COUNCIL MEETING - PUBLIC HEARING

DATE: March 14, 2019
TIME: 9:30 a.m. - 11:45 a.m.
LOCATION: Homewood Suites
2987 Apalachee Parkway
Tallahassee, Florida

Stenographically reported by:
Deborah Alfie, RPR

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COUNCIL MEMBERS IN ATTENDANCE:
Steve Mays, Chair, Prescription Drug Wholesalers
Joseph Lavino, CVS Health, Retail Pharmacy
Scott Brock, Pharmaceutical Manufacturers
Dean Ellis, Secondary Prescription Drug Wholesalers
Jeffrey Tuller, Primary Prescription Drug Wholesalers
Jennifer Goldman, Physician
Arlene Elliott, AHCA
Peter Hart, Medical Gas
Michael Mone, Primary Prescription Drug Wholesalers

DBPR STAFF ATTENDING:
Drew Winters, Division Director
Renee Alsobrook, Compliance Manager
Dinah Greene, Government Operations Consultant

ALSO PRESENT:
Heather Zenk, AmerisourceBergen
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PROCEDINGS

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

CHAIRMAN MAYS: Good morning, everyone. This
is Steve Mays. 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 to not put us on hold so we don't
have to listen to any hold music or anything,
please.

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

MS. GREENE: Steve Mays?

CHAIRMAN MAYS: Present.

MS. GREENE: Jeenu Philip?

(No response.)

MS. GREENE: Joseph Lavino?

DR. LAVINO: Present.

MS. GREENE: Michael Monc?

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MR. MONE: Present.

MS. GREENE: Steve Brock?

MR. BROCK: Scott Brock is here.

MS. GREENE: Oh, Scott, sorry.

Arlene Elliott?

MS. ELLIOTT: Present.

MS. GREENE: Dean Ellis?

MR. ELLIS: Present.

MS. GREENE: Jeffrey Tuller?

MR. TULLER: Present.

MS. GREENE: Patrick Barnes?

(No response.)

MS. GREENE: Peter Hart?

MR. HART: Present.

MS. GREENE: Jennifer Goldman?

DR. GOLDMAN: Present.

CHAIRMAN MAYS: Before we get started, I just want to recognize Tim Page as the new deputy secretary of the Division of Professions of DBPR. He's here with you today.

So I want to start the meeting off as usual by reading the goals of the council at stated in chapter 499.01211 of the Florida Statutes.

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

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

Okay. For the Chair's report today, we will get an update on the Drug Supply Chain Security Act from Heather Zenk. She's vice-president of global supply chain operations for AmerisourceBergen. Heather has been very active in working with the government and industry stakeholders since the law was passed, I believe, in 2013?


CHAIRMAN MAYS: So with that, Heather, I'll turn it over to you.

MS. ZENK: Great.

CHAIRMAN MAYS: And I'll get out of the way.
MS. ZENK: So for those on the phone, I am going to be going 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 wanted to do today is give a little bit of an update. Many of us in the room are quite familiar, but I think this is quite a lengthy statute to deploy. So 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 Mays 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 MAYS: Can everyone hear Heather speaking or --

MS. ELLIOTT: No. I would suggest she get closer to your microphone because I can hear you perfectly.
CHAIRMAN MAYS: Hang on, we'll see if we can get the sound a little better.

(Off the record for technical adjustments.)

MS. ZENK: 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 requirement, 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 outdated, quote, pedigree 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 way 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-U.S., we can't adhere to 50 different requirements and still have some type of

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commerce that could happen in the U.S. market.

The other thing that was starting to happen is
globally, many countries started to pass
serialization requirements. The thing that was
interesting is the first country on the planet that
passed the serialization 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 product
that was actually being given to patients in the
country of Turkey.

So there's other drivers that were causing
serialization 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
serialization in the market. So that's how we all
started on this journey.

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

(Laughter.)

MS. ZENK: 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 -- 503B, excuse me, enter the
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 PLs 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

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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 13 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-S,
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 serialization, 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've 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 2018 because there was a year of enforcement discretion issue 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 up-tick 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's a
serial number, there's a lot number, and there's an
expiration date. So all four of those data
elements are inside that bar code. And you can
tell bottle number one from bottle number two, from
bottle number 1,000,827.

