacy permit, by rule to determine inspection and inspection reports or entities determined by the Board, and in the past the Board has approved NABP through the rulemaking process to be an inspector for our special compounding permits.

So in regards to having another entity, so we do have experience with that and that has worked out well and the Board will have to be looking at that as far as the international export pharmacy program. It does require the inspection and we will be either using the Department, using the jurisdiction inspection which meets our Florida treaty entities through any rulemaking process to ensure that there is a proper inspection for the international export pharmacy program. Thank you.

CHIEF ALSOBROOK: Welcome back, David.

MR. FLYNN: Thank you so much, it is good to be back.

CHAIRMAN MAYES: Thank you, David. Any other questions on this section from council members or interested parties? Okay, Mr. Copeland, I think we have got it. Do you have one more item?

DIRECTOR COPELAND: Why don't you take that?

CHIEF ALSOBROOK: Thank you, Director. At the last meeting I believe we -- we, Mr. Tullor, up may have asked me if I had any data on the number of violations that we found pursuant to our inspections, And so I went through and gathered some data and I just wanted to present that to you.

During the 2018 calendar year, we collected a number of inspections on facilities, routine inspections, and I divided
records at other facilities that show that the
other facilities are purchasing drugs from
unauthorized -- unauthorized pharms or are
selling to unauthorized recipients.

We kind of rank the violation in reference
to a risk as purchasing from unauthorized and
selling to unauthorized individuals or pharma
as a serious violation. We are obviously
cognizant of the greater danger to the public
with prescription drugs and over the counter
drugs than cosmetics.

So that is kind of information that I
thought you wanted and I was able to get for
you. Any questions on that?

MR. MONE: Mr. Chairman,

CHAIRMAN MAYS: Yes,

MR. MONE: This is Michael Mone. I
appreciate the data. I think what would be
more beneficial to both me as an individual and
the industry as an entity, is to take this data
as it relates to the inspection violations and
drill down one step deeper and indicate under
the rule or the statute that the Department
found to be a violation, so that the industry
could take that information and action off of

it and look at this is what you are seeing
across the board.

Let's make sure that our locations don't
have this violation, I would hope we could
dwell down one step further.

CHAIRMAN MAYS: Yes, thank you, Mr. Mone.

Ms. Alsobrook, I would tend to agree. I know
from my experience, you know, we actually as a
company we actually will share all of our audit
reports of our other distribution centers and I
know you couldn't do that as far as sharing
that much detail with the regulated industry,
but I think if we could break that down into
maybe types of violations or at least as
Michael said, even though the section of the
statute that was in violation of, that would be
very helpful if that is possible to do.

CHIEF ALSOBROOK: Absolutely.

CHAIRMAN MAYS: Great.

CHIEF ALSOBROOK: Whether it will be
beneficial would be questionable, because I
doubt it is going to improve the performance,
but I will certainly get you the data.

CHAIRMAN MAYS: Thank you, I appreciate
that. Any other --
CHIEF ALSOBROOK: Yes.
MR. HART: This is Peter Hart.
CHIEF ALSOBROOK: Hey, Peter.
MR. HART: First to the committee my apology for appearing late. The pressures of the day got away from me. So I apologize for that.

The question I have for you, Chief Alsobrook, is on the medical gas you talked about the violations involving complaints with prescription requirements. You were asked if you noticed — I apologize for the background noise, contractors everywhere in my neck of the woods.

In reference to prescriptions did you find that to be more on the retail aspect of product prescription or more on the wholesale application? And if you didn't break it out that way that is perfectly fine as well.

CHIEF ALSOBROOK: Those were primarily, Mr. Hart, they were primarily in the retail setting and it is primarily without of state companies trying to run businesses with hospices offering what may have been — well to describe as pharmacy benefit services or durable medical equipment services acting as an intermediary between the hospice and the medical gas retailer and not providing the medical gas retailer with a prescription from the hospice.

And it is a situation that we are trying to resolve with the companies that are wanting to contract with the hospice and then contract with a retailer, but not give the retailer the actual prescription. Do you understand what I saying?

Yes, we go in and do the inspection of the retailer, they don't have an actual prescription to show us. They just have a rubber stamp from somebody's computer.

MR. HART: Thank you for the clarification.

CHAIRMAN MAYS: Jenny? Did I hear someone? Any — any other questions from council members or interested parties on the line? Ms. Alsobrook or Mr. Copeland, do we have any other business?

DIRECTOR COPELAND: I do not at this time. I am sure going forward I will have more stuff to bring up, but right now I don't. Chief

Alsobrook, do you have anything?

CHIEF ALSOBROOK: I do not, sir.

CHAIRMAN MAYS: Well, I think it has been a productive call and again, welcome Mr. Copeland, Ms. Prime to the council meeting and we look forward to the next one. I guess the last order of business, I just want to ask anyone on the line, is there any other business? Okay. Hearing none, do we have a motion to adjourn?

MR. PHILIP: Motion to adjourn, this is Jeenu Philip.

MR. BARNES: Second, this is Patrick Barnes.

CHAIRMAN MAYS: Do we have a second? We do. All in favor say aye.

(Chorus of ayes.)

CHAIRMAN MAYS: Opposed. Okay, The meeting is adjourned. Thank you very much.

(Whenupon, the meeting was adjourned.)

STATE OF FLORIDA )
COUNTY OF LEON )
I hereby certify that the foregoing transcript is of a tape-recording taken down by the undersigned, and the contents thereof were reduced to typewriting under my direction;

That the foregoing pages 01 through 31 represent a true, correct, and complete transcript of the tape-recording;

And I further certify that I am not of kin or counsel to the parties in the case; am not in the regular employ of counsel for any of said parties; nor am I in anywise interested in the result of said case.

Dated this 12th day of August, 2019.

CLARA C. ROTRUCK
Notary Public
State of Florida at Large
Commission Expires: November 15, 2022
Commission No.: GG 272880
### The Florida Senate

#### 2018 Florida Statutes

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#### 499.01211 Drug Wholesale Distributor Advisory Council.—

1. There is created the Drug Wholesale Distributor Advisory Council within the department. The council shall meet at least once each calendar quarter. Staff for the council shall be provided by the department. The council shall consist of 12 members who shall serve without compensation. The council shall elect a chairperson and a vice chairperson annually.

2. The Secretary of Business and Professional Regulation or his or her designee and the Secretary of Health Care Administration or her or his designee shall be members of the council. The Secretary of Business and Professional Regulation shall appoint 10 additional members to the council who shall be appointed to a term of 4 years each, as follows:
   
   a. Three persons, each of whom is employed by a different prescription drug wholesale distributor permitted under this part which operates nationally as defined in s. 499.003.
   
   b. One person employed by a prescription drug wholesale distributor permitted under this part as defined in s. 499.003.
   
   c. One person employed by a retail pharmacy chain located in this state.
   
   d. One person who is a member of the Board of Pharmacy and is a pharmacist licensed under chapter 465.
   
   e. One person who is a physician licensed pursuant to chapter 458 or chapter 459.
   
   f. One person who is an employee of a hospital licensed pursuant to chapter 395 and is a pharmacist licensed pursuant to chapter 465.
   
   g. One person who is an employee of a pharmaceutical manufacturer.
   
   h. One person who is an employee of a permitted medical gas manufacturer or medical gas wholesale distributor and who has been recommended by the Compressed Gas Association.

3. 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 distribution industry while ensuring protection of the public health.


