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

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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 Beshears, Secretary
Tim Page, Deputy Secretary
Renee Alsobrook, Compliance Manager
Stephanie Prine, Government Operations Consultant
Rebecca Burnett, Regulatory Supervisor

Call to Order: Steve Mays, Chair

TAB 1: Chair's Report – Steve Mays, Chair
- **a. 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

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 an 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

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.

(Laughter.)

MR. WINTERS: So that will teach me.

All right. Well, the last thing that we have on our agenda for today, we have "d." 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 on bills. And as we see them that may have an impact on chapter 499, we try to bring those 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 running 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

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 these 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 components 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, absent an FDA-approved drug that is coming from a permitted FDA-registered establishment and then

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 AHCA. 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 Importation 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 importation of safe and effective

prescription drugs from foreign nations with which the United States has current mutual recognition agreements and cooperation, memoranda of understanding, or other federal mechanisms recognizing their adherence to current good manufacturing practices.

The program does allow for, provides for definitions. Again, I won't go through each and every definition for you, but basically it allows for the -- an eligible importer to import from an eligible exporter certain drugs. Those drugs do have to meet the current standards for the United States Food and Drug Administration for safety, effectiveness, misbranding and adulteration, and there are specific limitations on page 12.

Again, it can't be a controlled substance, it can't be a biological product, it can't be an infused drug or an intravenous drug, and it can't be a drug that is inhaled during surgery, or that is a parenteral drug, the importation of which is determined by the United States Secretary of Health to be a public threat. And so those drugs would not be allowed to be imported.

The people that would be allowed to export these drugs is, one, an international prescription

drug wholesale distributor. That is a new permit that is actually created further on in the bill.

And a nonresident prescription drug manufacturer, that is, again, a permit we already issue. That is a permit that is already allowed to be outside of the United States. And those entities, as long as they are actually in current compliance with both federal and state laws, and are manufacturing an approved drug currently, again, can go ahead and import a prescription drug from the manufacturers, as most of us are already aware.

And so, the only other permit, one that is created is an international export pharmacy. That particular permit is a new permit type that is actually created in chapter 465 of the Florida Statutes, under the Florida Department of Health, for the pharmacy. And that permit is being analyzed by the Department of Health and Board of Pharmacy for implementation. Those entities would be eligible to export drugs into Florida if -- if they receive that, and they have to register their necessity to export with us.

And then as far as the importers go, importers within the state of Florida would be limited to a

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 exporter under the program with the agency, so 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 (inaudible) starts on page 14, there are, again, a large amount of documentation and items 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

number, and the professional license and permit number of the importer. All this information would have to be transmitted by the exporter and maintained by the importer to that, and they would have to submit that documentation to the agency.

Unlike modern requirements which are maintained by the individual person that does the information, this would actually be more along the lines as that of the report to the agency upon importation of these drugs.

The other thing is, is that when you have importation of a prescription drug shipped directly by the first foreign recipient, you have to provide documentation that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

You have to document the quantity of each lot of the prescription drug received by the first foreign recipient, and demonstrating the quantity being imported is not more than the quantity received by the first foreign recipient.

And then for initial shipments, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and

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 removed if, after investigation, it was adequately determined that there was protections from counterfeit or unsafe prescription drugs.

So I think that, in section three, you'll see the changes to chapter 465 creating the additional permits. Our permits, statute number 499.01, on page 20, again, is updated to both create the international drug wholesale distributor permit, but also to provide for changes to the prescription drug and nonresident prescription drug manufacturer permit, that would require this.

If they are an exporter or going to be importing on the International Prescription Drug Importation Program, that they would also have to register with the department before engaging in that activity. And you'll see some cross-references are also added regarding that program throughout the definition of that permit.

And then on page 23, the creation of the international prescription drug wholesaler distributor permit type. Again, it does require that this permit holder would only be able to issue to a distributor that was located in a country which the United States has a mutual recognition agreement or a cooperation agreement or other

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 distributor. 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 licensure 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 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, 2019. If it passes, the department would move forward with implementation of the program, but it would be also contingent upon, again, a federal authorization to engage in it. So, again, that was one aspect that needs to be remembered 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

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 Alsobrook.

And that's amendable 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.

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

MR. WINTERS: 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) --

(Background noise interference.)

MS. ZENK: It's called out in the Canadian one separate on page 8, in (7)(a), but it isn't called out specifically in the international section. So probably someone -- it's called out because I think, like I said, (7)(a), 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.

MR. BROCK: Does the Canadian do the serialization, coding, and et cetera that's included in that, does Canada do that currently?

MS. ZENK: 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

issues with, and hospitals and retailers have issues with, anything, if it's imported for use, there's a difficult situation for reimbursement purposes, so, trying to get reimbursed for those services and those products.

Fully understand that, in some of these examples, it will probably be a cash business, but I know, if there's any type of third-party engagement, such as the State of Florida or others, I don't know what the intent is from that, you know, health policy position to potentially reimburse foreign-labeled product.