More examples on slide 16. The numbering is
a little off, guys, sorry. Slide 6 went to slide
16 on the ones we sent 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 transact with our trading partners at a
case pack quantity, in particular our manufacture
partners.

Of course, the hospitals and the pharmacies
order at an individual unit bottle, but we do like
to transact 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 8, 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 AmerisourceBergen,
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 see, 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 some supply chain standardization, both for the ease of moving product, the ease of pharmaceutical manufacturers labeling product, and the ease of our trading partner 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 10, 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 worlds.

We are seeing some damages still occur in transit. Often the inks smears, the corner wraps
get damaged, et cetera, but these 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 38 is 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
non-standardization in what we call the human
readable component. So also in DSCSA's statute,
not only do you have to put the identifiers in a
bar code readable format, you also have to have it
in human readable. So then our lowest common
technology partner has an ability to see that human
readable component.

Well, none of that is standardized. So we
have different acronyms used, different ways that
we represent particularly the expiration date.
Globally, of course, we do things a little bit
different, so this is also causing some
opportunities.

So we're seeing things like UID in the human
readable in the second one. Well, we think it
stands for unique identifier, it does, and then
there's also a unique identifier for medical
devices in the marketplace, so this is causing a
lot of confusion and questions in the marketplace
on what this means.

We're also seeing a lot of -- this sounds very
stupid, but how close you put bar codes together
matters to both the wholesalers and the pharmacies.
So as a manufacturer, if you put two bar codes
close to each other, it needs enough white space so
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
acronyms on this one. I just wanted to give you a
flavor of what we're seeing. We have clearly a USP
guideline here in the U.S. It's more for the
practitioner community that wants the year and the
month of expiration date expressed in a numerical,
and then a two-year year.

In many of the technology systems,
manufacturers want 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,
large industry meetings. And a lot of the
content I'm presenting today is just not
AmerisourceBergen's content. This is content that
we've been working through with Pharma AAM, which
is the generic manufacturing community's
representation, the branding manufacturers'
representation, our HDA 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 techie talk. I
apologize.
Okay. So what's coming up next. So we're going on to slide 15 for those on the phone. Most of us in the room, and I'll spend a little bit of time here, what the wholesaling community has been working on now is, in November of this year, wholesale, the statute says, one, wholesale distributors can only engage in transactions that have serialized product. And the intent was to give the manufacturing community one full calendar year to get the serialized product into the market, and then allow the wholesalers a year later to say, okay, I'm only going to accept a product that has that serialized bar code on it.

Right now, we are still accepting into our network non-serialized product that was produced prior. We don't want to create drug shortages. We've talked at the FDA about some flexibility here, and also say that we don't want to be the police of the supply chain.

If I'm getting non-serialized product, we're trusting our manufacture trading partners that that was packaged prior to the date the requirement says that they had to put that bar code on the product.

So, going into a little bit of detail here
when we started to talk about this saleable return requirement in '19. 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 resell 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 -- oh, shoot, I meant to order one, I ordered 11, 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 Dania 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 pharmacies to say is there something that's going on, do you need an inventory management system?

But anything we 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 scale of the U.S. market.

For all of us in the U.S. market, particularly the wholesaling community at HDA, we all submitted our data and they compiled it into this slide. And there is about 58 million units every year in the U.S. that were sold and then come 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 is, it's
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. One 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
AmerisourceBergen, 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
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 Pfizer 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 bit. There's a build slide for those on the phone. And if it came through as a deck and you want to build it out you can, but how would it actually work?
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, et cetera. 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
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 sins 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 if, 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 then would be deemed as non-saleable. And
I would have to extract that from the U.S. supply
chain because we feel that, technically, that's not

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a legal thing to sell.

So going forward on some of the requirements, November 27 of 2020 has more to do with the dispenser community. They then have requirements that come into play at that point. I also know that a lot of people ask why isn't all of these dates November 27? That was day the law signed, and then, inside the statute it had, you know, four years from, six years from, from the date of signature. So it's not a logical date for many people, but that is why that's always this 27th of November date.

So the November/2020 requirements have to do with the pharmacy community now only engaging with products that have the product identifier on it or the serialized bar code.