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CHAPTER 2019-99

Committee Substitute for House Bill No. 19

An act relating to prescription drug importation programs; creating s. 381.02035, F.S.; requiring the Agency for Health Care Administration to establish the Canadian Prescription Drug Importation Program; defining terms; requiring the agency to contract with a vendor to facilitate wholesale prescription drug importation under the program; providing responsibilities for the vendor, including the payment of a bond; providing eligibility criteria for prescription drugs, Canadian suppliers, and importers under the program; authorizing a Canadian supplier to export drugs into this state under the program under certain circumstances; providing eligibility criteria and requirements for drug importers; requiring participating Canadian suppliers and importers to comply with specified federal requirements for distributing prescription drugs imported under the program; prohibiting Canadian suppliers and importers from distributing, dispensing, or selling prescription drugs imported under the program outside of this state; requiring the agency to request federal approval of the program; requiring the request to include certain information; requiring the agency to begin operating the program within a specified timeframe after receiving federal approval; providing certain documentation requirements; requiring the agency to suspend the importation of drugs in violation of this section or any federal or state law or regulation; authorizing the agency to revoke the suspension under certain circumstances; requiring the agency to submit an annual report to the Governor and the Legislature by a specified date; providing requirements for such report; requiring the agency to notify the Legislature upon federal approval of the program and to submit a proposal to the Legislature for program implementation and funding before a certain date; requiring the agency to adopt necessary rules; creating s. 465.0157, F.S.; establishing an international export pharmacy permit for participation in the International Prescription Drug Importation Program; providing requirements for permit application and renewal; requiring the Department of Health to adopt certain rules governing the financial responsibility of the pharmacy permittee; amending s. 465.017, F.S.; authorizing the department to inspect international export pharmacy permittees; amending s. 499.005, F.S.; providing that the importation of a prescription drug under the International Prescription Drug Importation Program is not a prohibited act under that chapter; amending s. 499.0051, F.S.; providing an exemption from prosecution as a criminal offense for the importation of a prescription drug for wholesale distribution under the International Prescription Drug Importation Program; amending s. 499.01, F.S.; requiring an international prescription drug wholesale distributor to be permitted before operating; requiring nonresident prescription drug manufacturers to register with the Department of Business and Professional Regulation to participate in the program; providing an exception; establishing an international prescription drug

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wholesale distributor drug permit; providing permit requirements; requiring the Department of Business and Professional Regulation to adopt certain rules governing the financial responsibility of nonresident prescription drug manufacturer licensee or permittee and international prescription drug wholesale distributor permittees; amending s. 499.012, F.S.; providing application requirements for international prescription drug wholesale distributors and nonresident prescription drug manufacturers to participate in the program; amending s. 499.015, F.S.; establishing that prescription drugs imported under the International Prescription Drug Importation Program are not required to be registered under a specified provision; amending s. 499.065, F.S.; requiring the department to inspect international prescription drug wholesale distributor establishments; authorizing the department to determine that an international prescription drug wholesale distributor establishment is an imminent danger to the public and require its immediate closure under certain conditions; creating s. 499.0285, F.S.; requiring the department to establish the International Prescription Drug Importation Program for a specified purpose; providing definitions; providing eligibility criteria for prescription drugs, exporters, and importers under the program; requiring participating importers to submit certain documentation to the department for prescription drugs imported under the program; requiring the department to immediately suspend the importation of specific prescription drug or the importation of prescription drugs by a specific importer if a violation has occurred under the program; authorizing the department to revoke such suspension under certain circumstances; requiring the department to adopt necessary rules; requiring the agency, in collaboration with the Department of Business and Professional Regulation and the Department of Health, to negotiate a federal arrangement to operate a pilot program for importing prescription drugs into this state; providing that implementation of the act is contingent upon the federal authorization; requiring the department to notify the Legislature before implementation of the pilot program and to submit a proposal for pilot program implementation and funding; providing an effective date.

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

Section 1. Section 381.02035, Florida Statutes, is created to read:

381.02035 Canadian Prescription Drug Importation Program.—

(1) PROGRAM ESTABLISHED.—The Agency for Health Care Administration shall establish the Canadian Prescription Drug Importation Program for the importation of safe and effective prescription drugs from Canada which have the highest potential for cost savings to the state.

(2) DEFINITIONS.—As used in this section, the term:

(a) “Agency” means the Agency for Health Care Administration.

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(b) "Canadian supplier" means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.

(c) "County health department" means a health care facility established under part I of chapter 154.

(d) "Department" means the Department of Health.

(e) "Drug" or "prescription drug" has the same meaning as "prescription drug" in s. 499.003, but is limited to drugs intended for human use.


(g) "Free clinic" means a clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to low-income recipients.

(h) "Medicaid pharmacy" means a pharmacy licensed under chapter 465 that has a Medicaid provider agreement in effect with the agency and is in good standing with the agency.

(i) "Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy pursuant to chapter 465.

(j) "Program" means the Canadian Prescription Drug Importation Program.

(k) "Track-and-trace" means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the Drug Quality and Security Act, Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.

(l) "Vendor" means the entity contracted by the agency to manage specified functions of the program.

(3) IMPORTATION PROCESS.—

(a) The agency shall contract with a vendor to provide services under the program.

(b) By December 1, 2019, and each year thereafter, the vendor shall develop a Wholesale Prescription Drug Importation List identifying the prescription drugs that have the highest potential for cost savings to the state. In developing the list, the vendor shall consider, at a minimum, which prescription drugs will provide the greatest cost savings to state programs, including prescriptions drugs for which there are shortages, specialty prescription drugs, and high volume prescription drugs. The agency, in consultation with the department, shall review the Wholesale Prescription

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Drug Importation List every 3 months to ensure that it continues to meet the requirements of the programs and may direct the vendor to revise the list, as necessary.

(c) The vendor shall identify Canadian suppliers that are in full compliance with relevant Canadian federal and provincial laws and regulations and the federal act and who have agreed to export drugs identified on the list at prices that will provide cost savings to the state. The vendor must verify that such Canadian suppliers meet all of the requirements of the program, while meeting or exceeding the federal and state track-and-trace laws and regulations.

(d) The vendor shall contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers and Canadian suppliers, to import drugs under the program.

(e) The vendor shall maintain a list of all registered importers that participate in the program.

(f) The vendor shall ensure compliance with Title II of the federal Drug Quality and Security Act, Pub. L. No. 113-54, by all suppliers, importers and other distributors, and participants in the program.

(g) The vendor shall assist the agency in the preparation of the annual report required by subsection (12), including the timely provision of any information requested by the agency.

(h) The vendor shall provide an annual financial audit of its operations to the agency as required by the agency. The vendor shall also provide quarterly financial reports specific to the program and shall include information on the performance of its subcontractors and vendors. The agency shall determine the format and contents of the reports.

(4) BOND REQUIREMENT.—The agency shall require a bond from the vendor to mitigate the financial consequences of potential acts of malfeasance or misfeasance or fraudulent or dishonest acts committed by the vendor, any employees of the vendor, or its subcontractors.

(5) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers, as described in subsection (7), may import a drug from an eligible Canadian supplier, as described in subsection (6), if:

(a) The drug meets the United States Food and Drug Administration’s standards related to safety, effectiveness, misbranding, and adulteration;

(b) Importing the drug would not violate federal patent laws;

(c) Importing the drug is expected to generate cost savings; and

(d) The drug is not:

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1. A controlled substance as defined in 21 U.S.C. s. 802;

2. A biological product as defined in 42 U.S.C. s. 262;

3. An infused drug;

4. An intravenously injected drug;

5. A drug that is inhaled during surgery; or

6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

(6) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may export prescription drugs into this state under the program if the supplier:

(a) Is in full compliance with relevant Canadian federal and provincial laws and regulations;

(b) Is identified by the vendor as eligible to participate in the program; and

(c) Submits an attestation that the supplier has a registered agent in the United States, including the name and United States address of the registered agent.

(7) ELIGIBLE IMPORTERS.—The following entities may import prescription drugs from an eligible Canadian supplier under the program:

(a) A pharmacist or wholesaler employed by or under contract with the department’s central pharmacy, for distribution to a county health department or free clinic for dispensing to clients treated in such department or clinic.

(b) A pharmacist or wholesaler employed by or under contract with a Medicaid pharmacy, for dispensing to the pharmacy’s Medicaid recipients.

(c) A pharmacist or wholesaler employed by or under contract with the Department of Corrections, for dispensing to inmates in the custody of the Department of Corrections.

(d) A pharmacist or wholesaler employed by or under contract with a developmental disabilities center, as defined in s. 393.063, for dispensing to clients treated in such center.

(e) A pharmacist or wholesaler employed by or under contract with a treatment facility, as defined in s. 394.455, for dispensing to patients treated in such facility.

(8) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers and eligible importers participating under the program:

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(a) Must comply with the tracking and tracing requirements of 21 U.S.C. ss. 360eee et seq.

(b) May not distribute, dispense, or sell prescription drugs imported under the program outside of the state.

(9) FEDERAL APPROVAL.—By July 1, 2020, the agency shall submit a request to the United States Secretary of Health and Human Services for approval of the program under 21 U.S.C. s. 384(l). The agency shall begin operating the program within 6 months after receiving such approval. The request must, at a minimum:

(a) Describe the agency’s plan for operating the program.

(b) Demonstrate how the prescription drugs imported into this state under the program will meet the applicable federal and state standards for safety and effectiveness.

(c) Demonstrate how the drugs imported into this state under the program will comply with federal tracing procedures.

(d) Include a list of proposed prescription drugs that have the highest potential for cost savings to the state through importation at the time that the request is submitted.

(e) Estimate the total cost savings attributable to the program.

(f) Provide the costs of program implementation to the state.

(g) Include a list of potential Canadian suppliers from which the state would import drugs and demonstrate that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations as well as all applicable federal and state laws and regulations.