MR. BROCK: Well, the reimbursement issue, that's obviously a business concern.

MS. ZENK: Yes.

MR. BROCK: That's not really a concern for the department or the agency or this council, but the track and trace ability and if they're not using the same codes that are in the federal law, they can't meet the track and trace requirements.

Unless Canada changes how they do things and start using the NDC codes that are in the United States at a minimum, I don't know where else they would have an opportunity to meet that, so I don't see how you could ever have a drug from

Canada meet that requirement of (7)(a).

MS. ZENK: (Nodding head.)

CHAIRMAN MAYS: 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 NDC numbers and things like that, so it's really tough from that perspective.

MS. ZENK: 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 possession 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, 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 MAYS: 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. WINTERS: 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.

But I believe, though, that it's prudent for us just to note that the Agency for Health Care 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, is many times what we -- we look to (inaudible) -- 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 areas where we don't know we can implement or could be costs to implement

those programs -- (inaudible) -- 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 MAYS: Mr. Brock?

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

MR. WINTERS: 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

looking at, but, again, as far as the actual implementations directive, the person that's going to be controlling the implementation, obviously, that would be an agency (inaudible) --

CHAIRMAN MAYS: I guess my concern -- and it's good to hear, I think, that there would be an additional inspector because I think that's probably going to need to be pretty aggressive.

MR. WINTERS: And like you said, we're looking at just simply to start as we move along because it's in -- we won't know how many people will seek to get this permit, and only time will tell, so that's really indeterminate. So we're just starting with the baseline of kind of what we think.

And so, like I said, from a policy standpoint, we're simply looking for implementation and we'll see how the policy discussion progresses at the legislative level.

CHAIRMAN MAYS: Yes, Ms. Alsobrook?

MS. ALSOBROOK: Mr. Brock, on page 8, they do incorporate the tracking and tracing, on lines 179 through 180. And then, of course, you have to seek approval of the Secretary of HHS, on lines 184 through 186, before you can implement the program.

And then they pick up the labeling requirements. That's on page 20, I think.

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

MS. ALSOBROOK: 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 372, 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 MAYS: 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. ALSOBROOK: Yeah.

CHAIRMAN MAYS: That's a false positive there.

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

CHAIRMAN MAYS: Right, right.

MR. WINTERS: Obviously, we'll be cognizant that when we implement the program, we may need some assistance from individuals with additional language skills. I can assure that I do not have --

(Indistinct, overlapping voices.)

CHAIRMAN MAYS: I do Tennessee, and that's pretty much it.

(Laughter.)

MR. WINTERS: But, anyway, we wanted the council to be aware of this because it does have a direct impact on 499. Again, we will continue to monitor these items as they come through for additional updates. As we have meetings, we'll let you know just how it progresses, but most of this is also just for you to be aware. If you want to track something from an industry standpoint, that if you're a member in the association that wants to track these, again, that's simply for information purposes so you can do that, as well.

CHAIRMAN MAYS: And one last comment. It seems like a lot of concerns have been addressed in here, a lot more than I've seen in other importation bills around the country, so I think that speaks well of --

MR. WINTERS: I will say --

CHAIRMAN MAYS: -- (inaudible) --

MR. WINTERS: -- there, as with every bill, it's got certain things that you can tell that people did put some, some substantial thought into it. There's always going to be areas where people will differ whether it's sufficient or not, but like I said, we'll see how this --

CHAIRMAN MAYS: It will be interesting to see how FDA puts their -- whether they approve --

MR. WINTERS: It will be --

CHAIRMAN MAYS: -- the process.

MR. WINTERS: If the bill does pass, it will be an interesting conversation with our counterparts with the FDA, also.

MS. ZENK: And HHS probably, too.

MR. WINTERS: There will probably be multiple.

MS. ZENK: Mm-hmm.

CHAIRMAN MAYS: Any other questions before we move on?

MS. ELLIOTT: This is Arlene from the Agency for Healthcare Administration. I just wanted you all to know that we haven't talked about much else lately. And at this point we have more questions than answers, but we are researching everything.

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 MAYS: Thank you.

MR. WINTERS: Thank you, Arlene. 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. ELLIOTT: Thank you so much.

MR. WINTERS: 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 499. 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 linked 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

substantially lengthy bill, 108 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 499.012, 499.0121, 499.05, and 499.051, and finally, 499.931. Each one of those 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 houses, in this particular instance it takes out all the -- the language specifics in our practice act, and then makes a blanket one in 688.01. So the record exemption,

it does create, as noted on page two of six on House Bill 761, the trade secret held by an agency is confidential and exempt 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, or the department, would be required to provide a specific notice of trade secret, and that that 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 prudent to note for everybody, is that not only does it require to notify the agency of the trade secret, but it requires a particular formatting of

that request.

And so it says, on page three 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 persons 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