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

Conference Call Number: 1-888-585-9008
Conference Code: 170778661

June 13, 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
Arlene Elliott, Agency for Health Care Administration
Dean Ellis, Secondary Prescription Drug Wholesalers
Jeffrey Tuller, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Peter Hart, Medical Gas
Jennifer Goldman, MD, Physician

DBPR Staff:
Walter Copeland, Division Director
Halsey Beshers, 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. March 10, 2019 Meeting Transcript (information only)
   b. 499.01211, F. S. – Drug Wholesale Distributor Advisory Council

TAB 2: Division Director’s Report – Walter Copeland
   a. Certified Designated Representative Update
   b. Legislative Update
      a. HB-19
      b. HB-7073
   c. Disciplinary Information
      a. 2018 Inspection Violations

TAB 3: Other Business
Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Drugs, Devices and Cosmetics

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

DATE AND TIME: June 13, 2019, 9:30 a.m.

PLACE: Conference Call Number: 1(888)585-9008, Conference code: 170778661

GENERAL SUBJECT MATTER TO BE CONSIDERED: General Business

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

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

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

For more information, you may contact: Stephanie Prine, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, FL 32399-1047, (850)717-1800, Stephanie.Prine@myfloridalicense.com.
COUNCIL MEETING – PUBLIC HEARING

DATE: March 14, 2019
TIME: 9:30 a.m. - 11:45 a.m.
LOCATION: Rosenwald Suites
7987 Apalachee Parkway
Tallahassee, Florida

Stenographically reported by:
Deborah Aliff, RPR

For the Record Reporting, Inc.
1500 Mahan Drive, Suite 110
Tallahassee, Florida

COUNCIL MEMBERS IN ATTENDANCE:
Steve Mayo, Chair, Prescription Drug Wholesalers
Joseph Levine, CVS Health, Retail Pharmacy
Scott Brock, Pharmaceutical Manufacturers
Dean Ellis, Secondary Prescription Drug Wholesalers
Jeffrey Toller, Primary Prescription Drug Wholesalers
Jennifer Goldsmith, Physician
Arlene Elliott, ARNA
Peter Hert, Medical Gas
Michael Moen, Primary Prescription Drug Wholesalers

DBR STAFF ATTENDING:
Drew Winters, Division Director
Reene Alsobrook, Compliance Manager
Ginah Greene, Government Operations Consultant

ALSO PRESENT:
Heather Zick, Amsourcebergen

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PROCEEDINGS

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

CHAIRMAN MAYS: Good morning, everyone. This
in Steve Mayo. I would like to call this meeting
of the Drug Wholesale Distributor Advisory Council
to order. And we have a court reporter in the
room. I wanted to remind everyone before we get
started to make sure you identify yourself before
you speak so the court reporter will know who's
speaking for the record.

For anyone who's on the phone, please mute
your line when you're not speaking. And whatever
you do, please don't put us on hold as we don't
have to listen to any hold music or anything.

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

MS. GREENE: Steve Mayo?

CHAIRMAN MAYS: Present.

MS. GREENE: Jeenu Philip?

(Ro response.)

MS. GREENE: Joseph Levine?

DR. LAVINO: Present.

MS. GREENE: Michael Moen?

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MR. WOHL: Present.

MS. GREENE: Steve Brook?

MR. ROCK: Scott Rock is here.

MS. GREENE: Oh, Scott, sorry.

Arlene Elliott?

MS. ELLIOTT: Present.

MS. GREENE: Dean Ellis?

MR. ELLIS: Present.

MS. GREENE: Jeffrey Fuller?

MR. FULLER: Present.

MS. GREENE: Patrick Baehr?

No response.

MS. GREENE: Peter Hart?

MR. HART: Present.

MS. GREENE: Jennifer Goldman?

DR. GOLDFMAN: Present.

CHAIRMAN MAY: Before we get started, I just want to recognize Tim Pop in the new deputy secretary of the Division of Professions of DOH.

He's here with you today.

So I want to start the meeting off as usual by reading the goals of the council as stated in chapter 489.011(1) of the Florida Statutes.

"The council shall review this part and the rules adopted to administer this part"

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MS. EZH: So for those on the phone, I am going to go through the slides. I'll try to keep you up to date because we [inaudible] -- on slide two.

So thanks for your time today from the board.

What we want to do today is give a little bit of an update. Many of us in the room are familiar with the law, but I think this is quite a lengthy statute to deploy. We're also dealing with a lot of different state agencies, both here locally but also with health in the United States that are working on updating certain documents to align with the federal requirements.

So I'll start off by saying I'm not an attorney. I am a pharmacist, Pharm.D. by schooling.

And we have been working in this field, along with Steve Mayo as my colleague in this space. So we'll do a little bit of how do we get there.

MS. GREENE: Steve, can you confirm everyone on the phone can hear her?

CHAIRMAN MAY: Can everyone hear Mayor speaking or --

MS. ELLIOTT: No. I would suggest she get closer in your microphone because I can hear you perfectly.

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CHAIRMAN MAY: Hang on, we'll see if we can get the sound a little better.

[Off the record for technical adjustments.]

MS. EZH: So let's start out on slide three on the phone. I think many of us in the room are familiar with how this came about, but for those who may not, believe it or not, many times throughout the course as we are implementing changes to adhere to the federal requirements, a lot of times we -- we forget, as an industry, we actually wanted this law. We wanted this statute.

And many of the reasons it was happening is because we had an FDA somewhat of a maybe casualized, quote, peddled on the books for the way that modern distributors were doing business.

We also had, clearly, a law on the books in the State of California that had serialization incorporated within it, also here in Florida. Many other states are starting to look at placing a very we can identify each bottle in the supply chain on the books.

The dilemma we were having as national suppliers or many of the manufacturers that are intraglobal, intra-0.5, we can't adhere to 50 different requirements and still have some type of
commerce that could happen in the U.S. market.

The other thing that was starting to happen is globally, many countries started to pass serialisation requirements. The thing that was most interesting is the first country in the planet that passed the serialisation law was the Country of Turkey. They did not pass it because of counterfeit or illicit activity. They passed the statute because of reimbursement fraud.

So they had a problem in Turkey where manufacturers were producing product and shipping it into this country of Turkey, but when Turkey was paying reimbursement claims as a country, so think Medicaid and Medicare in Turkey, they were paying for ten times the amount of pharmaceutical products that was actually being given to patients in the country of Turkey.

So there’s other drivers that were causing serialisation to be adopted globally. And many of the times it actually was not due to counterfeit or illicit activity, which was the driver here in the U.S.

So one little nugget again on Turkey is, what they’ve done is every unit that comes into the country of Turkey, a manufacturer has to upload the serial number, so the unique bar code on the bottle to a central database that the country of Turkey hosts. Think FDA of Turkey. And then, before it gets given to a patient, the pharmacy has to scan that serial number to the central database and make sure it’s a valid serial number. And then that pharmacy would get reimbursed for that product. If they scan and there’s no match, that pharmacy would not be reimbursed by the Turkish government for that prescription.

So there’s different approaches to how to use serialisation in the market. So that’s how we all started on this journey.

Many of you clearly are familiar. It’s the DQSR, Drug Quality Security Act. I speak a lot to our sales organization. I call them — it’s the Dairy Queen of superior awesome law because I’ll remember that.

(Laughter.)

Mr. HERNIK: I still get e-mails to say, “Hey, that Dairy Queen thing, can you help us understand it,” but it’s a way to remember. With that said, Title I has to do with compounding, so I think we are seeing a lot of 503C entities enter — 501B, excuse me, enter the

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market. But the second component of it is where we’ll spend most of our time today talking, and that’s the Drug Supply Chain Security Act, DSCSA.

I don’t have a fancy little acronym for that so if there’s any ideas, I’ll take suggestions afterwards.

There’s three components mainly to the law that was important to the industry and congress, local agencies, and also the FDA. The first one was a national system for tracing pharmaceutical products, and that’s of course where we’ll spend most of our time today talking about how we’re implementing and how the industry is going forward with that. It also sets a national license standard for three flat and wholesale distributors.

Unfortunately, the statute had a date that I believe was November of 2015, that the FDA was supposed to publish national guidelines. Unfortunately, as an industry we’re still waiting on those guidelines to be sent. And I know it’s causing pain in many states on what to do and how to act on public health, but we’re still awaiting those standards.

And last but not least, criteria on how to handle as an industry addressing what would be deemed a suspect or illegitimate product. And we can go through what some of those definitions mean also.

So it’s a 10-year law that was enacted and there’s various — and we started to call them gates or steps of the law that go into place over the course of 10 years. The law was passed the day before Thanksgiving in 2013.

You know, a little bit of a joke, we didn’t know if they, you know, passed the law or pardoned the turkeys, or pardoned the turkeys and passed the law.

But we had worked as an industry for over five years with Congress, with the federal Congress to get this law passed. Once that happened, we roughly had about one calendar year or 15 months to implement the new transactional information data exchange components, which commonly the industry refers to as either the three T’s or T-I, T-H, T-5, which would be some data sets that we’re passing now between trading partners as we conduct sales.

I’m going to spend most of the time today, though, talking serialisation, what is it, what does it look like, what are our opportunities, what are we seeing. Just so you have some gauge on

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what’s happening in the industry.

So on slide six, this is a package that you can see those, what the unique 2D bar codes look like. So one of the gates — and in the upper right-hand of the slide, you’ll see we highlighted the date and the requirement that each of these slides is linked to, so you can kind of follow a chronological timeline.

So this timeline was that manufactures — fewer manufacturer product on November 27 of 2011 because there was a year of enforcement discretion by the FDA. All products produced off the production line had to start to have the bar codes and the data elements that you are seeing on that slide. What that means is we currently have product today in the marketplace that is still not serialized because it was produced prior to that November 27 date. So we are starting to see much more uptick in serialized product in the market.

There are four data elements that are contained within that unique bar code. So the data elements contained within it is a product identifier. So here in the U.S. market, it must have an NDC number embedded within that. There is a

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from about 500 pharmaceutical manufacturers. None of the bar codes that are contained today on the homogeneous cases look similar. Many of the hospital community also orders in a case pack quantity, and as, unfortunately, the same opportunities of differences in standards across entities.

Slide nine is the goal. How do we move from a hodge-podge of different requirements into a more supply chain standardization, both for the case of merging product, the ease of pharmaceutical manufacturers labeling product, and the ease of our trading partners on the pharmacy side and hospital side to accept them, and also as regulators, for you guys to understand, you know, what is in, what is out, what’s happening here?