They also have additional requirements around suspect product. So if they think they have product that doesn't look quite right, it was bright pink, it's a little dimmed pink, what would they do? They need to retain packages of that and go back to the manufacturer at that point. So there's some more requirements that come into play with that.

And then for illegitimate, meaning, yes, we
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
statute lays that out pretty clearly.

DR. GOLDMAN: I have a quick question.

MS. ZENK: Yes, ma'am.

DR. GOLDMAN: This is Dr. Jennifer Goldman.

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. ZENK: 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,
ye 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. GOLDMAN: 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
from the pharmacy, is there any change in packaging there that the patient would need to know about?

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

Like Humira would be a product that people are familiar with, that you get the entire manufacturer packaging kit. We are seeing patients ask questions about what is this? Some of them think it's a QR 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 QR 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. GOLDMAN: Right. So as providers, as physicians, should we be educating our patients about this? Is there a campaign nationally to educate patients that this is what's coming? Because I'm expecting to get questions from patients and I think our community will have questions.
MS. ZENK: 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. ZENK: Yes, sir.

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

So really the arms and the teeth of this
particular law, from a pharmacy perspective, stop

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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. Goldman, 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. ZENK: Correct.

DR. LAVINO: -- they receive it today.

DR. GOLDMAN: 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
those individual products. I don't know.

DR. LAVINO: That would probably -- this is

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Joe Lavino again. That would probably require, it would definitely require a change in the pharmacy statutes or regulations to do that.

MS. ZENK: I think one of the many places we've seen some of the community dabble in this is with vaccines, so we are seeing some vaccines for Children Program that is mandated federally. They are scanning some of the bar codes on the vaccine prior to administering it to the child. And they are looking at, from a scholastic point of view, are we seeing any types of products that are having longer range benefits or health concerns? So there's kind of piloting and dabbling, but, to Joe's point, it's not widespread at this point.

So a little bit of last but not least here, the nirvana, we'll call it that, of this serialization requirement, which we'll be ten years from when it was enacted in 2013, which will be in 2023, which I think, when we pass it, everyone thought that's the end of time. Now it's becoming a little closer than anticipated. What will happen is they'll incorporate the serial number and the expiration date into the product information that's transacted today.

So today, every time I receive a shipment from
Pfizer Pharmaceuticals, I get that transaction information electronically in nature, on the right-hand side of this slide. In 2023, they will insert the serial number and the expiration date into that data set.

Kind of back to Jennifer's questions about technology needed at the pharmacy and dispensing level, many of our trading partners also have electronic mechanisms or a third-party partner that they've hired to accept the transactional information that will either come from the wholesaler, or if it's a direct purchase from a manufacturer or a drop ship, they can store that information inside a data set and database that they own and control, but many don't. Many of them either rely on their wholesale partner to hold that information for them, or, like I said, they purchase a third-party solution.

I know that was a lot of information and acronyms and I apologize. I tried to explain those three acronyms. That is where -- and when I say "industry," what we've been doing is a lot. We've been working in collaboration with NACDS, NCHP, ASHP. And now we're getting a lot more activity with the pharmacy and dispenser community.
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 dispenser community more. They're very comfortable in the manufacturing spaces. 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 coming 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 these 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 concerns. So it tends to become very confusing, very quickly, with all the global requirements here in the market.

And I know Mr. Mone is on the phone and others. I don't know if they have other intelligence they want to share with the group.

CHAIRMAN MAYS: 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?

MS. ZENK: They're all still awake in the room though, I'm saying it.

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

MS. ZENK: Mm-hmm.

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 --

MS. ZENK: Opportunities.

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

MS. ZENK: 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 --

MS. ZENK: That's a good question.

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

MS. ZENK: 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 orifice question, but one that, you know, was kind of interesting.

MS. ZENK: 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

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play here in the marketplace around technology use. And what we're seeing is, we are starting to see larger players arrive in the market. So for many of us, we use a tool called SAP, which is a workforce management type tool. Many of the manufacturers use it for efficiency of supply chain. So do many of the large distributors.

No 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 coalescing, but not, not at a point yet. I'm envisioning, the way we're rolling, it's probably going to be 2020, is my gut of when it's going to kind of start to come together.