(10) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

(a) The vendor shall ensure the safety and quality of drugs imported under the program. The vendor shall:

1. For an initial imported shipment of a specific drug by an importer, ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the federal act.

2. For every subsequent imported shipment of that drug by that importer, ensure that a statistically valid sample of the shipment is tested for authenticity and degradation in a manner consistent with the federal act.

3. Certify that the drug:

   a. Is approved for marketing in the United States and is not adulterated or misbranded; and

CODING: Words struck off are deletions; words underlined are additions.
b. Meets all of the labeling requirements under 21 U.S.C. s. 352.

4. Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section.

5. Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications.

(b) All testing required by this section must be conducted in a qualified laboratory that meets the standards under the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications for drug testing.

(c) The vendor shall maintain information and documentation submitted under this section for a period of at least 7 years.

(d) A participating importer must submit the all of following information to the vendor:

1. The name and quantity of the active ingredient of the drug.

2. A description of the dosage form of the drug.

3. The date on which the drug is received.

4. The quantity of the drug that is received.

5. The point of origin and destination of the drug.

6. The price paid by the importer for the drug.

(e) A participating Canadian supplier must submit the following information and documentation to the vendor specifying all of the following:

1. The original source of the drug, including:
   a. The name of the manufacturer of the drug.
   b. The date on which the drug was manufactured.
   c. The location (country, state or province, and city) where the drug was manufactured.

2. The date on which the drug is shipped.

3. The quantity of the drug that is shipped.

4. The quantity of each lot of the drug originally received and the source of the lot.

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5. The lot or control number and the batch number assigned to the drug by the manufacturer.

(f) The agency may require that the vendor collect any other information necessary to ensure the protection of the public health.

(11) IMMEDIATE SUSPENSION.—The agency shall immediately suspend the importation of a specific drug or the importation of drugs by a specific importer if it discovers that any drug or activity is in violation of this section or any federal or state law or regulation. The agency may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe drugs being imported into this state.

(12) ANNUAL REPORT.—By December 1 of each year, the agency shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the operation of the program during the previous fiscal year. The report must include, at a minimum:

(a) A list of the prescription drugs that were imported under the program;

(b) The number of participating entities;

(c) The number of prescriptions dispensed through the program;

(d) The estimated cost savings during the previous fiscal year and to date attributable to the program;

(e) A description of the methodology used to determine which drugs should be included on the Wholesale Prescription Drug Importation List; and

(f) Documentation as to how the program ensures the following:

1. That Canadian suppliers participating in the program are of high quality, high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations as well as all federal laws and regulations and state laws and rules;

2. That prescription drugs imported under the program are not shipped, sold, or dispensed outside of this state once in the possession of the importer;

3. That prescription drugs imported under the program are pure, unadulterated, potent, and safe;

4. That the program does not put consumers at a higher health and safety risk than if the consumer did not participate; and

5. That the program provides cost savings to the state on imported prescription drugs.
(13) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of federal approval of the program, the agency shall notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House of Representatives. After approval is received and before the start of the next regular session of the Legislature in which the proposal could be funded, the agency shall submit to all parties a proposal for program implementation and program funding.

(14) RULEMAKING.—The agency shall adopt rules necessary to implement this section.

Section 2. Section 465.0157, Florida Statutes, is created to read:

465.0157 International export pharmacy permit.—

(1) To participate as an exporter of prescription drugs into this state under the International Prescription Drug Importation Program established in s. 499.0285, a pharmacy located outside of the United States must hold an international export pharmacy permit.

(2) An international export pharmacy shall maintain at all times an active and unencumbered license or permit to operate the pharmacy in compliance with the laws of the jurisdiction in which the dispensing facility is located and from which the prescription drugs will be exported. Such jurisdiction must be in a country with which the United States has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country’s adherence to current good manufacturing practices for pharmaceutical products.

(3) An application for an international export pharmacy permit must be submitted on a form developed and provided by the board. The board may require an applicant to provide any information it deems reasonably necessary to carry out the purposes of this section.

(4) An applicant shall submit the following to the board to obtain an initial permit, or to the department to renew a permit:

(a) Proof of an active and unencumbered license or permit to operate the pharmacy in compliance with the laws of the jurisdiction in which the dispensing facility is located and from which the prescription drugs will be exported.

(b) Documentation demonstrating that the country in which the pharmacy operates has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country’s adherence to current good manufacturing practices for pharmaceutical products.

(c) The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for

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prescription drugs exported into this state under the International Pres-
scription Drug Importation Program.

(d) Written attestation by an owner or officer of the applicant, and by the
applicant’s prescription department manager, that:

1. The attester has read and understands the laws and rules governing
the manufacture, distribution, and dispensing of prescription drugs in this
state.

2. A prescription drug shipped, mailed, or delivered into this state meets
or exceeds this state’s standards for safety and efficacy.

3. A prescription drug product shipped, mailed, or delivered into this
state must not have been, and may not be, manufactured or distributed in
violation of the laws and rules of the jurisdiction in which the applicant is
located and from which the prescription drugs shall be exported.

(e) A current inspection report from an inspection conducted by the
regulatory or licensing agency of the jurisdiction in which the applicant is
located. The inspection report must reflect compliance with this section. An
inspection report is current if the inspection was conducted within 6 months
before the date of submitting the application for the initial permit or within 1
year before the date of submitting an application for permit renewal. If the
applicant is unable to submit a current inspection report conducted by the
regulatory or licensing agency of the jurisdiction in which the applicant is
located and from which the prescription drugs will be exported, due to
acceptable circumstances, as established by rule, or if an inspection has not
been performed, the department must:

1. Conduct, or contract with an entity to conduct, an onsite inspection,
with all related costs borne by the applicant;

2. Accept a current and satisfactory inspection report, as determined by
rule, from an entity approved by the board; or

3. Accept a current inspection report from the United States Food and
Drug Administration conducted pursuant to the federal Drug Quality and

(5) The department shall adopt rules governing the financial respon-
sibility of the pharmacy permittee. The rules must establish, at a minimum,
financial reporting requirements, standards for financial capability to
perform the functions governed by the permit, and requirements for
ensuring permittees and their contractors can be held accountable for the
financial consequences of any act of malfeasance or misfeasance or
fraudulent or dishonest act or acts committed by the permittee or its
contractors.

Section 3. Subsection (2) of section 465.017, Florida Statutes, is amended
to read:

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465.017  Authority to inspect; disposal.—

(2) Duly authorized agents and employees of the department may inspect a nonresident pharmacy registered under s. 465.0156, an international export pharmacy permittee under s. 465.0157, or a nonresident sterile compounding permittee under s. 465.0158 pursuant to this section. The costs of such inspections shall be borne by such pharmacy or permittee.

Section 4. Subsection (20) of section 499.005, Florida Statutes, is amended to read:

499.005  Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(20) The importation of a prescription drug except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act or s. 499.0285.

Section 5. Paragraph (e) of subsection (12) of section 499.0051, Florida Statutes, is amended to read:

499.0051  Criminal acts.—

(12) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(e) The importation of a prescription drug for wholesale distribution, except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act or s. 499.0285.

Section 6. Subsection (1) and paragraph (c) of subsection (2) of section 499.01, Florida Statutes, are amended, and paragraph (s) is added to subsection (2) of that section, to read:

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;

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(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; or
(s) An international prescription drug wholesale distributor.

(2) The following permits are established:

(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, an international 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

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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.

3.a. A nonresident prescription drug manufacturer that has registered to participate in the International Prescription Drug Importation Program pursuant to this section is not required to provide the list and approval required by subparagraph 2. for prescription drugs imported under that program.

b. To participate as an exporter of prescription drugs into this state under the International Prescription Drug Importation Program established under s. 499.0285, a nonresident prescription drug manufacturer located outside of the United States must register with the Department of Business and Professional Regulation before engaging in any activities under that section. Such manufacturer must be licensed or permitted in a country with which the United States has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country’s adherence to current good manufacturing practices for pharmaceutical products.

c. The department shall adopt rules governing the financial responsibility of a nonresident prescription drug manufacturer licensee or permittee. The rules will establish, at a minimum, financial reporting requirements, standards for financial capability to perform the functions governed by the permit, and requirements for ensuring permittees and their contractors can be held accountable for the financial consequences of any act of malafeance or misfeasance or fraudulent or dishonest act or acts committed by the permittee or its contractors.

(s) International prescription drug wholesale distributor.—

1. A wholesale distributor located outside of the United States must obtain an international prescription drug wholesale distributor permit to engage in the wholesale exportation and distribution of prescription drugs in the state under the International Prescription Drug Importation Program established in s. 499.0285. The wholesale distributor must be licensed or permitted to operate in a country with which the United States has a mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country’s adherence to current good manufacturing practices for pharmaceutical products. The wholesale distributor must maintain at all times a license or permit to
engage in the wholesale distribution of prescription drugs in compliance with the laws of the jurisdiction in which it operates. An international prescription drug wholesale distributor permit may not be issued to a wholesale distributor if the jurisdiction in which the wholesale distributor operates does not require a license to engage in the wholesale distribution of prescription drugs.