One of the main things we worked on is the homogeneous case pack quantities. The manufacturers have started to look at this, on slide 16, as regulated packaging. They are taking now a serial number and placing it on a homogeneous case that’s now become regulated packaging, in their minds and most of the — in their world.

We are seeing some damages still occur in transit, often the ink smears, the corner wraps

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social number, there’s a lot number, and there’s an expiration date. So all four of these data elements are inside that bar code. And you can tell bottle number one from bottle number two, from bottle number 1,000,127.

More examples on slide 16. The numbering is a little off, guys, sorry. Slide 6 went to slide 16 on the ones we went out. Sorry about that.

There is a unique number on each unit and there’s also a requirement to have a unique mark to put on each homogeneous case. So for many of us in the wholesaling industry, we actually tend to and like to interact with our trading partners at a case pack quantity, in particular, out manufacturing partners.

Of course, the hospitals and the pharmacies order at an individual unit bottle, but we do like to interact in the supply chain as much as possible at that case pack level.

We see this as an opportunity. What you’re seeing now on slide 1, like it’s just magical numbering, I guess. On slide 8, you’ll see a significant amount of different types of bar codes. That is what we see today in our space.

So we’re buying roughly, at American Drugstore, for the RECORD REPORTING, INC, TALLAHASSEE, FLORIDA 850-222-5491

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got damaged, et cetera, but there are real things that are happening every day out in the marketplace,

The other things we are seeing on slide 11, which you’ll kind of — on the upper right-hand, we’re kind of joking with the thumbs up, thumbs down.

This is not optimal if we’re seeing types of things that are coming in like this.

So as we mentioned, there were global serialization requirements from other countries.

Other countries have different standards,

Particularly, the country of India has an export requirement for serialization. So what India requires is anything that leaves their country has to have this serialization component on the packaging.

Well, you can see, particularly on the right-hand side where you see 91 in the first two numbers, that’s the country of India’s country code. We can’t read that here in the U.S. It looks like a big bowling ball to us. We don’t have an identifier to understand what that means.

So these are opportunities and challenges we’re running across as the entire globe is running towards serialization at this point.

The other things we’re seeing is really
our technology readers, even if it's an iPhone can pick up on that, that one bar code versus picking up two or three.

Speaking of a little detail here on slide 13, sorry for all the year-year/month-month/day-day

speech on this one. I just wanted to give you a flavor of what we're seeing. We have clearly a HIPAA
guideline here in the U.S. It's more for the

pharmaceutical community that wants the year and the

month of expiration date expressed in a numerical,

and then a two-year period. In many of the technology systems,

manufacturers went the actual physical day of the

month that something was produced. So for today,

the manufacturer would want March 14, 2019 in their
data sets. Well, it really is probably not going
to expire in March, let's just say it has two

years of expiration date. It's not going to expire

March of 2021. It would actually roll back to the

end of February if you're talking from a month

because otherwise, if we put just March, 2019, the

prescriber community thinks it's the end of the

calendar month, not the physical day.

So these types of things have really started to
come out. We sit in a lot of cross-functional,

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Large industry meetings. And a lot of the
content I'm presenting today is just not
AmexSource's content. This is content that
we've been working through with Pharma AMM, which
is the generic manufacturing community's
representation, the brand owners' representation, our
FDA which represents primary
wholesale distributors. We are working through all
of these topics industry wide. So don't think that
I'm the smartest person in the room because I'm
not. This is a lot of intelligence put into this,
and a lot of us understanding, we're kind of
struggling with the expiration date here, with
different ways to recommend it.

And then we're also seeing, unfortunately, the
FDA did publish a guideline draft on how it should
be represented. And then, believe it or not, our
repackaging plants, we got a letter that
contradicted that information from a different
agency within the FDA. So they're getting there
too. They're learning.

All right. I'm going to brief -- and I'm
sorry. That was a lot of pictures and a lot of
detail, and kind of a lot of techy talk. I
apologize.

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when we started to talk about this saleable return
requirement in '99. So the second part of what the
wholesalers had to do this year is, it says that we
can't take back a saleable product and recall that
in the marketplace without verifying the serialized
number on the package. A lot of people ask, well,
how often does this happen and why does this
happen?

Well, a lot of times we'll have a pharmacy —
ok, shoot, I mean to order one, I ordered it, I
don't need the other 10, I don't want to use my
company's capital to pay for those ten units to sit
on my shelf, so I call Dennis ABC, can I please
return ten units I inadvertently ordered?

And in today's world we would say yes, but,
please — we have them go through a process where
they ask for a return authorization. We ask for an
invoice number that they bought that against. We
then send them that, yes, you can send back 10
units. They put the ten units inside a tote or
inside some kind of mechanism to get back to the
wholesaler. They incorporate, unfortunately, a
piece of paper with it, but it's a piece of paper.
They also sign on the back of that that they've
complied with all storage and regulatory

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requirements in order to return those units back
to the wholesaler.

About two percent of everything we sell comes
back as a saleable return. We have done copious
amounts of things within the marketplace to try to
reduce that number, tried to give tools to
different pharma to say is there something
that's going on, do you need an inventory
management system?

But anything we seem to do, we can't seem to
get it below. About two percent of everything we
sell somehow comes back and needs to be, needs to
be identified as a saleable return. It doesn't
sound like much until you try to look at the size
of the U.S. market.

For all of us in the U.S. market, particularly
the wholesaling community at HMA, we all submitted
our data and they compiled it into this slide. And
there is about 50 million units every year in the
U.S. that were sold and then came back in as a
saleable return.

So when we started to look at these numbers,
we got a little freaked out, to be honest. And
many of the manufacturers said, 'Well, this is your
requirement in the statute because it's it's

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under the wholesaler requirement.'

And we said, 'Absolutely.'

My dilemma is, I need them to come along on
the journey with us because, if I have a product
with the serial number on it, I have to ask my
manufacturer partner, 'Is this a real number?'

So here's how we started to go about doing that.

We are going to have potentially two ways to
do this in November. The way that we can do this
is, we'll ask our manufacturer partners, 'Do you
have the ability to send me the serial numbers that
you are selling me?'

So I'll pick on Pfizer, so any Pfizer folks on
the phone, I apologize. We tend to use them
because everyone knows who they are. And I always
use Lipitor because everyone knows what Lipitor is.
So if they would sell 100,000 Lipitor units to
AmisourceBergen, they would send me 100,000 with
the unique serial numbers, and then the equivalent
of the case pack quantity serial numbers, too.

Many of the manufacturers thought that
requirement to pass the serialized data is not
until further down the timeline in the statute. So
we don't have a significant amount of manufacturers
that have the ability to pass us serial numbers for

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what they sell to each trading partner in a supply
chain.

So we identified that, and then we said we
need something else, another way to do this. So we
started to look at something that we've now kind of
branded as the verification router service.

So what that means is, think of it as if I
would have a product from Filter Pharmaceuticals,
I have a product from GlaxoSmithKline, and I have a
product from Lilly. All three of them come back in
one return. I would scan that serial number, it
would go into a phone-book-like directory that
would say, hey, I know that's a Lilly product
because the product identifier is in the bar code.
I'm going to go ask Lilly if this is a valid serial
number and then route that request back to the
person that asked it.

So we can start to ask different companies
different questions, and yet still have a way to
bring that two percent of the product back into the
supply chain safely and effectively.

So here's a little hit. There's a bold slide
for those on the phone. And if it came through as
dark and you want to build it out you can, but
how would it actually work?

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So a dispenser would send a request in for a
reverse for a saleable product. When we first
accept it, we're going to go under the premise that
everything is non-saleable until proven saleable.
We do our quality checks, meaning, is there a seal
on it, is the expiration date greater than one
year, did you sign the return authorization that
says you stored it correctly, etcetera. So
everything we do today, but now adding the serial
number check.
So the product identifier we would have. We
would have the scanning device and scan that
serial number. It would then route to a
verification router. And it goes, "I know that's
Lilly." I'm going to go over to Lilly, ask that
question, is it valid, yes or no? They would route
back to me. I would say thank you. I can tell
it's verified, I'm now going to move it from
non-saleable over to saleable.
And, oh, by the way, for the technology people
in the room, that takes less than one second.
Fingers crossed, both fingers crossed. Both hands
crossed, both toes crossed.
So this is what the industry is working to
build out right now. It seems quite simple when
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you put it on a slide with eight moving parts, but
there is a lot of — I'll say it in my words. This
is Heather talking, not ABC or not of the industry.
We've had a lot of sites of the past that are
coming back to bite us right now, as we're making
some of these decisions. One of it is, we don't
have the cleanest data on the planet. So if I
think it's a Lilly product, the system says it's a
Pfizer product, my phone book is going to try to go
to Pfizer. So we're working through a lot of what
this looks like. Any questions on that?
There has been a lot of talk right now in the
industry and how we're doing this. And we have
some concerns because we have heavily-engaged
manufacturers that are involved and know what's
happening. So it, out of our 450 manufacturers,
roughly 200 and 200-plus understand they have to
help us with this. I have half of my manufacturing
community that says, "I have to do what?"
And we said, if we choose to not verify, let's
say they don't do any of this on this slide, on
slide 19. Everything that would come back from a
pharmacy than would be deemed as non-saleable. And
I would have to extract that from the U.S. supply
chain because we feel that, technologically, that's not
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have credible evidence that the product is not the
manufacturer's product in that bottle, they need to
retain that for additional laboratory use. And the
status lays out pretty clearly.
DR. GOLDSMITH: I have a quick question.
MS. ZERK: Yes, ma'am.
DR. GOLDSMITH: This is Dr. Jennifer Goldsman.
I have a question about the technology requirements
for the pharmacies at this point. What are the
requirements for them to read these new bar codes?
MS. ZERK: So right now, there is no
requirement for anyone to read bar codes at this
point. Other than the fact, if you think you have
suspect or illegitimate, most of the manufacturers
would ask you what's the serial number on the
package. And because it's in human readable form,
they usually could read that component off. So
right now, there is not a requirement in the
statute today to read any bar codes with any type
of technology device at this point.
DR. GOLDSMITH: Okay. And a second question for
patients. From the patient's perspective, I
believe, two years ago when you came and spoke
about them, I think that you said that, on the
individual bottle that patients actually take home
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from the pharmacy, is there any change in packaging
that the patient would need to know about?