MS. ALSO BROOK: 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 idea or thought as to whether

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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 --

MS. ZENK: Yes. We at AmerisourceBergen have
submitted three. So we have one that we are
partnering with Xavier 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
what that means is 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
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 there 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 VRS or the reverse processing component. From a technology point of view, what can we prove out that works?

I think what our 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 Lipitor. So we can store those records on their
behalf, and then just teach them how to access it.

I think what we're struggling with is what do we do when they change from Jeff to me and me to Jeff? How do we change records or should we? I think that's some open things we're working through, but those are the types of things we're hoping come out.

I think one concern we had with the way FDA published it, it seemed a little restrictive in timeline. I mean, I know they can't leave it open-ended forever because they have to publish something, so we don't know how many they're going to accept.

MS. ALSOBROOK: With our conversations with them, they indicated they were going to try to close it in December of 2019, then compile the information and hopefully publish.


MS. ALSOBROOK: And then hopefully have a meeting where they can bring folks in and discuss.

MS. ZENK: Yes.

MS. ALSOBROOK: I guess my interest is, what are they going to do if the industry will share the data for what we consider trademark information?

Have you-all considered how you're going to try to
protect that, or is that going to be something
that, like customer --

MS. ZENK: Yes.

MS. ALSOBROOK: -- lists and whatnot, you-all
are going to try to --

MS. ZENK: So to date we're trying to figure
out how we identify every entity the same across
the industry. So the global standard that's used
is something called a global location number. It's
called a GLN, a global location number. And GS1
Global, they're the same people that developed the
UPC for the retail. They have an ability to issue
global location numbers to entities that are
eligible to receive them. And then they post them
to one common database.

We're hoping that -- I think what's difficult
is it becomes the dispenser community. They have a
HIN number, a NCPDP number, a DEA number, a
pharmacy's license number for each state. They're
not necessarily interested, I hate to say it, in a
fifth number or a tenth number or an NC, you know,
it becomes burdensome.

And then if it's a physician-based business,
they may, they may just work at that clinic or they
have rights at different locations. So what we are
struggling is how do we identify everyone the same way?

I think GLN will be the way we go between, particularly between manufacturer and wholesaler. It's going to be that wholesaler to dispenser 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 Pfizer sells to AmerisourceBergen, 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 rule.

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
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. ALSOBROOK: Thank you.

DR. GOLDMAN: 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 medication is subject to recall because there
are so many recalls happening of late. And I'm
wondering if this technology and serialization
will, in any way, aid the consumer or the
individual pharmacies in tracing that to the source
rapidly.

MS. ZENK: There's been significant talk about
that as a use case -- exactly right on, Jennifer --
that if, if a pharmacy or hospital knew which
serial number was dispensed to which patient, if
there is a recall, they can slim down that targeted
recall list to maybe a hundred patients instead of
thousands of patients.

DR. GOLDMAN: And the patient would actually
be able to look at their bottle because right now
when they're --

MS. ZENK: Not right now, not right now.

DR. GOLDMAN: -- (inaudible) subject to
recall --

MS. ZENK: Yeah. And it would still be on the
premise that that pharmacy would have some type of
an idea. I mean, you know, back to Joseph's point,
if I have a thousand-count bottle and I dispense it
in 30s, I now have 300 that I would still have to
communicate with, assuming I know which serial
number I put into --

DR. GOLDMAN: Right, that's been the problem.

MS. ZENK: Yeah. So there's still a
significant gap in the way the U.S. pharmaceutical
market functions when they service patients to
date.

CHAIRMAN MAYS: Any other questions?

DR. LAVINO: Just one quick one for me.

This is Joe Lavino.

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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 or 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 ingrained in the bar code on the outside or how does that work?

MS. ZENK: 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 24 units inside the case. If the manufacturer can send me serialized data, I would get 25 serial numbers.

The way it would work on our side is, I scan the one serial number on the outer homogenous corrugated box case, and my system would go, "Here's the 24 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.
DR. LAVINO: Okay.

MS. ZENK: So today we're seeing markings, but
the usability of the markings is still quite limited
in the market at this point.

DR. LAVINO: But future state, the usability
of those markings will give you --

MS. ZENK: Yep.