2. The department shall adopt rules governing the financial responsibility of an international prescription drug wholesale distributor permittee. The rules will establish, at a minimum, financial reporting requirements, standards for financial capability to perform the functions governed by the permit, and requirements for ensuring permittees and their contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest act or acts committed by the permittee or its contractors.

Section 7. Subsection (2), paragraph (a) of subsection (4), subsections (8), (10), (11), and (14), and paragraphs (a), (b), and (f) of subsection (15) of section 499.012, Florida Statutes, are amended to read:

499.012 Permit application requirements.—

(2) Notwithstanding subsection (6), a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed; however, a new permit for a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, an international prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

(4)(a) Except for a permit for a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor, an application for a permit must include:

1. The name, full business address, and telephone number of the applicant;

2. All trade or business names used by the applicant;

3. The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs;

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4. The type of ownership or operation, such as a partnership, corporation, or sole proprietorship; and

5. The names of the owner and the operator of the establishment, including:

   a. If an individual, the name of the individual;

   b. If a partnership, the name of each partner and the name of the partnership;

   c. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

   d. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

   e. If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company, and the name of the state in which the limited liability company was organized; and

   f. Any other relevant information that the department requires.

     (8) An application for a permit or to renew a permit for a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor submitted to the department must include:

     (a) The name, full business address, and telephone number of the applicant.

     (b) All trade or business names used by the applicant.

     (c) The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs.

     (d) The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

     (e) The names of the owner and the operator of the establishment, including:

        1. If an individual, the name of the individual.

        2. If a partnership, the name of each partner and the name of the partnership.

        3. If a corporation:

           a. The name, address, and title of each corporate officer and director,

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b. The name and address of the corporation, resident agent of the corporation, the resident agent's address, and the corporation's state of incorporation.

c. The name and address of each shareholder of the corporation that owns 5 percent or more of the outstanding stock of the corporation.

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

5. If a limited liability company:
   a. The name and address of each member.
   b. The name and address of each manager.

c. The name and address of the limited liability company, the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(f) If applicable, the name and address of each affiliate of the applicant.

(g) The applicant's gross annual receipts attributable to prescription drug wholesale distribution activities for the previous tax year.

(h) The tax year of the applicant.

(i) A copy of the deed for the property on which applicant's establishment is located, if the establishment is owned by the applicant, or a copy of the applicant's lease for the property on which applicant's establishment is located that has an original term of not less than 1 calendar year, if the establishment is not owned by the applicant.

(j) A list of all licenses and permits issued to the applicant by any other state or jurisdiction which authorize the applicant to purchase or possess prescription drugs.

(k) The name of the manager of the establishment that is applying for the permit or to renew the permit, the next four highest ranking employees responsible for prescription drug wholesale operations for the establishment, and the name of all affiliated parties for the establishment, together with the personal information statement and fingerprints required pursuant to subsection (9) for each of such persons.

(l) The name of each of the applicant's designated representatives as required by subsection (15), together with the personal information statement and fingerprints required pursuant to subsection (9) for each such person.

(m) Evidence of a surety bond in this state or any other state in the United States in the amount of $100,000. If the annual gross receipts of the applicant's previous tax year are $10 million or less, evidence of a surety bond in the amount of $100,000 is required.
bond in the amount of $25,000. The specific language of the surety bond must include the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. In lieu of the surety bond, the applicant may provide other equivalent security such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, which includes the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. The purpose of the bond or other security 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.

(n) For establishments used in wholesale distribution, proof of an inspection conducted by the department, the United States Food and Drug Administration, or another governmental entity charged with the regulation of good manufacturing practices related to wholesale distribution of prescription drugs, within timeframes set forth by the department in departmental rules, which demonstrates substantial compliance with current good manufacturing practices applicable to wholesale distribution of prescription drugs. The department may recognize another state’s or jurisdiction’s inspection of a wholesale distributor located in that state or jurisdiction if such state’s or jurisdiction’s laws are deemed to be substantially equivalent to the law of this state by the department. The department may accept an inspection by a third-party accreditation or inspection service which meets the criteria set forth in department rule.

(o) Any other relevant information that the department requires.

(p) Documentation of the credentialing policies and procedures required by s. 499.0121(15).

(q) For international prescription drug wholesale distributors and nonresident prescription drug manufacturers to participate in the International Prescription Drug Importation Program established under s. 499.0285, documentation demonstrating that the applicant is appropriately licensed or permitted by a country with which the United States has a mutual recognition agreement, cooperation agreement, memorandum of understanding, or other mechanism recognizing the country’s adherence to current good manufacturing practices for pharmaceutical products.

(10) The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor if:

(a) The applicant has not met the requirements for the permit.

CODING: Words struck are deletions; words underlined are additions.
(b) The management, officers, or directors of the applicant or any affiliated party are found by the department to be incompetent or untrustworthy.

(c) The applicant is so lacking in experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health.

(d) The applicant is so lacking in experience in managing a wholesale distributor as to jeopardize the reasonable promise of successful operation of the wholesale distributor.

(e) The applicant is lacking in experience in the distribution of prescription drugs.

(f) The applicant's past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.

(g) The applicant is affiliated directly or indirectly through ownership, control, or other business relations, with any person or persons whose business operations are or have been detrimental to the public health.

(h) The applicant, or any affiliated party, has been found guilty of or has pleaded guilty or nolo contendere to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country, regardless of whether adjudication of guilt was withheld.

(i) The applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period.

(j) The applicant has furnished false or fraudulent information or material in any application made in this state or any other state in connection with obtaining a permit or license to manufacture or distribute drugs, devices, or cosmetics.

(k) That a federal, state, or local government permit currently or previously held by the applicant, or any affiliated party, for the manufacture or distribution of any drugs, devices, or cosmetics has been disciplined, suspended, or revoked and has not been reinstated.

(l) The applicant does not possess the financial or physical resources to operate in compliance with the permit being sought, this chapter, and the rules adopted under this chapter.

(m) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund.

CODING: Words stricken are deletions; words underlined are additions.
(n) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, any federal or state drug law, or any felony where the underlying facts related to drugs, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld, other than through the ownership of stock in a publicly traded company or a mutual fund.

(o) The applicant for renewal of a permit under s. 499.01(2)(e) or (f) has not actively engaged in the wholesale distribution of prescription drugs, as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by not fewer than 12 wholesale distributions in the previous year and not fewer than three wholesale distributions in the previous 6 months.

(p) Information obtained in response to s. 499.01(2)(e) or (f) demonstrates it would not be in the best interest of the public health, safety, and welfare to issue a permit.

(q) The applicant does not possess the financial standing and business experience for the successful operation of the applicant.

(r) The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under this part, similar federal laws, similar laws in other states, or the rules adopted under such laws.

(11) Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor permit to the applicant.

(14) The name of a permittee or establishment on a prescription drug wholesale distributor permit, an international prescription drug wholesale distributor permit, or an out-of-state prescription drug wholesale distributor permit may not include any indicia of attainment of any educational degree, any indicia that the permittee or establishment possesses a professional license, or any name or abbreviation that the department determines is likely to cause confusion or mistake or that the department determines is deceptive, including that of any other entity authorized to purchase prescription drugs.

(15)(a) Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor must designate in writing to the department at least one natural person to serve as the designated representative of the wholesale

CODING: Words striken are deletions; words underlined are additions.
(b) To be certified as a designated representative, a natural person must:

1. Submit an application on a form furnished by the department and pay the appropriate fees.

2. Be at least 18 years of age.

3. Have at least 2 years of verifiable full-time:
   a. Work experience in a pharmacy licensed in this state or another state or jurisdiction, where the person's responsibilities included, but were not limited to, recordkeeping for prescription drugs;
   b. Managerial experience with a prescription drug wholesale distributor licensed in this state or in another state or jurisdiction; or
   c. Managerial experience with the United States Armed Forces, where the person's responsibilities included, but were not limited to, recordkeeping, warehousing, distributing, or other logistics services pertaining to prescription drugs.

4. Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs. This requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year.

5. Provide the department with a personal information statement and fingerprints pursuant to subsection (9).

(f) A wholesale distributor may not operate under a prescription drug wholesale distributor permit, an international prescription drug wholesale distributor permit, or an out-of-state prescription drug wholesale distributor permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.