MS. EIN: There is some. I mean, we are
getting questions as we're hearing from
manufacturers, patients are now -- so let's say,
what would you -- I'm trying to think.

Like Numbra would be a product that people are
familiar with, that you get the entire manufacturer
packaging kit. We are seeing patients ask
questions about this. Is there some of them
think it's a QD code, which looks like a 2D bar
code, very similar, and a lot of them were used to
scanning that bar code and getting information
about the product through the QD code. So they
were getting side-effect profiles -- don't take
grapefruit juice with it, so they were getting
information that way. And now when they scan it,
it comes up as numbers and they're like what?

DR. GOLDEN: Right. So as providers, as
physicians, should we be educating our patients
about this? Is there a campaign nationally to
advocate patients that this is what's coming?
Because I'm expecting to get questions from
patients and I think our community will have
questions.

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once you take pills from a big bottle and put it
into a little bottle, if you think about it. So I
think what you're getting to, Dr. Golden is, does
every patient who receives a medication require
some type of education on the law, so that, if
they're looking at their product that they receive
and they see something funky, that they know what
it is.

The practical reality is, if they receive a
unit dose product directly from the manufacturer
that would have that bar code on it, then, yes, but
the great majority of those products would be
repackaged into a different form. And unless
there's some type of change in the pharmacy
labeling law that would require such a thing,
they would receive their product no differently
than --

MS. EIN: Correct.

DR. LAVINO: -- they receive it today.

DR. GOLDEN: Thank you for that
clarification, that helps. I'm just wondering if
coming down the pike will be some type of law that
says, you know, to extend that serialization to
these individual products. I don't know.

DR. LAVINO: That would probably -- this is
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MS. EIN: We think it would be wonderful to
be able to tell the patients that the manufacturing
community and wholesaling community and provider
community and the FDA went through all of this
effort to make sure you're getting a safe and
viable product.

I think what we're struggling with now, as an
industry, is the requirements of the statute are
really when you change ownership of product. So to
that patient level, the law doesn't really mandate
it, but logically, you would think they're going to
start to want to use that tool. And so we are
working on what information could we give them.

Right now, if a wholesaler gets information,
we tend to pass them back to the manufacturer to
address from a clinical perspective what they want
the patient to understand. It's a little clunky,
We'll get better. Good question, very good
question.

DR. LAVINO: Can I make just --

MS. EIN: Yes, air.

DR. LAVINO: -- one comment on that? This is
Joe Lavino.

So really the aim and the thought of this
particular law, from a pharmacy perspective, stop

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understanding I need to have a voice in what’s happening. Up to date, most of this work has been done between the manufacturing community and the wholesaling community.

And there are a lot of internal conversations, too, that we’re attempting to help the FDA understand the wholesaling community and the dispensing community more. They’re very comfortable in the manufacturing space. They’ve regulated that for years. They’re less comfortable, I think, with what do distributors do and what do health care practitioners do, what do pharmacies do every day and what are their capabilities?

I think we still have a lot of education to do. And they’re moving a long way. And of course, also, what we see the FDA get stuck in — I’ll put it in my words — there’s a lot of global requirements, so they get invited to all those like World Health Organization things. Well, then they get into — you have 70 countries that have passed a law. Every country has a little bit of a different flavor. And the U.S. is the same. So then they kind of come back and are confused.

Well, pharmacies have to scan. In the European mandate, pharmacies have to scan these bar codes. In the U.S., mandate, it’s not in the statute that way. So if that’s something that’s wanted, there’s a concern. So it tends to become very confusing, very quickly, with all the global requirements here in the market, And I know Mr. Hone is on the phone and others.

I don’t know if they have other intelligence they want to share with the group.

CHAIRMAN MAY: Any other questions from council members?

How about any interested parties on the line or in the room, does anybody have any questions for Heather?

MR. WINTERS: Heather, I did have one question, something we have talked about and —

MR. ESKY: Ma'am.

MR. WINTERS: You mentioned that there’s no standardization in the technology itself. And like you said, I think you mentioned this, that you’re not seeing any move towards necessarily that.

You’re seeing more of an open market competitive and that’s leading to multiple —

MR. ESKY: Opportunities.

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MR. WINTERS: -- opportunities, but I was just wondering, is that -- obviously, sooner or later it’s got to --

MR. ESKY: Shake out.

MR. WINTERS: -- shake out. But are you seeing anything that, you know, leads you to believe that’s going to be happening sooner than later, or are there any times that you think are going to --

MR. ESKY: That’s a good question.

MR. WINTERS: Because I know from a regulatory standpoint, you know, one of the things that we’ve talked about is how do we —

MR. ESKY: Yeah.

MR. WINTERS: -- as regulators, we’re going to be coming in behind this, trying to figure out what to do, you know, how we can read that information? So I know that’s kind of an offsite question, but one that, you know, was kind of interesting.

MR. ESKY: So I think, if anybody has been doing cocktail party or read any Wall Street Journal, I think block chain is everywhere. I said that I think block chain might be able to cure cancer and drive my car for me and maybe even make new toothpaste. I don’t know. I know that’s been one of the very, very hot topics that’s come into
play here in the marketplace around technology use.

And what we’re seeing is, we are starting to see larger players active in the market. So for many of us, we use a tool called SRS, which is a workforce management type tool. Many of the manufacturers use it for efficiency of supply chain. So many of the large distributors.

So one in the healthcare provider space or the retail space uses that tool, so that’s why we’re having these third parties emerge as helping the industry. And what we’re trying to do is stay in touch with the third parties that are supporting particularly the pharmacy community, to make sure we can exchange information, so that burden doesn’t get pushed on every single health system around the U.S.

We are starting to see some coalitions, but not, not at a point yet. I’m envisioning the way we’re rolling, it’s probably going to be 2019, is my gut of when it’s going to kind of start to come together.

MS. ALBROOK: And the FDA has put out a request for interested parties to participate in a pilot project to try to develop some standards.

Do you have any ideas or thoughts as to whether

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are kind of the rules to play in the sandbox? That you have to be a licensed provider, you have to be a licensed et cetera, et cetera.

So what do we want those to be rules about, who can see what data, what does it look like, how does that happen? And that’s – we have also submitted that pilot work. And then last but not least is one around the VMX or the reverse processing component. From a technology point of view, what can we prove out that works?

I think what we fear is, is we know an independent pharmacy isn’t going to be able to probably purchase their own, buy their own. I mean, they’re health care professionals. They’re not supply chain experts. So we’re also taking it on.

I think most of the wholesaling community will have a solution, that some type of ease of use, an app on a phone, do you want to scan serial numbers for receipt, teaching them how to retrieve records out of an online ordering system.

Many of our pharmacies use an online ordering platform. I mean, think about like you’re logging into Banana Republic and you’re ordering shirts and pants. They log in and order like Tylenol and laptop. So we can store those records on their

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manufacturers and wholesale distributors are going to play? I mean, are they going to participate so that there will be some standards developed so we can possibly know what to do then.

MS. EBER: Yes. We at AmericanMedSource have submitted theirs. So we have one that we are partnering with Caviar Health. And that would be a pilot that we have for manufacturers sending us serialized information, and us sending serialized information to pharmacies. It’s the first time we’ll probably go end to end, from manufacturer all the way to health system and retail.

We’ve also engaged, we’re going to engage in what is called a governance policy or pilot. And that what means in kind of back to the point of, if we don’t have one set of standards, we need some type of overarching pharmaceutical governance group that can say yes, you can do it this way, or no, you can’t.

Kind of back to Drew’s point that this is a bit of a wild west right now. How do we control who comes in? And we definitely don’t want a third party to enter and not have the standards of security that the rest of us want. So what this governance group is attempting to do is, say what

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struggling is how do we identify everyone the same way?

I think GSN will be the way we go between, particularly between manufacturer and wholesaler.

It's going to be that wholesaler to dispense that we're going to still have some hurdles to jump through.

And then other information we've agreed upon is, you know, static information on the product, and DC number, a lot number, expiry date, package size, strength. Those, if you will, commonplace, let that roll.

The serial number component has been a bit more. We're thinking the way the U.S. market is going to shake out is we will all still have distributed data models, so, once filter sells to distributors, that data becomes mine. Once I sell to a health system, that data becomes theirs. So we're still, I think, kind of playing in that water.

We do not think the U.S. market will support one big, large serialized database for the whole U.S. We just don't think it's viable. And we don't know who would, you know, who would raise their hand to host that because if it's down, the data needs to be down.

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supply chain is down, the U.S. market is down. And I think, one, there's fear of, "Holy Hannah, that's horrible." But there's also fear of, we, in the U.S., have the most transactions on the planet. Turkey can do it, but Turkey's volume is the size of Kentucky, so there's a little bit of a different scale. So we do think it will be a distributed database model, but how it all rolls together is still rolling through.

MS. ALGROOK: Thank you.

DR. GOLEMAN: I have a question. Will serialization then on a global scale, even without that technology that you're talking about, will that impact in any way the speed at which consumers can identify if their medication -- and probably not because they're in the smaller bottles, but if their medications is subject to recall because there are so many recall happening of late. And I'm wondering if this technology and serialization will, in any way, aid the consumer at the individual pharmacies in tracing that to the source rapidly.

MS. BENN: There's been significant talk about that as a use case -- exactly right on, Jennifer -- that if, if a pharmacy or hospital knew which
You had mentioned earlier, just around

wholesalers operating at the tote or case type

level more often than not, and given the fact that,

in looking at this timeline, you'll have a

requirement to accept serialized product fairly

shortly. When you receive a case or a tote of a

pallet, and you had mentioned that there's now a

bar code on there with a special serialized number

on there, how do you know the stuff inside those

boxes are all serialized and bar-coded

effectively? Is that data stored in the bar

code on the outside or how does that work?

MS. SNY: So the way that the data exchange

mechanism would happen is, think of it like a

parent-to-child. So the exterior of the case,

let's say there's 16 units inside the case. If the

manufacturer can send me serialized data, I would

get 16 serial numbers.

The way it would work on our side is, I scan

the one serial number on the outer homogeneous

corrupted box case, and my system would go,

"Here's the 16 children that are attached to that

one case." So it's kind of a parent-to-child

relationship is the goal. That won't really

start to happen until 2023.

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MS. TULLER: So we're talking about

aggregation from the pallet to the case to the

bottle, and that's not till 2023?