DR. LAVINO: -- the 25 serial numbers inside
that package --

MS. ZENK: Yes. So then when I sell, for
example, if I would sell a clean case of something
to Jennifer's group, I would send the same intact
information the manufacturer sent to me in that
parent-to-child. I would just leave it intact. In
the event maybe a retail pharmacy ordered two
units, then I would have to scan each of those
units separately, and know those two units were
going to that retail pharmacy. It's actually
really cool when you think about it, but it gets a
little overwhelming with volume and scale.

DR. LAVINO: Sure. Thank you.

MR. TULLER: This is Jeff Tuller. I just have
a quick question. So we're talking about
aggregation --

MS. TULLER: So we're talking about aggregation from the pallet to the case to the bottle, and that's not until 2023?

MS. ZENK: 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. ZENK: Yeah. And they just -- if you will, from our manufacturer partner lens, 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, shoot, I had 142.

MR. TULLER: Yeah.

MS. ZENK: 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 48, 72, they're not quite as proficient 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
the data. And it's kind of funny is another joke, we call "aggregation" aggravation because, for many of the manufacturers, that's all of the rework time that they've spent doing that. Yeah.

MR. TULLER: Yeah.

CHAIRMAN MAYS: Any other questions?

(No response.)

MS. ZENK: Well, thank you for the time. And like I said, thanks for the attention. It's not the easiest topic at times to --

MS. ALSOBROOK: And thank you for the excellent report. Thank you, thank you.

CHAIRMAN MAYS: Thank you. Very, very informative.

MS. ALSOBROOK: Absolutely.

CHAIRMAN MAYS: Now, I'll turn it over to Mr. Winters with the Division Director's Report under tab two.

MR. WINTERS: Thank you, Mr. Chairman.

Again, we are going through the Division Director's Report. This is Drew Winters for the Division.

I wanted to stop and just say thank you to Heather. We know that she's traveled a long way to be here for us today, and that that presentation
was outstanding and is something that is, 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. ZENK: 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 our 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.
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 forms, 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
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're 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 updated 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 499, we do

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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 our 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 DDC, 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 OPS inspection staff
available to us, and with the hard work that
Division Chief Alsobrook has implemented, we felt
like this would be a good place 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
that seems like a simple item, but it is something that we wanted to bring to the council for discussion, for concerns 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 or have a question regarding that potential process change implementation?

CHAIRMAN MAYS: 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 a -- a good help to us as an individual agency, as well, from going through that.
MR. HART: So, Mr. Winters, this is

Peter Hart.

MR. 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 499, 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
that three-year would be, it coincided with that
element, and that was what led us to that kind of
three-year mark. We could certainly go back and
look at that, but, like I said, I think the other
issue we want to look at is, I also have to be
cognizant from a budgetary standpoint in moving
those two, two periods of what I would say, we'll
see an influx of cash on one year and then lower
the next year, so we do have to take that into
consideration, as well. And that's why we looked
at the potential for that three-year. All would
seem to point towards that, that three-year being a
good option in -- in at least under that Part III
licensing.

CHAIRMAN MAYS: So there's currently a
three-year inspection cycle that's required then?

MR. WINTERS: Currently, we're running on
about a three-year inspection protocol for our
medical gas, and that's due -- again, I'll pass it
on to Chief Alsobrook, who has done an outstanding
job with her team of implementing those new medical
gas staff. And they've done a superb job and I'll
take this chance to sing their praises. From a
director's standpoint, I would say they've been
fabulous.
MS. ALSOBROOK: Chairman, one of the things that the 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 still some 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 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 benefit 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 MAYES: Mr. Hart, anything else?

MR. HART: No. I think that I certainly can

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appreciate the -- keeping the licensing on the
inspection cycle. And as Ms. Alsobrook 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
was, you know, comfortable with us to even, you
know, kind of start to broach 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, 
negating 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. BROCK: Personally, I think it's a good 
blend of your budgetary needs with the -- with the 
cost savings from the manage -- from a personnel 
management standpoint from the licensees, I think 
that's a good approach.

DR. LAVINO: So a quick question from me. 
This is Joe Lavino. And, Mr. Brock, I appreciate 
that, but I just want to piggyback on this a little 
bit. So what specifically are you measuring with 
the pilot?

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 --
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 so we've looked to,
again, streamline our regulation and look at
benefits to the industry that can do that.