Section 8. Subsection (1) of section 499.015, Florida Statutes, is amended to read:

499.015 Registration of drugs and devices; issuance of certificates of free sale.—

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CODING: Words stricken are deletions; words underlined are additions.
(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or device in this state must register such drug or device biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or device at the time of registration.

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(c) Registration under this section is not required for prescription drugs imported under the International Prescription Drug Importation Program established in s. 499.0285.

Section 9. Subsections (1) and (3) of section 499.065, Florida Statutes, are amended to read:

499.065 Inspections; imminent danger.—

(1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale distributor establishment, international prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, and retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part as often as necessary to ensure compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities at any reasonable time.

(3) The department may determine that a prescription drug wholesale distributor establishment, international prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, or retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part is an imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public’s health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

Section 10. Section 499.0285, Florida Statutes, is created to read:

499.0285 International Prescription Drug Importation Program.—

CODING: Words struck are deletions; words underlined are additions.
(1) PROGRAM ESTABLISHED.—The department shall establish a program for the importation of safe and effective prescription drugs from foreign nations with which the United States has current mutual recognition agreements, cooperation agreements, memoranda of understanding, or other federal mechanisms recognizing their adherence to current good manufacturing practices for pharmaceutical products.

(2) DEFINITIONS.—As used in this section, the term:

(a) "Exporter" means an international prescription drug wholesale distributor, a nonresident prescription drug manufacturer registered to participate in the program, or an international export pharmacy that exports prescription drugs into this state under the program.


(c) "Foreign recipient" means an entity other than the original prescription drug manufacturer which receives the prescription drug before its importation into this state under the program.

(d) "Good manufacturing practice" refers to the good manufacturing practice regulations in 21 C.F.R. parts 210 and 211.

(e) "Importer" means a wholesale distributor, pharmacy, or pharmacist importing prescription drugs into this state under the program.

(f) "International export pharmacy" means a pharmacy located outside of the United States which holds an active and unencumbered permit under chapter 465 to export prescription drugs into this state under the program.

(g) "International prescription drug wholesale distributor" means a prescription drug wholesale distributor located outside of the United States which holds an active and unencumbered permit under this part to export and distribute prescription drugs into this state under the program.

(h) "Nonresident prescription drug manufacturer" means an entity located outside of the United States which holds an active and unencumbered permit under this part to manufacture prescription drugs and has registered with the department to export and distribute such prescription drugs into this state under the program.

(i) "Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy under chapter 465.

(j) "Pharmacy" means an entity that holds an active and unencumbered permit under chapter 465.

(k) "Prescription drug" has the same meaning as defined in this part, but is limited to drugs intended for human use.
(l) "Program" means the International Prescription Drug Importation Program established under this section.

(m) "Qualified laboratory" means a laboratory that has been approved by the department for the purposes of this section.

(3) ELIGIBLE PRESCRIPTION DRUGS.—An eligible importer may import a prescription drug from an eligible exporter if:

(a) The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;

(b) Importing the drug would not violate the patent laws of the United States; and

(c) The drug is not:

   1. A controlled substance as defined in 21 U.S.C. s. 802;
   2. A biological product as defined in 42 U.S.C. s. 262;
   3. An infused drug;
   4. An intravenously injected drug;
   5. A drug that is inhaled during surgery; or
   6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

(4) EXPORTERS.—

(a) The following entities may export prescription drugs into this state under the program:

   1. An international prescription drug wholesale distributor.
   2. A nonresident prescription drug manufacturer.
   3. An international export pharmacy.

(b) An eligible exporter must register with the department before exporting prescription drugs into this state under the program.

(c) An exporter may not distribute, sell, or dispense prescription drugs imported under the program to any person residing outside of the state.

(5) IMPORTERS.—

(a) The following entities may import prescription drugs under the program:

CODING: Words struck are deletions; words underlined are additions.
1. A wholesale distributor.

2. A pharmacy.

3. A pharmacist.

(b) An eligible importer must register with the department before importing prescription drugs into this state under the program.

(c) An importer may not distribute, sell, or dispense prescription drugs imported under the program to any person residing outside of the state.

6. PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

(a) A participating importer must submit the following information and documentation to the department:

1. The name and quantity of the active ingredient of the prescription drug.

2. A description of the dosage form of the prescription drug.

3. The date on which the prescription drug is shipped.

4. The quantity of the prescription drug that is shipped.

5. The point of origin and destination of the prescription drug.

6. The price paid by the importer for the prescription drug.

7. Documentation from the exporter specifying:
   a. The original source of the prescription drug; and
   b. The quantity of each lot of the prescription drug originally received by the seller from that source.

8. The lot or control number assigned to the prescription drug by the manufacturer.

9. The name, address, telephone number, and professional license or permit number of the importer.

10. In the case of a prescription drug that is shipped directly by the first foreign recipient from the manufacturer:
   a. Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.
   b. Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being

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imported into this state is not more than the quantity that was received by the first foreign recipient.

c. For an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

11. In the case of a prescription drug that is not shipped directly from the first foreign recipient, documentation demonstrating that each batch in each shipment offered for importation into this state was statistically sampled and tested for authenticity and degradation.

12. For an initial imported shipment of a specific drug by an importer, the department shall ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the federal act. The agency may contract with a vendor for these functions.

13. For every subsequent imported shipment of that drug by that importer, the department shall ensure that a statistically valid sample of the shipment was tested for authenticity and degradation in a manner consistent with the federal act.

14. Certify that the drug:

a. Is approved for marketing in the United States and is not adulterated or misbranded; and

b. Meets all of the labeling requirements under 21 U.S.C. s. 352.

15. Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section.

16. Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications.

(b) All testing required by this section must be conducted in a qualified laboratory that meets the standards under the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications for drug testing.

(c) The vendor shall maintain information and documentation submitted under this section for a period of at least 7 years.

(d) A participating importer must submit the all of following information to the department:

1. The name and quantity of the active ingredient of the drug.

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2. A description of the dosage form of the drug.

3. The date on which the drug is received.

4. The quantity of the drug that is received.

5. The point of origin and destination of the drug.

6. The price paid by the importer for the drug.

(e) A participating International Importation Drug supplier must submit the following information and documentation to the agency or the agency's designated vendor specifying all of the following:

1. The original source of the drug, including:
   a. The name of the manufacturer of the drug.

2. The date on which the drug was manufactured.

3. The location (country, state or province, and city) where the drug was manufactured.

4. The date on which the drug is shipped.

5. The quantity of the drug that is shipped.

6. The quantity of each lot of the drug originally received and from which source.

7. The lot or control number and the batch number assigned to the drug by the manufacturer.

8. The name, address, and telephone number, and professional license or permit number of the importer.

(f) The department may require any other information necessary to ensure the protection of the public health.

(7) IMMEDIATE SUSPENSION.—The department shall immediately suspend the importation of a specific prescription drug or the importation of prescription drugs by a specific importer if it discovers that any prescription drug or activity is in violation of this section. The department may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe prescription drugs being imported into this state.

(8) RULEMAKING AUTHORITY.—The department shall adopt rules necessary to implement this section.

Section 11. Notwithstanding the Federal Food, Drug, and Cosmetic Act, the Department of Business and Professional Regulation, in collaboration

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with the Department of Health, shall negotiate a federal arrangement to operate a pilot program for importing prescription drugs into this state. The proposal to operate such a pilot program shall demonstrate that the program sets safety standards consistent with the current federal requirements for the manufacturing and distribution of prescription drugs; limits the importation of prescription drugs under the program to entities licensed or permitted by the state to manufacture, distribute, or dispense prescription drugs; and includes inspection and enforcement authority. Implementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval. The department shall notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House of Representatives before implementation of the pilot program. The department shall submit to all parties a proposal for program implementation and program funding.

Section 12. This act shall take effect July 1, 2019.

Approved by the Governor June 11, 2019.

Filed in Office Secretary of State June 11, 2019.

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SAFE IMPORTATION ACTION PLAN

Under President Trump’s leadership, the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) are releasing this Safe Importation Action Plan to describe steps HHS and FDA will take to allow the safe importation of certain drugs originally intended for foreign markets. The Action Plan describes two pathways to provide safe, lower cost drugs to consumers.

Under Pathway 1, a Notice of Proposed Rulemaking ("NPRM") would rely on the authority in the Federal Food, Drug, and Cosmetic Act ("FD&C Act") section 804 to authorize demonstration projects to allow importation of drugs from Canada. The NPRM would include conditions to ensure the importation poses no additional risk to the public’s health and safety and that it will achieve significant cost savings to the American consumer.

Under Pathway 2, manufacturers could import versions of FDA-approved drug products that they sell in foreign countries that are the same as the U.S. versions. Under this pathway, manufacturers would use a new National Drug Code (NDC) for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

Some elements of the final proposal may differ from the descriptions below to reflect further consideration of the relevant issues.