MS. SNY: Some manufacturers have, are

building it into their capabilities now. The vast

majority of them will not be until 2023.

MR. TULLER: Yeah, that's an issue.

MS. SNY: Yeah. And they just -- if you

will, from our manufacturer partner lane, they have

concerns with the quality of that. What they're

seeing is -- and you're going to start to see case

pack changes, too, because a lot of times now we

see, particularly with eye drops or ophthalmology

products, they might have 72 or 144 units in a

case. As they're doing studies, they are seeing

the parent-to-child or the aggregation be, oh,

sheesh, I had 142.

MR. TULLER: Yeah.

MS. SNY: So we're starting to see many of

them say if I -- I can do 24-to-1 pretty good, and

much at a higher quality level. When I get larger

case packs of 72, 144, they're not quite as

profitable yet. I think it will get better over

time, too, the more they work through it, but we're

seeing them not be comfortable with the quality of

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was outstanding and is something that as, is very valuable to both, I think, the industry and to us as an agency to have that insight of what the industry is facing, both from the manufacturing realm and the distribution realm. So many thanks to her and for the time she spent to come here.

MS. ZEHR: Thank you for the invitation.

MR. WINTERS: With that, I'm going to try and make this a quick director's report. If you'll look, the first item, of course, is the rules report. I have no major update from the previous report.

We do have seven of our applications that are still in process to being adopted a rule, and we have slowed that down a little bit. Some items that we're going to be talking about, and our Legislature, of course, may have an impact on those, but again, we are working through those right now.

We have already made some improvements to the current Doing Business, as well, that is available to our applicants, but we have not finished up the adoption process yet. We will continue to do that.

Also, the general definitions on the establishment, security, and storage exemptions

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have the ability to move up to a four-year renewal cycle on our permits. And we had looked at the medical gas permits to possibly be one kind of a pilot project to see about moving those particular permits to a three-year renewal cycle. That would mean that the permit would only be renewed every three years.

And, unfortunately, with the budget the way it is for BOC, it would not alleviate the cost. The annual cost would still be the same, but the overall renewal time period would allow for a three-year license to be issued with payment. And that would avoid one year of work each, each biannual renewal would allow an extra year.

Based on the inspection protocols and the fact that we've got additional OHS inspection staff available to us, and with the hard work that Division Chief Knobbuck has implemented, we felt like this would be a good point to focus, to see if a three-year renewal would be something that would be beneficial to the industry and start with that area. And I open that up basically for discussion.

It would not change any type of requirement. It would simply extend out the time frame. And so

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that we had previously discussed in the two previous board meetings are still on hold right now, going through the general counsel's office. I anticipate those will clear here very shortly and we'll be able to move forward in that process as to those items.

Again, I'll keep the council updated, but I anticipate that those would be moving here within the next week or two to be published. So we've at least moved on for final approval to get them to the publishing.

So with that, if there's any questions on the rules report, I'll certainly welcome those, but I think they're basically status quo for right now.

And we'll continue to push those on and have a more detailed update at the next meeting.

Without any questions I see from the audience or from council, I'll move on to the next item.

And the next two items on the agenda are simply discussion items for us.

One of the things at the agency is we look to improvements and potential changes. And while we talk about them internally, counsel is here to help us understand if there's a concern from the industry. And one of them was, under 699, we do

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that seems like a simple item, but it is something that we wanted to bring to the council for discussion, for council or other items. So I'll open that up to the council first, and then after that we'll have interested parties.

So are there any council members currently that would like to either speak to us or have a question regarding that potential process change implementation?

CHAIRMAN WINS: You said it's currently a two-year renewal?

MR. WINTERS: Currently, all permits issued by the agency are at a two-year renewal if they are required to be renewed. The only other exception to that would be the CDR, which is, does not have a permit renewal requirement, but all other permits are on a biannual renewal.

We changed the wholesaler permits approximately a year and a half going from a one-year to a two-year to alleviate some of the personnel burden on our wholesale distributor permit holders. And that has worked well and has been well received in both the industry and we have seen it -- a good help to us as an individual agency, as well, from going through that.

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MR. HART: So, Mr. Winters, this is Peter Hart.

MS. WINTERS: Good morning, Mr. Hart. Thank you for joining us on the phone.

MR. HART: Good morning, sir.

CHAIRMAN MAYS: Go ahead, sir.

MR. HART: Good morning. I would like to start by offering my apologies to you and your staff, Mr. Winters, and to the council, that I was unable to attend in person, but, as always, I think about you in the warm weather.

(Laughter.)

MR. HART: But my thought on this is, I think it's an excellent idea. And I would actually like to suggest, since this would be a pilot approach, why don't we consider taking advantage of the allowable length and go from two to four?

MR. WINTERS: Well, that is certainly something we could go back and look at. One of the reasons we looked at the three-year approach is because of the language inside of 439, Part III, that requires the three-year on the inspection route, and that's the implementation of the medical gas inspection protocols with our new staff.

Again, those... those led us to believe that

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MS. ALDBROOK: Chairman, one of the things that this three-year cycle -- Mr. Hart might help -- reduces the impact of small businesses. There are several large medical gas manufacturers and companies, but there are also small businesses, and trying to have a four-year renewal cycle where they have to pay the fees for four years would have a pretty stiff impact upon a mom-and-pop operation. Three years is going to hit them kind of hard, but if you plan that in advance, that's something they can probably do. It's just another half a year. But when you have to pay double your renewal cycle, that's going to be a little tough on them.

So the director recommending three years is kind of a -- well, it's better for big business because they get to reap the benefits of not having personnel involved, but it won't be such a hard whack on the small business owner. So that was one of the things that I think we have to think about, when you go from two to three or four, but that is just my thoughts on it.

Thank you for that compliment, though.

CHAIRMAN MAYS: Mr. Hart, anything else?

MR. HART: No. I think that I certainly can appreciate the -- keeping the licensing on the inspection cycle. And as Ms. Aldbrook is -- is wise as always in pointing out that. Yes, I do think of it on the big company side of the spectrum, and you're right as always, and I appreciate your insight.

CHAIRMAN MAYS: Yes, Mr. Brock?

MR. BROCK: This is Scott Brock with Bristol-Myers Squibb. Do you have a timeline for piloting other of the applications, other licenses?

MR. WINTERS: At this point in time, this is kind of -- one of the reasons I brought it was, this is kind of a first shot at this. And it's, again, the medical gas, because it is under Part III, is unique in those aspects. So it was one of those that I really just -- we were focusing on it, and then see the lessons learned. And then, you know, as far as moving out into further items, I thought that, you know, this was, was a good area to look at. And again focusing on the possible lessons learned from it.

So I don't want to put necessarily a time frame on it, but mostly just see that the council use, you know, comfortable with us to even, you
Know, kind of start to brush down that road, to
look at it as a potential process improvement.

It was, you know, as the agency, we always
want to look at items that we can do better, ways
that we can benefit the industry without, again,
needing any of the safeguards that we, as an
agency, are there to implement. And we thought
this would be one to start to research. And this
was kind of my first stop in those activities was
to give those thoughts to the council.

Mr. Broock: Personally, I think it's a good
blend of your budgetary needs with the -- with the
cost savings from the merger -- from a personnel
management standpoint from the licensees, I think
that's a good approach.

Dr. Savina: So a quick question from me.

This is Joe Lavine. And, Mr. Broock, I appreciate
that, but I just want to piggyback on this a little
bit. So what specifically are you measuring with
the pilots?

Mr. Winters: Well, and I apologize if that --
the term 'pilot' obviously is one that could be
taken in another way. And I'll say this. This is
our first move to a three-year renewal in any
license type. We've had two in one, and we've --

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about a major budget concern. And we can, we can
look at, from that standpoint, to see if there's
development of ideas that we can pose to new
permits later.

Dr. Savina: And would those be, such as going
from two years to three years, would the fees that
you take in change in any regard, so is it a
yearly fee or --

Mr. Winters: The fees are just the way
they're set up in the statute, so that gives us a
range of an annual fee. That annual fee, though,
is then assessed on the number of years we're
permitting, much like your tags on your car. You
know, you can take on a one-year, two-year.

Unfortunately, we don't necessarily have the
ability to pick a one, two or three in our system
right now. So we generally have to set that for
the license type as such, that you know, our renewal
process doesn't get off line.

So the change would not necessarily be in the
amount that they pay. The change would be in the
fact that, as Chief Alshemk also indicated and Council
Member Buller indicated, that the improvements that
come through is that the personnel costs that are
associated each time that you have to renew can be

in the statutory change not too many years ago,
there was the ability put in to go up to, to that
four years in the statute. And as we've looked to,
again, streamline our regulation and look at
benefits to the industry that can be done.

This was the first step in that, that
potential as to looking at how it's going to impact
both the permit holders, us from an industry or
from a regulatory standpoint, both from the
processing side and from, again, in this particular
realm we had the -- it's got a medical gas
inspection staff and items that were allowing us to
look at this as kind of that area that we could
focus on for this particular change.

And like we said, it's from a pilot standpoint,
it just gives us that information to start, okay,
look at this, what would the impact -- how do we
see this as -- how did that extend out in our
budgeting, how did that go as far as cash flow goes
when it impacted us?

And from a division standpoint because it's --
it's one of our license types, but it's not as big
of a license type, we can again learn some lessons
from that without endangering any type of operation
of the agency, without the division having to worry

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substantial, as you get together the documentation
and the items that are necessary and then, of
course, you pay that fee. And so that has elements
to it both from our staff and the agency, both, and
outside of the agency with the permit holders. So
that is really where we're going to look at those
items. The change will not be in the cost.

The cost change for the individual permit
holders is that, again, as we all know and as
Chief Alshemk also indicated, if I have to cough
up three years, you know, yes, I'll go two years
without having to cough it up again, but you're
still -- that's a big check to have to pay right
then and there, so that was one of the things we
were looking at.

And that would, with the counsel's -- not
necessarily blessing, but obviously as support, we
will, we would look at that. We would develop it
through a change in rule process with the
application. We would look at an implementation
schedule. We would also look at making sure that
we rolled it out in a method that people would
know ahead of time that it will be coming down the
road.

The good news for us is, at the division, is

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MR. WINTERS: I would not anticipate a change in the application. Of course, we would look at that element to see if there was something that was going to be there, but I'll be -- honestly, I don't think the extension of time is going to have any type of negative impact on our health, safety and welfare requirements, but it's certainly something that we look at as we move forward to implement.