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
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. LAVINO: And would there be, such as going
from two years to three years, would the fees that
you take in change in any regard, so is that 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 a one-year, two-year.

Unfortunately, we don't have necessarily 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 so 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 Alsobrook indicated and Council
Member Tuller indicated, that the improvements that
come through is that the personnel costs that are
associated each time that you have to renew can be
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 Alsobrook 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
that our permit renewals go on a monthly basis, so they're not all solidified into one date or one month each year, each other year, so that will again allow us some time to --

CHAIRMAN MAYS: It's their anniversary though --

MR. WINTERS: It's their anniversary. It's the end of the month of the anniversary of their applying and obtaining their permit. So if you were permitted in May, your expected expiration date is the end of May of the year. And then going out the next two years, right now, is when their expiration -- we would look to, look at, once we implemented it, give people time to know that. And then start at a certain point definitive, to say to those people and put it out in an announcement, you'll be going to three-year renewal and it will be this much, and we expect to do that at this point in time.

CHAIRMAN MAYS: This is Steve. I think the last question was that going from a two-year to a three-year, would that mean that application might change, or maybe be a little bit more rigor in the application since there's so much time between renewals?
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 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 FTD that are assigned to medical gas, again, that new resource, I think, is what has led us down to this potential, also.

DR. LAVINO: This is Joe Lavino. 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 disciplines 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. LAVINO: 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 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

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the comments seem to be positive for us.

So what that tells us is that we'll go back, and Chief Alsobrook 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 Tuller. 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
significantly -- you have more non-compliant folks
with a three-year, then you would probably go back
and re-assess is what I think what you were saying
before. You've already done the impact study to
say that somebody who does a two-year. All of a
sudden you go to three-year and you've addressed
that, Doctor, with that comment, I think. You've
already looked at that. My question was if you
have more medical gas providers, are you
significantly going to be able to inspect and
approve and comply, and so on and so forth?

MR. WINTERS: I do think, though, in looking
at some of our reporting, we have not -- I've not
seen a substantial increase overall in the number
of permit types in those particular ones, so, from
that standpoint. And I'll also turn it over to
Chief Alsobrook to address your question as well,
because she does have boots on the ground --

MR. TULLER: Yeah.

MR. WINTERS: -- and some other information.
From a licensing standpoint, we do track that on a
quarterly basis to see the differential, the delta
between permitting. And I -- we haven't seen any,
a massive increase or influx of those permit types
in my comparisons going forward --
MR. TULLER: Do you track those for all of the --

MR. WINTERS: We look at, quarterly, we look at all of the licensing permit types and to see what their permit numbers are, due to, you know, going through some reports we do here. 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. WINTERS: But I will turn it over to Chief Alsobrook, though, to answer your questions as well.

MS. ALSOBRook: 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
list of those we inspect per year based upon some
criteria, such as, the last time you were
inspected, violations in the past, complaints that
may have been received on that company. And we
rank them as those that are priority to be
inspected in a particular calendar year based upon
those factors.

And our goal is to inspect every permitted
establishment every three years. So, some may get
inspected every two years because they have had a
complaint against them.

The trend is consolidation of corporate
ownership, so there is less and less smaller
businesses, but more and more corporate businesses.
So when you find a violation, it's systemic.
It's usually a recordkeeping issue or something
like that. Usually, it's easier to deal with
because of the corporate level, you can get the
change. There's policy and procedure systemic
issues, and usually at the corporate level you can
get the change.

What's amazing is, the medical gas rule has
about a 30-percent violation rate, but with other
industries it's about 90 percent. So if you want
to look at someone to move to a three-year renewal,
medical gas was the right area because we're seeing
a much lower violation rate. And we believe that
to be a good area to start.

So we would look at, as you indicated, do the
violations go up, does the running in the red for
the division, you know, are we losing money and
therefore the Legislature is looking at us because
we went to the three-year, and does it increase the
issues for the inspectors?

So overall, I think that it's a good pilot
project the director has come up with for us to
try, and I don't think it will impact the health
and safety and welfare as much.

I would be more interested in, what would be
the recommendation for the other permit types to
extend to three years, you know, what would be the
council's recommendation? If this works, what
would they want to us try for the next one?

CHAIRMAN MAYS: I've got one last question.