Pathway 1: Under this pathway, States, wholesalers, or pharmacists could submit plans for demonstration projects for HHS to review outlining how they would import Health-Canada approved drugs that are in compliance with section 505 of the FD&C Act. The importation would occur in a manner that adequately assures the drug is what it purports to be and that meets the cost requirements of the rulemaking. The demonstration projects would be time-limited and require regular reporting to ensure safety and cost conditions are being met.

The NPRM would address the following:

- Past Consideration of Section 804: The NPRM would address past consideration of importation under section 804 and discuss what has changed since those previous reviews.

- Implements Section 804(h)-h): The NPRM would implement section 804(b)-(h), which allows for importation of drugs from Canada by pharmacists and wholesalers if certain conditions are met regarding drug quality, record keeping, testing, and protections against counterfeiting. The NPRM would list those requirements and invite proposals as to how those conditions would be met by a demonstration project.

- Conditional Certification: Section 804(l) requires a certification to Congress that implementation of section 804 will pose no additional risk to the public’s health and safety and will result in a significant reduction in the cost of covered products to the
American consumer. The NPRM would propose to condition certification on the ability to limit the program to demonstration projects under section 804(b)-(h) and would seek comments on that proposal.

- **Demonstration Projects:** The NPRM would propose that States, wholesalers, or pharmacists submit applications to HHSS demonstrating how they will comply with the statutory safety and cost conditions as well as additional requirements that would be imposed to approve a demonstration. The demonstrations would be time limited and require reporting and renewal and could be revoked if conditions are not met. Applications from States would need to propose an arrangement with a wholesaler or pharmacist that meets the conditions of the NPRM.

- **Eligible Drugs:** The NPRM would propose that drugs eligible for importation must be drugs authorized for sale in Canada that are versions of FDA-approved prescription drugs. Specifically, such drugs would be eligible for importation if they contain only active pharmaceutical ingredients (API) manufactured at facilities that also manufacture API for the FDA-approved version, and if they are formulated using processes, specifications, and facilities that are used in accordance with the approved new drug application for the FDA-approved version. The NPRM would require attestation and supporting documentation regarding the authenticity and eligibility of a drug.

- **Non-Eligible Drugs:** The NPRM would restate the exclusions listed in section 804(a)(3); namely, controlled substances, biological products, infused drugs, intravenously injected drugs, drugs inhaled during surgery, and certain parenteral drugs would be excluded from this pathway. The NPRM would additionally exclude any drug with a REMS.

- **Additional Safety Requirements:** HHSS may not have access to data that would verify that a drug imported under this pathway is the same as the FDA-approved drug. The NPRM will help address this issue by requiring applicants to demonstrate how they will comply with:
  - track and trace requirements to allow drug tracing from manufacture to pharmacy;
  - certain labeling requirements to ensure the imported drugs meet all labeling requirements of the FD&C Act;
  - requirements to ensure foreign sellers engaged in the distribution of the imported drugs are registered;
  - importation entry requirements (e.g., providing certain electronic information demonstrating that each shipment should be allowed into the U.S.); and
  - post-importation requirements such as adverse event reporting, procedures to facilitate recalls, and CGMP for certain manufacturing activities such as relabeling.

- **Cost Requirements:** The NPRM would explain the requirement for demonstrating that drugs imported under this pathway must result in a significant reduction in the cost of covered drug products to the American consumer. As such, the NPRM would seek
feedback on the best way to identify the expected acquisition cost of the imported drug, the cost of assuring the drug is safely imported, and the mechanism for delivering those savings to the consumer (as opposed to the savings being absorbed by the supply chain).

- **Transparency**: The NPRM would require some indication in the labeling that drugs imported under this program were originally intended for distribution in Canada. In particular, the NPRM would seek comment on requiring that the label include the NDC, part of which would be unique to drugs imported under this program.

- **Compliance**: The NPRM would explain that in addition to FDA’s typical compliance tools (e.g., import alerts, warning letters, etc.), the Secretary would have broad discretion to terminate a demonstration project if the continuation could pose additional risk to public health and safety.

- **Severability**: The rulemaking would be clear that if any provision of Pathway 1 in a final rule is invalidated by a court, the entirety of Pathway 1 should be invalidated, because the certification would be based on the ability to implement section 804 with the conditions imposed in the rulemaking.

**Pathway 2**: Manufacturers of FDA-approved drug products would be able to import versions of these FDA-approved drugs that they sell in foreign countries into the U.S. To use this pathway, the manufacturer or person authorized by the manufacturer would need to establish with FDA that the foreign version is the same as the U.S. version (such as through manufacturing records). If this condition is met, FDA would allow the drug to be labeled for sale in the U.S. (potentially with labeling that identifies the product as originally manufactured for sale abroad) and imported pursuant to section 801(d) of the FD&C Act under the existing approval for the U.S. approved version.

The Administration has reason to believe that manufacturers might use this pathway as an opportunity to offer Americans lower cost versions of their own drugs. In recent years, multiple manufacturers have stated (either publicly or in statements to the Administration) that they wanted to offer lower cost versions but could not readily do so because they were locked into contracts with other parties in the supply chain. This pathway would highlight an opportunity for manufacturers to use importation to offer lower-cost versions of their drugs.

A manufacturer that met the requirements for this pathway could sell a foreign version of a drug product in the U.S. under a different NDC number than the U.S. version, which could allow the manufacturer to introduce the product at a lower price. Because the manufacturer would be able to cause its drug to be imported through conventional supply channels, this pathway generally would rely on applicable existing safeguards to ensure supply chain integrity. HHS is considering whether any additional safeguards would be necessary to establish that the drug being imported is in fact, for example, the European version of an FDA-approved drug that the manufacturer has caused to be labeled to be marketed in the U.S.
HHS may seek comments on whether manufacturers would seek to lower costs under this pathway, what additional elements might be important to include, and whether this pathway could more effectively be implemented by using authority under section 804. If costs can be lowered significantly through this pathway, there may be reduced need for the demonstration projects outlined in Pathway 1.
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Avant Dental
25
Avg. days to ship
3
Standard shipping
$8.95
Free shipping at
$250
Ships from
FL

View 823 products

Brite Sources USA
28
Avg. days to ship
2
Standard shipping
Free
Free shipping at
N/A
Ships from
TX

View 1,475 products

Carolina Dental
125
Avg. days to ship
6
Standard shipping
$10.95
Free shipping at
N/A
Ships from
NC
DDI Supply
289
Avg. days to ship 4
Standard shipping $4.99
Free shipping at $300
Ships from IA

Dental Connection
2
Avg. days to ship 5
Standard shipping $9.50
Free shipping at $100
Ships from NC

DentalProdX
29
Avg. days to ship 1
Standard shipping $9.95
Free shipping at $500
Ships from TN
Dental Supply Depot
46
Avg. days to ship 3
Standard shipping $8.95
Free shipping at $500
Ships from MD

View 1,186 products

Dental Wholesale Direct
269
Avg. days to ship 3
Standard shipping $3.00
Free shipping at $24
Ships from FL

View 4,487 products

Dentify
10
Avg. days to ship 2
Standard shipping $4.50
Free shipping at $15
Ships from FL

View 113 products

DirectCrown Products

Avg. days to ship 1
<table>
<thead>
<tr>
<th>Vendor</th>
<th>Address</th>
<th>Avg. days to ship</th>
<th>Standard shipping</th>
<th>Free shipping at</th>
<th>Ships from</th>
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<tbody>
<tr>
<td>Discount Disposables</td>
<td>15</td>
<td>2</td>
<td>$4.96</td>
<td>$300</td>
<td>CA</td>
</tr>
<tr>
<td>Duraline Systems</td>
<td></td>
<td>1</td>
<td>Free</td>
<td>N/A</td>
<td>NY</td>
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<tr>
<td>e-Dentist Supply</td>
<td>125</td>
<td>2</td>
<td>$4.75</td>
<td>$100</td>
<td>CA</td>
</tr>
</tbody>
</table>
Efficient Dental Technologies
2
Avg. days to ship 2
Standard shipping Free
Free shipping at N/A
Ships from OR

View 49 products

Elite Dental
1
Avg. days to ship 2
Standard shipping Free
Free shipping at N/A
Ships from FL

View 337 products

Exacta Dental
2
Avg. days to ship 1
Standard shipping $7.95
Free shipping at $100
Ships from MI