If there is something that we're concerned about, like I said, the addition of the medical gas inspections protocol that we have with our four medical gas assigned, plus our 1.5 FTE that are assigned to medical gas, again, that new resource, I think, is what has led us down to this potential, also.

DR. LAVINE: This is Joe Lavine, when, on the application of the renewal, are you asking these licensees any specific questions about any type of discipline or, you know, criminal actions or anything like that, that have occurred in the --

MR. WINTERS: Each one of our applications has a background indication that any discipline taken against their license or any other -- there are several. And those applications are posted on line with the -- at the department, and you can, you can see those. And you can certainly, as we move forward, we'll be happy to bring copies of those in the future to see those if you have questions about them. But, yes, they are required to disclose, when their application is processed, any previous discipline that has occurred since the last licensure.

DR. LAVINE: So, like moving from a two-year to three-year, there's a possibility that a licensee that's been disciplined would be disciplined for one year with a license out there, that you wouldn't be aware of because you're now lengthening the time frame, is that possible?

MR. WINTERS: There would be a potential, yes.

We would go an additional year before somebody disclosed to us the -- a disciplinary or potential background question. But again, that is kind of the differential here with the medical gas because we do have those additional inspectors that are able to inspect in that time frame. We had expected that would also help solidify and protect against potential health, safety and welfare issues.

So thank you for those questions. They're all very helpful, and help us kind of map our potential for this. And all -- at this point in time, all the comments seem to be positive for us.

So what that tells us is that we'll go back, and Chief Aaldriek and my processing manager, Rebecca Burnett and I will work on looking at how we would like to structure this and move forward, and then kind of circulate that internally to us, and bring that back to the next council meeting for additional information on a change in the application.

CHAIRMAN MAYS: Yeah. You know, coming from the pharmaceutical distribution side, I'll have to confess, I don't have a lot of knowledge of medical gas distribution or in that industry, but I think, overall, it sounds like a positive move, in my opinion.

Any other questions from anybody?

MR. TULLER: I just have one question. This is Jeff Puller. This is really for the chief and the director. Have you seen a tick-up of medical gas providers, based on the population here in Florida is getting older like myself?

(Laughter:)

MR. TULLER: So my question is, going to this move, I think you touched on the health and welfare issue in terms of the delta, if it's
MR. TULLER: Do you track those for all of the --

MR. KUPFER: We look at, quarterly, we look at all of the licensing permit types and see what their permit numbers are, due to, you know, going through some reports we do have. And so yes, I have that comparison that I run each quarter looking at those. So we'll have our -- here run the licensing quarterly so we can see that.

Now, on a day-to-day basis, we may have a permit that is relinquished and one that comes to due, so you know, that is a cumulative total, but overall the number inside of the industry itself has -- it fluctuates in small amounts, but not -- I've not seen a large increase based on the numbers.

MR. TULLER: Okay.

MR. KUPFER: But I will turn it over to Chief Asbetrock, to answer your questions as well.

MR. ASBETROCK: Mr. Tuller, we have six bodies that do inspections, and one is a half-time employee, but -- and we take the total number of medical gas manufacturers, wholesale distributors, and retailers. And there is, by far, a larger number of retailers. And we identify the priority.

MR. KUPFER: I'd also like to mention that we have an internal agency, the department of health that does all of the inspections. And I've had -- I've been on the board of directors for that department.

MR. ASBETROCK: We do that for about 3000 permits; we do 2000 audits a year.

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MR. TULLER: Okay.

MR. KUPFER: But I will turn it over to Chief Asbetrock, to answer your questions as well.

MR. ASBETROCK: Mr. Tuller, we have six bodies that do inspections, and one is a half-time employee, but -- and we take the total number of medical gas manufacturers, wholesale distributors, and retailers. And there is, by far, a larger number of retailers. And we identify the priority.

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MR. ALBRIGHT: No, but the wholesale

distribution, you'll have around 300. The medical

gas retailers is substantially higher than that.

The director may know the number. He sees those

numbers every --

CHAIRMAN MAYS: I was just curious about how

many. I just have no idea.

MR. WINTERS: This is one of those times that

I know the numbers, but I know just enough to

probably get them wrong.

[laughter]

CHAIRMAN MAYS: Don't worry about it.

[indistinct, overlapping comments]

CHAIRMAN MAYS: We probably spent a whole lot

more time on this subject than we planned anyway.

MR. WINTERS: Conversations like this are good

for the agency, helps us in trying to implement

things.

CHAIRMAN MAYS: Okay.

MR. WINTERS: So thank you, Council Members.

The next item which is Tab C in the Director's

Report is paperless licensing. This is a discussion

only. This is more of a -- it's a discussion, but

it's also mostly an announcement, that this is

something that the agency itself has to move

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that.

And so the agency is moving toward what's

called paperless licensing. What that means is,

instead of sending a hard stock paper license, what

we would do is we would transmit a digital license

via a PDF version of the actual license to the

permit holder. That would be sent to -- upon

approval of the license renewal or the initial

application, that would be sent to the applicant

contact, the individual person that is listed on

the actual application. And it would be able to

be uploaded. They could print that license for

display. And then also, in the event that they

needed a duplicate copy, they could actually be

able to produce an additional copy of that

license as necessary.

The benefit to that is, also, as many of you

are aware, when you need to get duplicates, you

have to pay $25 for us to go out there, research

it, pull it, and reprint that license for you and

send that hard card permit to you. And it takes

days to do that, plus the time to mail. We also do

that, so this would be the availability to do that

digitally so the individual person would have

that.

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That is the move that the agency is making.

The licensees will still have the safety protocols

that they had, from a standpoint of, they'll still

have a QR code that can be seen to ensure the

authenticity of the license, and also the current

status of the license that is built into every one.

And so that is a move that the agency is, is

looking to make, and I, as the director, am moving

to make that, implementing it at OCC.

The other thing is, is in the event that

somebody did need to get a copy of their license,

it could be tied to their Versa online account,

that you could log on to that account from an

entity standpoint, with the access to the Versa

account, and be able to again produce a copy of

that permit in the event that you need it for

regulatory purposes. It's a cost saving. It's a

time saving, it's from that standpoint.

One other thing that we looked at, which was

to again assess whether or not it was going to have

an impact on the health, safety and welfare. And

while the old physical cards themselves didn't used

to have in them some built-in items that much like

dollars bills, it had a -- you know, you couldn't

photocopy it.

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We've looked at that issue and the problem is
with new digital technology, many of these are --
they're just not effective as far as the current --
and were just --

(Music noise interference.)

MR. WINTER: -- in many respects we're not
seeing that as a problem. And as we build our GB
code, those built-in items that allow to be
authenticated are the better protocols. Plus, the
industry benefit of being able to do this, avoiding
costs, having to spend time on printer
time, paper, etc., associated with that by
being able to send it to you digitally, being able
to print it yourself.

I see almost all positives from this, and no,
what I'll call, real definitive drawback to it. So
I'll put that out there for comment, just to
receive the council's or any industry's or
interested parties' comment about that, as to
whether or not there's concern from the industry.

CHAIRMAN MAYS: Any questions from our
council?

MR. FULLER: Jeff Fuller. I just have one
question on that. I think it's a great idea,
long overdue. Nest states are practicing that.

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obviously, now.

My question is on the replication piece that
you talked about. If you do need a hard copy, is
there going to be a $25 charge for that replication,
and you can actually get a hard copy, so I guess
that's two questions?

MR. WINTER: That that question is, is still
in place. The answer is that right now, I would
anticipate that that would be what would happen,
The only issue, I think, right now, is we're going
to have to look at long term, the necessity to
maintain the equipment to create these, those
licenses, is where we're going to have an impact
because those, as those pieces of equipment again
are -- start to fall out otherwise, or if we're only
reproducing once in a while, it would lead to an
issue from that standpoint. So we'll have to look
at that.

Right now, we're leaving in place from a
transactional standpoint in the system and
everything, that there would still be that $25
charge. So we're leaving that aspect in place for
now, but the anticipation would be, is it
eventually would phase out and we would not do
that. It's kind of in for a penny, in for a

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pound. At some point in time we're going to have
to go ahead and move to that, just because of a
personnel and an equipment standpoint.

MR. FULLER: Thank you.

DR. LAVINO: Joe Lavino. Quick question from
me. This makes perfect sense just from a risk
benefit standpoint.

Would you anticipate that there could possibly
be any regulatory impact as far as any existing
language, either in wholesale or pharmacy or
whatever the case may be, that would require or
mandate what a posted license looks like in their
facility?

MR. WINTER: The answer to that, I don't
anticipate any impact. The other issue is that
upon receipt of the statute requiring posting of those
licenses, it simply says you have to post the
license. And the department would still, because
we're going to transmit this in a form that it
can't be altered, that when you print it, that
would, in fact, be your license. So it is,
literally, simply your official license being
digitally sent to you.

So I do not anticipate any regulatory impact
of, of that, and any necessity to change any, any

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major statutory provisions because the department,
in general, has looked at this, and it's actually
implemented in multiple states and professions
already.

Luckily for us, we're not always, you know,
in this particular case we weren't the guinea pig.
I hate to say it that way, but, one board has to be
the first one out of the gate.

I believe that they -- one of the professional
boards that did it, I think cosmetology was the
one that actually did that, and that rolled out and
so far has been very well received. And we have
not seen any major issues that has been reported
to me,

And again, with the benefits, I think, in this
particular case outweigh the potential dangers.

Again, the license would only be transmitted to
the applicant contact via a secured e-mail to them.
And then the only other way to access that permit
would be to go to the Veris online access, which
requires password and identifiers to get into that
account, to be able to access that license through
that account.

So the safety protocols in that are that you
have to go through the validation process to even

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MR. LANGRO: Thank you.

CHAIRMAN MAYS: I probably have a dumb question. Heather can tell you, I'm not very technically savvy. The PDF, like you said it would be a PDF file, so can that be printed off like multiple times or is it just once like one time?

MR. WINTER: It would be able to be printed off multiple times. The expectation is, is that you would be able to reproduce it as needed.

Again, the tradeoff of that is, is that, as we all know, we do worry about counterfeit documents. The agency has come across counterfeit documents. In our profession, not as often as other professions, but with the advent of technology, we've seen that the modern technology is able to get around many of the -- what I'll call more manual style of prevention items that are available for them to reproduce these.