MS. ALSOBROOK: Yes, sir.

CHAIRMAN MAYS: I'm just curious. As far as
the number of permits on medical gas versus like
wholesale distributors, pharmaceutical distributors
in this state, do you know approximately what the
numbers are?
MS. ALSOBROOK: No, but the wholesale
distributors, you-all have around 360. The medical
gas retailers is substantially higher than that.
The director may know the number. He sees those
numbers every --

CHAIRMAN MAY: 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 MAY: Don't worry about it.

(Indistinct, overlapping comments.)

CHAIRMAN MAY: 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 MAY: 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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forward.

As modern technology increases for items, the necessity to issue a paper license, one of those, you know, more card stock licenses, it creates two issues for the agency. One is that there's an expense associated with it. There's unique printers, and I think the agency had four or five different, very unique printers for each permit. And so it was a workload issue, a cost issue from a personnel standpoint. And it also, from a standpoint of our working with the industry, it allows for a quicker dissemination if we move to what we would call a paperless licensing system.

The department, as most of you are aware, has a licensing portal. That portal can confirm the licensure of any individual permit holder on a web site, but it doesn't allow you to, quote, print a license. We don't want that out there because we don't want anybody to be able to print the license.

However, with the -- the opposite of that is that we don't want it to take weeks or, you know, for an individual person to be able to get a hold of their actual license if they need to print and -- or need to have it physically to display, or if they need it for paperwork purposes for confirming
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 licenses 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 DDC.

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

(Background noise interference.)

MR. WINTERS: -- in many aspects we're not
seeing that be a problem. And so we build our QR
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 personnel time, printer
time, paper, all the costs 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 comments, 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. TULLER: Jeff Tuller. I just have one
question on that. I think it's a great idea,
long overdue. Most states are practicing that
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. WINTERS: 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 those, those licenses, is where we're going to have an impact because those, as those pieces of equipment again are -- start to fail or 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
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. TULLER: 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. WINTERS: The answer to that, I don't
anticipate any impact. The other issue is that
upon most 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
major statutory provisions because the department, in general, has looked at this, and it's actually implemented in multiple orbs 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 Versa 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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get in to find that permit and be able to request
and secure another digital version.

DR. LAVINO: 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 like one time?

MR. WINTERS: It would be able to be printed
off multiple times. The anticipation 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're 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 there
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,
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, 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 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 licensure.

CHAIRMAN MAYS: And that would still require the card to be posted?
MR. WINTERS: 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 Dean wanted to print his on green paper, it wouldn't really matter, right?

MR. WINTERS: 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 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. WINTERS: 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.
where you can see your licenses, here it is.

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

CHAIRMAN MAYS: Great.

MR. WINTERS: I'm still trying to get to --
I keep an iPad, 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 wholesalers, we're obviously
required to have a prescription drug wholesaler
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.
And some of these wholesalers are trying to make the decision to move out of the prescription drug supply side of it. And when I'm talking about this, this is not a dispenser, but this is a company that would supply a doctor's office or a surgery center with injectables, that sort of thing, but they would also supply devices.

So right now, we have to have, if you're a medical device distributor, my understanding is, the only permit that we have is a prescription drug wholesaler license to use. But when I look at the requirements for that, to have that license, you have to have X number -- I think it's 10, 15, 20, I'm not sure what the number is, of transactions with prescription drugs.

MR. WINTERS: Twelve per year is the --

MR. ELLIS: Twelve per year. So if a distributor decides we -- we can't, it's not, it doesn't make sense to continue to distribute injectables, and most of what these distributors are selling are injectables to the physicians, and we want to, they want to move out of that. The problem becomes the manufacturers we're buying the devices from, they want a license because, on that device, it's on the order of a physician.
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. WINTERS: 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 MAYS: It's a little clunky for devices. Sometimes it's Rx devices --

MS. ZENK: Sometimes it's Rx only, sometimes it's --

(Indistinct, overlapping voices.)

MR. ELLIS: Yeah, it could have the statement
or it could have a little R, but it's not --
there's no tracking other than lot numbers.

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

MR. ELLIS: Correct.