View 107 products
<table>
<thead>
<tr>
<th>Vendor</th>
<th>Code</th>
<th>Avg. days to ship</th>
<th>Standard shipping</th>
<th>Free shipping at</th>
<th>Ships from</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Dent Supply</td>
<td>82</td>
<td>4</td>
<td>Free</td>
<td>N/A</td>
<td>NJ</td>
</tr>
<tr>
<td>Franklin Dental</td>
<td>61</td>
<td>3</td>
<td>$9.99</td>
<td>N/A</td>
<td>NY</td>
</tr>
<tr>
<td>GPS Dental Products</td>
<td>19</td>
<td>5</td>
<td>$7.25</td>
<td>$200</td>
<td>NJ</td>
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<tr>
<td>Hey Dental</td>
<td>218</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Free shipping at $5.95
Ships from MD

View 6,464 products

IDS
83
Avg. days to ship 5
Standard shipping $6.95
Free shipping at $500
Ships from FL

View 2,127 products

iSmile Dental Products
51
Avg. days to ship 4
Standard shipping $9.99
Free shipping at $300
Ships from CA

View 4,501 products

Jeweldent
18
Avg. days to ship 3
Standard shipping Free
Free shipping at N/A
Ships from CA
Laschal Surgical

Avg. days to ship 4
Standard shipping $8.95
Free shipping at $100
Ships from NY

LV Dental Supply

Avg. days to ship 3
Standard shipping $4.50
Free shipping at $30
Ships from CA

Massco Dental

Avg. days to ship 1
Standard shipping $13.99
Free shipping at N/A
Ships from AR
Max Dental
52
Avg. days to ship 1
Standard shipping $4.50
Free shipping at $10
Ships from FL

View 143 products

Medical Dental Max
39
Avg. days to ship 3
Standard shipping $4.00
Free shipping at $200
Ships from NY

View 615 products

Megadental International
162
Avg. days to ship 2
Standard shipping Free
Free shipping at N/A
Ships from FL

View 380 products

Novus Dental Supplies
Avg. days to ship 2
<table>
<thead>
<tr>
<th>Vendor Name</th>
<th>Category</th>
<th>Avg. Days to Ship</th>
<th>Standard Shipping</th>
<th>Free Shipping at</th>
<th>Ships From</th>
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</thead>
<tbody>
<tr>
<td>ODS Online</td>
<td>178</td>
<td>3</td>
<td>$4.95</td>
<td>$150</td>
<td>IA</td>
</tr>
<tr>
<td>Orange County Dental</td>
<td>165</td>
<td>6</td>
<td>$3.00</td>
<td>$395</td>
<td>CA</td>
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<tr>
<td>OrthoExtent</td>
<td>3</td>
<td>3</td>
<td>$15.95</td>
<td>$400</td>
<td>VA</td>
</tr>
</tbody>
</table>

https://www.net32.com/vendor  8/6/2019
Orthogen

1
Avg. days to ship 9
Standard shipping $15.00
Free shipping at N/A
Ships from NJ

PA Dental

173
Avg. days to ship 3
Standard shipping $5.95
Free shipping at $10
Ships from MD

Practicon

35
Avg. days to ship 2
Standard shipping $9.95
Free shipping at $200
Ships from NC

View 297 products

View 11 products

View 7,199 products

View 2,335 products
Premium Plus Dental
18
Avg. days to ship 1
Standard shipping $8.95
Free shipping at $300
Ships from NY

View 237 products

Professional Dental Supply
29
Avg. days to ship 2
Standard shipping $5.00
Free shipping at $50
Ships from NJ

View 960 products

Prophy Magic
2
Avg. days to ship 1
Standard shipping Free
Free shipping at N/A
Ships from NV

View 61 products

River Dental Supplies
107
Avg. days to ship 2

https://www.net32.com/vendor

8/6/2019
Russman Debubblizer & Dental Supply, LLC

Avg. days to ship 3
Standard shipping $10.50
Free shipping at $75
Ships from CA

View 53 products

Sentry Dental

7
Avg. days to ship 1
Standard shipping $4.00
Free shipping at N/A
Ships from WI

View 153 products

Shine Dental

36
Avg. days to ship 5
Standard shipping $6.75
Free shipping at $250
Ships from WA
SmartChoice Dental

31
Avg. days to ship 1
Standard shipping $4.70
Free shipping at $100
Ships from CA

Supply Doc

12
Avg. days to ship 3
Standard shipping $4.99
Free shipping at $49
Ships from CA

Ting Dental

6
Avg. days to ship 1
Standard shipping $10.00
Free shipping at N/A
Ships from PA
<table>
<thead>
<tr>
<th>Vendor Name</th>
<th>Code</th>
<th>Avg. days to ship</th>
<th>Standard shipping</th>
<th>Free shipping at</th>
<th>Ships from</th>
</tr>
</thead>
<tbody>
<tr>
<td>TradealZ</td>
<td>72</td>
<td>2</td>
<td>Free</td>
<td>N/A</td>
<td>FL</td>
</tr>
<tr>
<td>Tradent Supply</td>
<td>676</td>
<td>2</td>
<td>$3.00</td>
<td>$10</td>
<td>NY</td>
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<td>True North Dental</td>
<td></td>
<td>3</td>
<td>$3.50</td>
<td>$15</td>
<td>NJ</td>
</tr>
<tr>
<td>US Dental Supplies</td>
<td>6</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
VibraJect

Avg. days to ship 8
Standard shipping Free
Free shipping at N/A
Ships from CA

Washington Trade International

Avg. days to ship 3
Standard shipping $45.00
Free shipping at N/A
Ships from WA

Wisdom Dental Supply

Avg. days to ship 4
Standard shipping Free
Free shipping at N/A
Ships from NJ
YourDent

Avg. days to ship 2
Standard shipping $6.00
Free shipping at $100
Ships from NY

Start selling your products now.

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Join over 38,000+ dentists receiving the best deals every week.

Enter email

Submit
Become a Net32 Vendor

If you are in the business of selling dental products directly to dentists, we can help you reach your target customers. Whether you are a Full-line Dental Vendor, a Dental Distributor or a Dental Manufacturer, the Net32 channel can help you expand your business by giving you full access to a proven online marketplace established over the past 22 years, with more than 110,000 registered users across the United States of America.

How it works

1. We upload your product inventory
   
   Provide Net32 your product information in our user-friendly Excel form and we will take care of the rest.

2. Customers buy your products
   
   Net32 helps customers make quick, easy and worry-free purchases.

3. Get paid
   
   Customers pay you directly.

4. You ship products to customers
   
   Receive order notifications via email and ship your orders directly to customers.

5. Net32 collects a market competitive commission
   
   Receive a monthly invoice from Net32 based on your monthly sales.

Need help? Call (800) 517-1997 Extended hours M-F 6am-8pm ET
Keywords, Manufacturer, or vendor codes

Vendors

Search vendor by name

Filter by: State

Discount Medical
335
Avg. days to ship 3
Standard shipping $4.50
Free shipping at $400
Ships from CA

View 281 products

Smart Med Supply
289
Avg. days to ship 4
Standard shipping $7.95
Free shipping at N/A
Ships from IA

View 1,160 products

Washington Trade International

Avg. days to ship 3
Start selling your products now.

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Join us to receive the best deals every week.

Enter email

Submit
Our Mission

Help you take control.
Many doctors focus solely on increasing their top line by producing more instead of reducing their overhead, missing out on huge profits. Large retail suppliers take advantage of this by charging more for supplies and paying sales reps big money that comes from your pocket. Med32 can help a business-conscious doctor like you take control of your bottom line, save money, and make greater profits.

Save you time and money.
You will save up to 40% off retail by shopping online at Med32. We have made comparison shopping convenient so you won’t waste time browsing catalogs in search of the same products.

Give you a competitive advantage.
What will you do with the money you save? By reducing your overhead and increasing your bottom line you will be able to run a more efficient practice than your competitors.

Testimonials

“We have saved an average of $250.00 a week!!! We are getting the same quality products and brands our staff and patients are accustomed to! Thanks.”
— Dr. Coral Pou-Perez

“Prices are unbeatable! Great customer support! Could not be happier!”
— Dr. Harry Goza

“Easy to use for a comparison shopping, saving us a lot of money.”
— Dr. Harry Kama

“Same brand name products that we’ve always used at 25% - 50% less.”
— Dr. Brian O’Lear

“I am very happy with the huge savings over the last two years.”
— Dr. Arnold Dragon

“An amazing tool to allow true free market shopping. This service has come at exactly the right time. You’ve got to try it.”
— Dr. Wayne E. Lyerly

“I have saved an average of 50% on products our office uses every day over the national distributors.”
— Dr. Richard Schram

“I love the ease of ordering and the quick check out, as well as the peace of mind that
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— Dr. Richard Schram

"I love the ease of ordering and the quick check out, as well as the peace of mind that I am getting the best pricing available."
— Dr. Darryl Pearlman

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8/6/2019
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If you are in the business of selling medical products directly to physicians, we can help you reach your target customers. Whether you are a Full-line Medical Vendor, a Medical Distributor or a Medical Manufacturer, the Med32 channel can help you expand your business by giving you full access to a proven online marketplace established over the past 10 years, with full access to registered users across the United States of America.