The benefit comes from we've embedded in these particular items and document numbers and QR codes that allow us to authenticate the actual permit itself, rather than authenticating the paper version of what is printed. So in the industry,

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MR. WINTER: This would change nothing as far as the requirements to post your licenses. It requires no statutory change. This is just a modern version of your permit and how you can obtain it.

CHAIRMAN MAYS: If I wanted to print it on like orange paper and even wanted to print his on green paper, it wouldn't really matter, right?

MR. WINTER: It would not. It would not matter.

[Indistinct, overlapping comments.]

[Laughter.]

MR. ELLIS: I like the green, though.

CHAIRMAN MAYS: I just never -- I really always have had a hard time grasping the posting requirement because, like for a wholesale distributor, we have all these licenses for all these states posted on this big board, and the only people who see it are our employees. So that always kind of baffled me.

MR. WINTER: Yeah. So it doesn't change any of that. Those are requirements that are mostly created for everybody.

CHAIRMAN MAYS: It would be nice if we could have an electronic bulletin board at some point.

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what we would do is put out some information on how people can validate those permits, because they'll be able to see the permit.

Plus, they'll be able to take that information, the QR code, you know, I know the QR code with serialization and everything that we just talked about with Heather kind of falls in there, but they would be able to confirm through that system that that permit is exactly the person they intended, the name matches up with the actual name printed. So in the event that somebody did try and alter one or change it, they would be able to validate it.

Again, the same issue comes up now when we have somebody who takes a hard card or something and tries to reproduce it and make a counterfeit license, because of the way digital -- digital scanners now, and the way that they can get around that, we've -- that benefit is being -- we're using protections that that can't get around. So as technology improves, so do our security protocols, and that allows us to transition to a more modern style of licensing.

CHAIRMAN MAYS: And that would still require the card to be posted?

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where you can see your licenses, here it is.

MR. WINTER: I'm sure that will be, will eventually come down the way, as everything does.

CHAIRMAN MAYS: Great.

MR. WINTER: I'm still trying to get to -- I keep an issue, but, ironically, I write everything down on a piece of paper. Even I understand that going digital sometimes is not as easy as it sounds.

But with that, I just wanted to put it out there, if there's any other concerns other than that, I think this was --

CHAIRMAN MAYS: Sounds good to me. Any other questions from anyone or on the phone?

MR. ELLIS: This is Dean Ellis. Several times today I've heard "small business" mentioned by the Department. As a small business owner, we appreciate that.

My question is, or I'm not exactly sure if I want an answer, but I just -- I want to bring this up. In the secondary wholesales, we're obviously required to have a prescription drug wholesale license, but as these requirements keep getting tougher and tougher, a lot of the small businesses are going to be -- their resources are going to be stretched to meet these things.

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So is there anything that can help that situation? In other words, if a distributor who is distributing devices does not want to be burdened with the prescription drug wholesale requirements, what other license or is there another license that we -- that could be obtained to allow them to operate?

MR. WINTER: And I want to, this may be something that we can have additional dialogue about, but when you're talking about devices, we -- I know there's a combination on those, that most any devices are combination product because they have both the device aspect. And the prescription drug aspect, are these mostly the combination products you're talking about or are we talking about ones that don't have --

MR. ELLIS: Basically, the labeling, as federal law prohibits -- don't hold me to this -- prohibits dispensing without a doctor's order.

CHAIRMAN NATH: It's a little clumsy for devices. Sometimes it's Rx devices --

Mr. ELLIS: Sometimes it's Rx only, sometimes it's --

(inaudible, overlapping voices.)

MR. ELLIS: Yeah, it could have the statement

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or it could have a little R, but it's not --

there's no tracking other than lot numbers,

Mr. WINTER: Right. But the reason I asked you, you mentioned mostly injectables as far as the example that --

Mr. ELLIS: Correct.

Mr. WINTER: -- when you say injectables, you know --

Mr. ELLIS: Would be lidocaine, Kenalog, you know, those type of things. B-12, you know, that type of thing.

Mr. WINTER: I think that, you know, I think the problem that we have with this -- and I'll also let, again, Chief Alsheik is my expert when dealing with those items -- is that, when it comes to a pure device, one of the items that we have is that there's no significance exception in the Florida law for devices, as well as no requirement for the actual -- no distributor's permit for that type.

Mr. ELLIS: Correct.

Mr. WINTER: Those particular devices, we see the -- the elements that come in for us is when we have a device, it also has a prescription drug, which again makes the regulatory --

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MR. ALBROOK: Understand, I'll get there.

MR. ELLIS: Okay.

MR. ALBROOK: And if you had that, then that would solve your issue that, no, you're not a manufacturer. But there's currently a provision in the statute that talks about applying for it and not needing it if you do A, B and C.

MR. ELLIS: Oh, there is?

MR. ALBROOK: Yeah. We'll look at -- the director and I will look at that, and see if he would be able to issue you a letter that indicates you've submitted this information and you don't need a permit from the division, and that may satisfy the people that you're purchasing from, because, if you don't need a permit, you don't need a permit, right?

So we'll look at that when we get back to the office and maybe call you and have a conference call or something like that and --

MR. ELLIS: Oh, that would be wonderful.

MR. ALBROOK: -- and figure that out.

MR. ELLIS: Because it's a concern because there's a lot of small business distributors who are struggling. We already -- I'm sure you know this because --

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been, as best we can, we work with those individuals. We've even reached out to other states' regulatory entities to try and provide the additional backup necessary for phone calls, you have, coordination with them, and we will continue to do that,

But, as Chief Albbrook indicated, there may be an opportunity for us to provide some additional documentation, not necessarily in the form of a license, but possibly a validation of a confirmation, written confirmation that this particular entity based on what their --

(Microphone failure.)

MR. ELLIS: That would be excellent. And may I follow up with an e-mail for both of you?

MR. ALBROOK: That would be great. Send it to Dinah.

MR. ELLIS: Should I forward this to Dinah?

(Indistinct, overlapping voices.)

CHIEF ALBROOK: Dinah is the gatekeeper.

MR. WINTERS: Dinah is the gatekeeper, the traffic controller and probably in charge --

MR. ELLIS: Well, thank you for that answer.

It's a -- I haven't known how to answer that in my industry, as I was hoping to get something today

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and I appreciate that.

MR. WINTERS: And you're always welcome to come to us with those items, and we'll do our best to craft solutions. And if that requires us to do some outreach on our part, that is something that we, as a division, do.

MR. ELLIS: Thank you,

Oh, I here -- I'm sorry. Dean Ellis again.

One other question. I'm sorry. The paperless licensing, how are we progressing on the electronic applications?

MR. WINTERS: We -- actually, I'm glad that you asked that. We have been moving very quickly towards that. Matter of fact, we have already submitted an RV request, have gone through all the transaction types inside of the agency for DOC, and crafted additional items, electronic templates,

And that is a high priority for the agency right now, across the board. And we've seen a lot of activity just in the last couple weeks.

I'll talk a little bit of -- I'd like to compliment my staff because I do have a great one.

Bryan Wadeles is our data steward and Rebecca Burnett on my staff, many of you know that I'm working with them. They have been working with IT
in order to get to the online application process, which again, hopefully we'll streamline the availability of that documentation on our system and produce the inaudible as necessary. To do that, we have already gone through as addition of templates and those are inaudible to technology. I don't have a specific timeline, but again, the end of the year is a general standpoint that we're either going to be there or be very close.

MR. ELLIS: So the other ones that you have already implemented have been successful?

MR. WINTERS: The -- as far as the online application --

MR. ELLIS: Yes.

MR. WINTERS: -- process?

MR. ELLIS: Yes.

MR. WINTERS: Those that -- that we have been able to implement. Obviously, the Division of Drugs, Devices and Cosmetics is very unique to the agency, in the fact that our applications are more detailed. And we also have a little more detailed review process, both for initials and for renewals. But right now, I will tell you that most of our renewals are online, and you can go through the

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(Versa online application process and get that. Our goal is to get everything on line, including initials and renewals. And we've identified those and are in the process of creating those individual templates, so people can go in to our online portal and submit those.

Like I said, we've got an aspirational goal to try and get everything on line by the end of the year. That is, that is a courageous goal, but one that I think, is one that needs to be put out there. So we're hoping that that would be forthcoming quickly.

And I thank you for the question because we know that that's something that the industry is wanting. And that does help us, again, on the changes that the current administration has been highly looking at that, and is moving closely or very quickly towards that because they know that benefits the small business.

MR. ELLIS: Thank you.

MR. WINTERS: All right. With that, do you want to move on? Does anybody need to take a quick break for the restroom? I feel like I'm being long-winded today, so I'll never say I'm going to try and make this quick ever again.

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(Laughter.)

MR. WINTERS: So that will teach me.

All right. Well, the last thing that we have on our agenda for today, we have "A," There's actually three items underneath this. As you all know, 'tis the season, this is the legislative season. The session kicked off over -- I believe it was March 4, and the Legislature is in full swing and moving on in bills. And as we see then that may have an impact on chapter 499, we try to bring these to the council's attention.

The one that is in front of you right now, I'll start with, which is House Rule 19. This is a bill that was filed. It does have both the pending bill from the Senate, which is Senate Bill 1452.

There is also a similar bill in there that actually uses the very first portion of it, which is the Canadian importation provision, and that that portion -- that bill is coming with only that portion.

But with that, just a reminder, though, from an agency standpoint, we bring these to you, as the Council, for your knowledge. As the agency goes, our job is generally for review and analysis of what it would take to implement the bills and

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any potential regulatory impacts that this may bring about to our permit holders and the fiscal impact.

We generally are not -- we are not to bring those to you as far as telling you the Department's policy statement, but only for the knowledge. We generally recognize that absent the ability to run directly by the agency, we'll let the supporters and proponents of the bills provide the overall policy statements that they have on -- on the reasoning behind the bills.

The bills that you have in front of you today are not run by the agency, and so these are here for your knowledge. The first one is House Bill 19. This does create, again, the Canadian prescription drug importation program within the Agency for Healthcare Administration, and the international prescription drug wholesale importation program for us. This is -- it is a not a lengthy bill, but it's a bill that does provide for some unique aspects to 499.

As most of us are aware that under the current FDA requirements and under Florida's guidelines, without an FDA-approved drug that is coming from a permitted FDA-registered establishment and then

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It's shipped directly in Florida, a Florida
prescription drug manufacturer's permit, you're not
permitted to bring wholesale drugs in from other
countries, only from inside of the United States.
The program that is in front of you that I'll
focus on, because the first portion of Canadian
drug importation program is situated at ANCA. I
will simply note for everybody its existence and
that it does allow for certain drugs to be imported
by entities that are regulated and overseen by the
Agency for Healthcare Administration under certain
provisions.