MR. WINTERS: -- 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. WINTERS: I think that, you know, I think
the problem that we have with this -- and I'll also
let, again, Chief Alsobrook is my expert when
dealing with these items -- is that, when it comes
to a pure device, one of the items that we have is
that there is no significance exemption 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. WINTERS: 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 --
MR. ELLIS: Right, that's -- I understand that.

MR. WINTERS: Again, so when we look at that, that obviously lends us to that, leads to us where we get to the prescription drug wholesaler, the manufacturer's permit. And so with those elements, that would, I believe that would require probably a statutory change in order for us to create a different permit.

But I also know that when we look at the movement of the actual medical device in Florida, because the 49.015 has a built-in exemption for those that are FDA approved on, on that, that there's a lot of the elements that don't require licensure, but again, like you've said, you've got aspects where it points to both sides, and that's when we get to the prescription -- factor.

Chief, I know that you dealt with this for many years and --

MS. ALSOBROOK: Yes, sir. There was a time way back when, before the director and I, when the Department of Health did issue some device manufacturer permits. And I believe that was, that stopped because of some issues with the regulation.

MR. ELLIS: No, the --
MS. ALSOBROOK: Understand, I'll get there.

MR. ELLIS: Okay.

MS. ALSOBROOK: And if you had that, then that would resolve 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?

MS. ALSOBROOK: 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.

MS. ALSOBROOK: -- 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 --
MS. ALSOBROOK: We hear it all the time when distributors call us and ask, "Do we need a permit?"

And we tell them, "If you're distributing FDA-approved devices, no, you do not, if they do not contain prescription drugs."

We understand that they have Rx on the side of them and they cannot be distributed without a doctor's order or prescription. We deal with that every day. Prosthetics are good examples.

So as the director indicated, without a statutory authority, we can't issue a permit, we don't have a permit to issue; but we'll certainly look at that one provision in there and see if there's some kind of document he could craft for you, that you could use for the companies that you're trying to buy from.

MR. WINTERS: And we've also -- I will offer this, that we do regularly work with individuals that especially -- not only in this room but in the veterinary device realm, basically this same issue, which is, our regulatory scheme is different than other states. And they are looking for people that are here in Florida that are trying to, again, move device products. Those devices, they're asked for a local license from the home state. And we have
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 know, coordination with them, and we will continue to do that.

But, as Chief Alsobrook indicated, there may be an opportunity for us to provide some additional documentation, not necessarily in the form of a license, but possibly maybe a validation or 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?

MS. ALSOBROOK: That would be great. Send it to Dinah.

MR. ELLIS: Should I forward this to Dinah?

(Indistinct, overlapping voices.)

CHAIRMAN MAYS: 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, so 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 have -- 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 IT request, have gone through all transaction types inside of the agency for DDC, 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 Wombles 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 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 online, 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 online 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

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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
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

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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 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

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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

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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.

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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

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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

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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
this does go effective, because currently we do have a more streamline process by which somebody can simply check on 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 across 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 499, 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 upgrades to our application to notify people of changes, and to remove, obviously, elements that might mislead people to the effect that a simple rule -- check box to notify of trade secret.

We would have to make some upgrades to ensure that everybody understood what to do in order to

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comply with trade secret (inaudible) --

That is for your information. Any questions,
I'll of course take them, but that's -- that
concludes my Director's Report for today, my
long-winded Director's Report.

MR. ELLIS: It was an excellent report.

CHAIRMAN MAYS: Any questions from council
members or from other interested parties?

(No response.)

CHAIRMAN MAYS: Well, we might have set a
record today, we've been going over two hours.

Is there any other business? Hearing none, do
we have a motion to adjourn?

MR. BROCK: So moved.

CHAIRMAN MAYS: Do we have a second?

MR. ELLIS: I second.

CHAIRMAN MAYS: All in favor say "aye."

(Chorus of ayes.)

CHAIRMAN MAYS: Any opposed?

(No response.)

CHAIRMAN MAYS: The meeting is adjourned.

Thank you.

(Whereupon, the council meeting was adjourned
at approximately 11:45 a.m.)

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CERTIFICATE OF REPORTER

COUNTY OF LEON )

STATE OF FLORIDA )

I, DEBORAH ALFF, do hereby certify that
I was authorized to and did report the foregoing
proceedings, 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.

[Signature]

DEBORAH ALFF, COURT REPORTER

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