1. We upload your product inventory
   Provide Med32 your product information in our user-friendly Excel form and we will take care of the rest.

2. Customers buy your products
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3. Get paid
   Customers pay you directly.

4. You ship products to customers
   Receive order notifications via email and ship your orders directly to customers.

5. Med32 collects a market competitive commission
   Receive a monthly invoice from Med32 based on your monthly sales.

Need help? Call (877) 996-3832 Extended hours M-F 6am-8pm ET
**COMPANY INFORMATION**

| Legal Name: |  |
| TRADE/DBA NAME: | Pharmacy |
| FACILITY/LICENSE TYPE: | Pharmacy |
| Street Address: | 123 Winter Garden Vineland Rd, Ste 2 |
| City: | Winter Garden |
| State: | FL |
| Zip: | 34787 |

This address is: Legal: [ ] Shipping: [ ] Billing: [ ]

**CONTACT INFORMATION**

| Main Phone #: |  |
| Fax #: |  |
| Email Address: | snprepharmacy@gmail.com |
| Website: |  |
| Contact Name: | Arnie Perl |
| Title: | Owner |
| Phone: | 4075284320 |
| Email: | snprepharmacy@gmail.com |
| Owner/Officer Name: | Arnie Perl |
| Title: | Owner |
| Phone: |  |

**LICENSE INFORMATION**

| DEA License No: | 1086490169 |
| DEA Exp. Date: | 2021-09-30 |
| State License No: |  |
| State Exp. Date: | 2021-02-28 |
| NPI License No: | 1376909759 |
| Other License No: |  |
| Other Exp. Date: | 0000-00-00 |
| Federal Tax ID No: | 832477557 |
| 340B Status: | No |

**BUSINESS REFERENCES**

| Technology Reference Name: |  |
| State: | FL |
| Phone No: | 8002897930 |
| Bank Reference Name: | BANK OF AMERICA |
| State: | FL |
| Phone No: | 8655511512 |

**INDUSTRY REFERENCES**

| Primary Supplier: McKesson |
| State: | FL |
| Phone No: |  |

| Secondary Supplier: |
| State: |  |
| Phone No: |  |

This is an universal application requesting the creation of a new account and credit facility with Trxade and all Trxade Supplier Members.

This application is being submitted to each Trxade Supplier Member for the purpose of obtaining credit with whom you chose to do business. The undersigned hereby contests that all information contained is correct and complete and that the Trxade / Trxade Supplier Member may rely on this information, contact all financial, trade and other references, and obtain any necessary credit reports in deciding to extend or decline credit. They understand that their account and credit line is subject to periodic review, change in payment terms and total credit limit, suspension or termination of any purchase orders, at the sole discretion of the Trxade Supplier Member at any time without liability for implementing such changes. The undersigned further represents that all professional licenses are in good standing and that any legal proceedings or action taken against these licenses will be reported to Trxade and all Trxade Supplier Members immediately. Should an entitlement to special/contract pricing not be realized for any reason other than the gross negligence of the Trxade Supplier Member then the undersigned understands that they will be liable for the difference in cost between the special/contract price and the Trxade Supplier Member's price at the time of sale.

The undersigned agrees to pay daily 0.05% service/interest fees or the highest lawful rate and all incurred attorney costs, court costs, and collection costs on all outstanding balances. The undersigned personally guarantees unconditionally the indebtedness of the above corporation or business entity to the Trxade Supplier Member with whom they conduct business transactions. The personal guarantee is on all payments of existing and future obligations and the guarantor unconditionally waive all notice of acceptance of this guarantee. This agreement is binding on their heirs, representatives, successors, and assignees. The guarantor agrees to subject their company and themselves to the jurisdiction and venue of the courts in the state where the supplying Trxade Supplier Member operates.

**Authorized Representative Name:**

| Authorized Representative Signature: | Date: |

Trxade
The trusted marketplace for independent pharmacies.
Here is the fourth company I was thinking of:

https://pharmsaver.net

**The Fine Print.** PharmSaver lets pharmacies, hospitals, clinics and governmental agencies buy prescription shopping while saving money and better managing inventory. PharmSaver verifies all pharmacies and will State. This ensures they always get safe, top quality pharmaceuticals at fantastic prices. Remember - it's a

---

**Amy Pistner, Pharm.D.**
Drug Inspector  
Division of Drugs, Devices and Cosmetics  
Department of Business & Professional Regulation  
11351 Ulmerton Road, Suite 309E  
Largo, FL 33778  
Ph: (727) 518-3244
To: Drug Wholesale Advisory Council

From: Renee Alsobrook, Chief, Compliance and Enforcement

Date: August 6, 2019

Re: Compliance and Enforcement Unit report

Council Members:

At the meeting in June 2019, you were provided information as to percentage of violations found during inspections in calendar year 2018. The information provided to the Council at the meeting was:

Violations found in 2018 during Inspections
Non-medical gas 96% of firms include prescription drug wholesale distributors, prescription drug manufacturer, veterinary prescription drug retail establishment but majority of inspections were wholesale distributors
100% of the prescription drug wholesale distributors inspected had violations
   60% resulted in cases against the firm
   40% resulted in notice of inspections issued to the firm

You indicated at the June meeting that “more useful” information would be the type of violations committed or those violations observed/found during inspections of prescription drug wholesale distributors. References to “FS” are to Florida Statutes and references to “FAC” are to Florida Administrative Code. The citations to Florida Statutes and Florida Administrative Code may not be the only way to allege the allegations.

Please find the specific violations found during inspections and prosecuted during the calendar year 2018 and the percentage that the violation would be for the violations found:

9.3% Purchase of prescription drugs from an unauthorized source in violation of 499.005(14) FS

9.3% Failure to provide transaction history, transaction information, or transaction statement as required under this part and the rules adopted under this part, Rule 61N-1.030, FAC, Wholesale Distributor Requirements for Product Tracking and Tracing in violation of 499.005(28), FS

4.7% Firm operating without a permit when a permit is required in violation of 499.005(22) and 499.01(1)(e)(2)(e), 499.005(22) and 499.012(12), FS

2.3% Unauthorized possession of prescription drugs in violation of 499.03, FS
Halsey Beshears, Secretary

2.3% Firm failed to notify the division of change of address/change of location in violation of 499.005(4) and 499.012(6), FS and in violation of Rule 61N-1.015(1)(2), FAC

4.7% Firm caused the adulteration of prescription drugs in violation of 499.005(1)(2)(3), FS

4.7% Firm is receiving and providing incomplete and inaccurate business records in violation of 499.0121(6)(a)(b)1.,2., and 5., FS

2.3% Operating without a CDR in violation of 499.012(12) and (15)(a) and (d), FS

2.3% Failure to notify the department of the departure of the CDR within 10 business days and continuing to operate as a wholesale distributor in violation 499.012(15)(e), FS

2.3% Failure to notify the department within 10 days of the identity of the new CDR and operating as a prescription drug wholesale distributor in violation of 499.012(15)(f), FS

7% Submitting false information to the department in the Personal Information Statement; false information in the application in violation of 499.012(3)(a), (8), (9), and (10)(j); 499.005(19) FS

4.7% Firm sold prescription drugs to unauthorized recipients in violation of 499.005(4) and (15), FS

2.3% Failure to maintain accurate or complete business records in violation of 499.0121(6), FS and Rule 61N-1.012(1)(a) and (2)(a), FAC

2.3% Failure to maintain records on-site and readily available and immediately retrievable for inspection in violation of 499.0121(4)(c) and (6)(c), FS and Rule(s) 61N-1.001(2) (definition) and 61N-1.102(6), FAC

9.3% Failure to comply with federal, state and local laws and regulations in violation of 499.0121(10), FS

2.3% Failure to notify the department in writing within 10 days of a change in firm’s vendor’s list in violation of 499.0121(7), FS

4.7% Failure to report distributions of controlled substances in violation of 499.0121(14), FS

4.7% Failure to maintain records required by this part (or rules) in violation of 499.005(18), and 499.0121(4)(c) and (6)(b), FS

9.3% Failure to have required policy and procedure in violation of 499.0121(8) and (15)(a), FS; i.e., federal verification requirements; due diligence on customers
7% Failure to comply with temperature and humidity monitoring requirements in violation of 499.0121(3), FS

2.2 %CDR not present in compliance with 499.012(15)(d), FS

(document: File name: dwac violation for 2018)