I will -- there is a -- we can go to both the
Senate and the House of Representatives' web sites
for additional information from their analysis
of it, and so, too, the Agency for Healthcare
Administration, but I will focus on the

International Prescription Drug Reimportation Program.

That portion of the bill actually starts on --
If you'll note, on page 10 of the bill that's in
your agenda materials. And that program, again,
does establish within the Department of Business
and Professional Regulation, specifically in the
Division for Drugs, Devices and Cosmetics, a
program for the reimportation of safe and effective

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wholesale distributor or a pharmacy or a pharmacist
under this particular program. Again, there would
be an additional registration requirement for those
entities that are going to be exporting or
importing from a lawful supplier under the program
with the agency, as there will be additional
registration requirements that are going to be
required in order to provide for this program.

Again, the importation of that, again, has many
restrictions on it, and so I will, again, let the
council members review that.

I believe that if you look, though, on
page six, which starts on page 13, but the
(insoluble) starts on page 14, there are, again,
a large amount of documentation and issues that
would be required in order for drugs to be imported
under the authority of this particular program.

And so, that those requirements, again, in
some respects mimic some of the items that are
already required under current federal regulation;
but again, there are multiple items that have to be
brought in, too, including the price paid, the
original point of origin and destination of the
prescription drug, the quantity of the drug, lots,
control numbers, the name, address, telephone

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tested for authenticity and degradation. And subsequent shipments by the importer, again, there would have to be a statistically valid sample of the shipment and tested for authenticity.

If it's shipped from a non-first foreign recipient, that means a secondary wholesaler, it would have to show demonstration that each batch in each shipment offered for importation into the state is statistically sampled and tested. That testing would have to be done by a qualified laboratory, and they have to submit those certifications, the information has to be submitted along with the documentation.

And the other important thing is, in this particular case, is that all the testing has to be done by a qualified laboratory under the terms of the bill. That qualified laboratory would have to be a laboratory that has been approved by the department. And we would have to implement a program by which we would determine the qualifications for the qualified laboratory.

It does provide for the immediate suspension of the ... anybody's importation authority in the event we found a potential or discovered any potential violation. That suspension would be able to be...

mechanisms that would allow for the United States to ensure compliance with the applicable federal standards.

So the bill goes on, again, to change the section 499.012, to provide the cross-references to our other requirements, including the international prescription drug wholesale distributors. The purpose of this is to know that a CDR would be required for an international prescription drug wholesale distributor, so they -- any entity that wanted to do that would still have to comply with our CDR requirements, so again, for those, those items. And again, it would be a requirement for anybody seeking this permit, that they have to demonstrate that they have the appropriate licensees from the country, and they have the federal agreements in place to allow us to provide that permit, so the duty would be upon the permit applicant to provide that additional information.

That's the highlights. I won't go -- there's a multitude of additional items that we could go over in detail, but I mostly wanted to bring this to your attention because this does have a direct impact on the division. And it does have a direct impact on the agency.
I think the most important aspect of it, I will draw your attention to the last point of subsection 11. It says that notwithstanding the Federal Food and Drug Administration's Cosmetic Act, that the department, in collaboration with the Department of Health, would have to negotiate with the federal government in order to arrange for this program to be put in place. So absent some federal guidance or authorization of some sort, this program will actually not — would not be able to be implemented into totality.

The bill itself is effective July 1, 2010. If it passes, the department would move forward with implementation of the program, but it would also contingent upon, again, a federal authorization to engage in it. So, again, that was one aspect that needs to be considered is that it does key highly on the federal government's authorization of it, also, and compliance with the permit requirements.

So that, in a nutshell, is the bill, I wanted to again bring it to the council's attention because it does have a significant impact on our division. We would anticipate that there will be a fiscal impact because of additional personnel needed for the program. And we would expect that way this would work is if the products are brought in meeting all the requirements of the FDA-approved drug. But again, until we receive the approval of the passage of the bill and then in contact with the FDA, you know, part of that would be the registration with (inaudible) —

(Background noise interference.)

MS, EDM: It's called out in the Canadian one separate on page 8, in (71a), but it isn't called out specifically in the international section. So probably someone -- it's called out because I think, like I said, (71a), on page 8 of the 39 in the Canadian section, it's called out, but it's not in the -- I didn't see, in my quick scan, the international one.

MS, BROCK: Does the Canadian do the serialization, coding, and so on? That's included in that, does Canada do that currently?

MS, EDM: They do not have a formal statute, but they are using the international global standards that we use in the U.S., but they would encode it with the Canadian global trade identification number that would not equate to a national drug code.

So a lot of the times, what third parties have

we would need at least one more processor and two pharmacists, one to be a senior pharmacist for purposes of reviewing applications and other information, and one additional inspector for Chief Almbrook.

And that's amenable as we also don't know how big the program will be in its -- in its aspect once it became operational after receiving the FDA authorization. So we would have to see how far and how large that particular program got in the event that it does pass.

OK, GOLDMAN: Question, this is Jennifer Goldman. What are the serialization requirements for the drugs that will be coming from other countries?

MS, WINTER: Again, that is, the answer to that question is, is that they would have to meet the FDA's requirements. In this particular case, it applies the FDA's requirement, labeling, misbranding, adulteration, approval. So in some respects, it has to be a fully compliant FDA-approved drug.

So I would expect that, you know, obviously, as this program develops and we see the information, again, I would expect that the only

way this would work is if the products are brought in meeting all the requirements of the FDA-approved drug. But again, until we receive the approval of the passage of the bill and then in contact with the FDA, you know, part of that would be the registration with (inaudible) —

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So a lot of the times, what third parties have
Canada meet that requirement of 7(b)(a).

Ms. EDEN: (nodding head.)

CHAIRMAN WATTS: There's some issues, I know, now, because FDA will allow, in extreme circumstances where there's drug shortages for importation, for the temporary importation of some drugs for a long time. We can't. It's very difficult for us to handle those drugs in our system because of the bar codes and the no-wau numbers and things like that, so it's really tough from that perspective.

Ms. EDEN: It's, I think, where they run into policy versus the application ability of it. I think, fully understood, this is a -- you know, a national issue that is -- and I'm sure the agency is in a position where you've got policy that's putting you guys in a difficult position from a regulatory point of view and how to secure public health. But the business side, to Scott's point, it is very difficult for us to administer. Although, policy point of view is such that it sometimes doesn't always coalesce with what's applicable or can be executed.

CHAIRMAN WATTS: Mr. Brock?

MR. BROCK: Drew, did I understand you to say, from a regulatory perspective, the international section clearly is in your -- under your purview. The Canadian, the section two is not really under your purview? Is that -- did I understand that?

MR. WATERS: The drugs, obviously, in the state of Florida, our agency has authority to inspect and investigate the possession of drugs in the state of Florida, but implementation of the actual program was actually deferred to the Agency for Healthcare Administration because it's limited to entities that would be under their authority.

So those drugs that they're importing would only be for a select number of entities. And they're general public entities, Department of Corrections, free clinics, things like that, that the Agency for Healthcare Administration would be dealing with.

And so in some respects, as far as implementation of the actual program, it does defer to the Agency for Healthcare Administration, which is one of the reasons why, as an agency, I'm not going to say that it doesn't impact us specifically because it would require -- have the ability for additional drugs to go into the state.

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But I believe, though, that it's prudent for us just to note that the Agency for Healthcare Administration has the authority for implementation of that. They also have to meet with the federal government in order to secure an appropriate implementation of that bill.

And so that is, that is the only reason I said I kind of would defer to them because each agency has a responsibility for analyzing and determining the impacts to its -- each individual entity for implementation.

And like I said, we recognize that when we bring these to the council, that from an industry standpoint and from policy concerns, there's much that can be brought up by these bills that could be both good and bad from industry and different elements from industry. And so that policy discussion is, in many times what we -- we look to (insubstantial) -- to provide as far as legislative input.

From our standpoint, the agency, what we look at is for them to understand that we identify regulatory issues that have come from us. Any particular area where we don't know we can implement or could be costs to implement those programs -- (insubstantial) -- so very similar, we provide awareness to the Legislature if they -- they determine policy warrants the change in law, that we will be able to implement the program and we will need the resources to do it.

MR. BROCK: One followup.

CHAIRMAN WATTS: Mr. Brock?

MR. BROCK: So the implementation of the Canadian program is ARCA's, but the regulatory, I mean, it will have a regulatory impact on you all?

MR. WATERS: It will. And what we will be doing as we do with every issue, we do have contacts with the Agency for Healthcare Administration, as well as the Department of Health, so we will be exercising the ability to work with things they need from us, as far as their implementation, but we will reach out to them to ensure that we provide as much information from our standpoint, and guidance to them, as well.

So we -- we maintain a good, close-working relationship with all of our sister agencies and we will continue to do that. And especially in these realms where you've got two programs that are very similar and kind of the scope of what they're...
And then they pick up the labeling requirements.

That's on page 26, I think.

MS. ALSBROOK: It just references separate sections of the bill, but they're both in there.

MS. ALSBROOK: And they picked up the labeling, I lost that provision, but they picked up the United States Code. Oh, there it is, on page 15, on lines 373, 373. So there are citations in the bill that do try to protect and make it equivalent to the Florida — excuse me — the United States requirements for the drugs.

The interesting part, to me, will be when they come from the French province, that how are we going to read those, but it will be fine.

CHAIRMAN WATTS: Especially when you start looking at, you know, the FDA's suspect, illegitimate, suspect identification requirements, you know, you're seeing foreign language on the bottles.

MS. ALSBROOK: Yeah.

CHAIRMAN WATTS: That's a false positive there.

MS. ALSBROOK: That's one of those, that's one of the items, isn't it, Mr. Watts?

CHAIRMAN WATTS: Right, right.

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As you know, it's been a couple of days ago
with the committee, the community discussion, and
they have so many questions and we are addressing
all those questions. So whenever we have an update
or more information than what I have today, I will
let you all know.

CHAIRMAN MVS: Thank you.

MR. WIPERS: Thank you, Allen. We really do
appreciate it. Again, if there's anything from the
Department's standpoint we can assist you with,
please do reach out to us. We'll be happy to
assist where we can.

MS. ELIOTT: Thank you so much.

MR. WIPERS: All right. With that, I'll
change to the next item, which is House Bill 759,
I bring this one to you because it does have an
impact on 496. Please note for this, there are two
bills here and I'm going to take them together
because they have -- they are actually what we call
related bills. The passage of one is tied to the
passage of the other. So if one goes into effect,
the other one will go into effect, as well. If one
doesn't go into effect, the other won't go into
effect.

So the first one, House Bill 759, it is a
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it does create, as noted on page two of six on
House Bill 761, the trade secret held by an agency
is confidential and except from chapter 119.07(1),
and section 24(a), Article I, of the State
Constitution.

The important aspects for this from a
standpoint is that, if you'll look, starting on
page two, it requires a specific notice of trade
secret when you're submitting records to the
agency. That means that, if you're an applicant,
if this were to go effective, then an applicant who
was, or any individual that was submitting
documents that were trade secret to the division,
that the department would be required to provide a
specific notice of trade secret and that the
notice has to provide certain information, again,
the name, telephone number and mailing address of
the person claiming that the record was trade
secret. And that, also, it puts the requirement
for that person to update their contact information
specifically with the agency.

The most other portion of this, I think, is
prevent to note for everybody, is that not only
does it require to notify the agency of the trade
secret, but it requires a particular form filling of
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Substantially lengthy bill, 100 pages. If you'll
look, actually, on page 52, in sections 40, 41, 42,
43 and 44 of the bill, it makes changes to sections
409.021, 499.021, 499.05, and 499.051, and
finally, 499.931. Each one of these provisions
specifically has to do with the trademark
protections that are currently specifically
enumerated in chapter 499. The bill is actually
striking on these specific items in 499, and is
removing the references to trade secrets.

Then as, in effect, we currently, when
somebody asks us about trade secret information,
we do reference those particular points inside of
our statute. Those would be removed if this bill
went into effect.

The reason I noted the companion bill is
because, if you'll note in the companion bill, it
actually creates a new section under chapter
688.01, which basically creates a trade secret
exemption from inspecting or copy of public
records.

It basically hones, in this particular
instance it takes out all the -- the language
specific in our practice act, and then makes a
blanket one in 688.01. So the record exemption,
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that request.

And so it says, on page these of six: "In
submitting a notice of trade secret to the agency,
the submitting party shall verify to the agency
through a written declaration in the manner
provided under 92.525 the following..."

And it has specific language.

'"I have/my company has read the definition
of trade secret as provided in 688.01, and the
information contained in this record is trade
secret as defined under section 688.01."

And that they have taken, again,
specifically taken measures to prevent disclosure
of this particular one, and, again, that the
record or specific portion of a record claimed to
be a trade secret has not been reasonably
obtainable without consent by other person by use
of legitimate means.

Again, the agency will be looking and
monitoring this. It does still provide for the
trade secret information, but we will have to
implement some potential upgrades and changes to
the application forms, and will again make sure
that we do a substantial outreach to our individual
applicants and license holders in the event that
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this does go effective, because currently we do
can simply check our applications if they
intended for that application to be trade secret.
Now, it will require an additional notification
from any person, but that is access the board for
anybody that is submitting trade secret
information. Because it does have an impact on
the agency, and did eliminate specific enumerated
items from 419, I’d like to bring it to the
attention of the council for your knowledge.

So with that, again, the applicability of this
is, you know, the department is monitoring it for
determination as to its impact and for
implementation purposes, but, for informational
purposes, I’m providing it to you today.

The implementation from the agency standpoint
would be ensuring disclosure to all parties about
the change, and then making updates to our
application to notify people of changes, and to
remove, obviously, elements that might misled
people to the effect that a single rule -- check
box to notify of trade secret.

We would have to make sure updates to assure
that everybody understood what to do in order to

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1 comply with trade secret (inaudible) --
2 That is for your information. Any questions,
3 I’ll of course take them, but that’s -- that
4 concludes my Director’s Report for today, my
5 long-winded Director’s Report.
6 MR. ELLIS: It was an excellent report.
7 CHAIRMAN WAYS: Any questions from council
8 members or from other interested parties?
9 (No response.)
10 CHAIRMAN WAYS: Well, we might have set a
11 record today, we’ve been going over two hours.
12 Is there any other business? Hearing none, do
13 we have a motion to adjourn?
14 MR. BROCK: So moved.
15 MR. ELLIS: I second.
16 MR. ELLIS: I second.
17 CHAIRMAN WAYS: All in favor say “aye.”
18 (Chorus of ayes.)
19 CHAIRMAN WAYS: Any opposed?
20 (No response.)
21 CHAIRMAN WAYS: The meeting is adjourned.
22 Thank you.
23 Whereupon, the council meeting was adjourned
24 at approximately 11:45 a.m.

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I, DEMORAH ALFF, do hereby certify that
I was authorized to and did report the foregoing
proceedings, and that the transcript, pages 1
through 119, contains a true and complete record
of my stenographic notes and recordings thereof.

Dated this 4th day of April, 2019, at
Tallahassee, Leon County, Florida.

DEMONIA ALFF, COURT REPORTER

FOR THE RECORD REPORTING, INC.
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The 2018 Florida Statutes

Title XXXIII
REGULATION OF TRADE, COMMERCE, INVESTMENTS, AND SOLICITATIONS

Chapter 499
FLORIDA DRUG AND COSMETIC ACT

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.

Chairman Mays: please find a report of the CDR pass/fail rate for the examination. The efforts by DWAC and the division to improve the effectiveness of the examination continue to show a positive results. Overall the pass rate exceeds 50% total and for first time takers it is 52%. R

Stephanie: you will need to include this information in the agenda for the next DWAC meeting please, r

Renee Alsobrook
Chief
Compliance and Enforcement
Division of Drugs, Devices and Cosmetics
Department of Business and Professional Regulation
2601 Blair Stone Road
Tallahassee, Florida 32399-1047
Voice: 850.717.1804
Fax: 850.414.8240
Renee.alsobrook@myfloridалиcense.com

From: Carr, Susan
Sent: Wednesday, April 10, 2019 3:26 PM
To: Alsobrook, Renee
Cc: Janecek, Andrew; Bosque, Alex
Subject: CDR Pass/Fail Report

Good Afternoon Renee

I have attached the performance summary report for the Certified Designated Representative exam for January through March 2019. The pass rate is still doing well, and I will be monitoring the performance on a monthly basis. I will send the performance report for April through June at the beginning of July. I will be adding new pilot items to the exam and replacing a few of the lower performing items. Finally, I am adding language to the fail report to let candidates know that they can review the CDR Candidate Information Booklet for crucial information about studying for their exams. Please let me know if you have any questions. Thanks!

Susan Carr
Examination Development Specialist
Bureau of Education and Testing
Department of Business and Professional Regulation
(850) 717-1313
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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 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.
(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

(1) "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 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:
      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:
(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(1). 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
   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.
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
(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 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 prescription drugs exported
into this state under the International Prescription 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

(5) The department shall adopt rules governing the
financial responsibility 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:
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 (a) 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;
(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 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 malfeasance 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, or an out-of-state prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor, the new permits issued under this section shall expire 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.
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;

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.
         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 $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
departamental 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.

(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 imprudent.
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.

(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 distributor. Such person must have an active certification as a designated representative from the department.

(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.—

(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.—

(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.

(b) "Federal Act" means the Federal Food, Drug, and
as amended by the Drug Quality and Security Act, 21 U.S.C. 351 et seq.

(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:
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 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.

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.
   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 from which source.

5. The lot or control number and the batch number assigned
to the drug by the manufacturer.
6. 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 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.
An act relating to permit and inspection fees; amending s. 465.0157, F.S.; requiring initial and renewal fees for international export pharmacy permits; amending s. 499.012, F.S.; requiring late renewal fees for international prescription drug wholesale distributors; amending s. 499.041, F.S.; requiring annual permit and inspection fees for international prescription drug wholesale distributors; providing a contingent effective date.

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

Section 1. Subsection (4) of section 465.0157, Florida Statutes, as created by HB 19, is renumbered as subsection (5), and a new subsection (4) is added to that section to read:

465.0157 International export pharmacy permit.—

(4) The fee for an initial permit and biennial renewal of the permit shall be set by the board pursuant to s. 465.022(14).

Section 2. Paragraph (d) of subsection (5) of section 499.012, Florida Statutes, is amended to read:

499.012 Permit application requirements.—

(d) A permit issued under this part may be renewed by making application for renewal on forms furnished by the
department and paying the appropriate fees.

1. If a prescription drug wholesale distributor, or an
out-of-state prescription drug wholesale distributor, or an
international prescription drug wholesale distributor renewal
application and fee are submitted and postmarked later than 45
days before the expiration date of the permit, the permit may be
renewed only upon payment of a late renewal fee of $100, plus
the required renewal fee.

2. If any other renewal application and fee are submitted
and postmarked after the expiration date of the permit, the
permit may be renewed only upon payment of a late renewal
delinquent fee of $100, plus the required renewal fee, not later
than 60 days after the expiration date.

3. A permittee who submits a renewal application in
accordance with this paragraph may continue to operate under its
permit, unless the permit is suspended or revoked, until final
disposition of the renewal application.

4. Failure to renew a permit in accordance with this
section precludes any future renewal of that permit. If a permit
issued pursuant to this part has expired and cannot be renewed,
before an establishment may engage in activities that require a
permit under this part, the establishment must submit an
application for a new permit, pay the applicable application
fee, the initial permit fee, and all applicable penalties, and
be issued a new permit by the department.
Section 3. Paragraph (i) is added to subsection (2) of section 499.041, Florida Statutes, and subsection (8) of that section is amended, to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—

(2) The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

(i) The fee for an international prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.

(8) The department shall assess an out-of-state prescription drug wholesale distributor applicant or permittee or an international prescription drug wholesale distributor applicant or permittee an onsite inspection fee of not less than $1,000 or more than $3,000 annually, to be based on the actual cost of the inspection if an onsite inspection is performed by agents of the department.

Section 4. This act shall take effect on the same date that HB 19 or similar legislation takes effect, if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.
Violations found in 2018 during Inspections
(Chair May had asked if division had information)

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

Medical gas 34%-primarily records violations including no
prescription for medical oxygen and change of ownership without
notification to division/unlicensed activity. 74% addressed with
notice of inspections; 26% addressed with case against the firm.