

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND
PROFESSIONAL REGULATION
DIVISION OF DRUGS, DEVICES, AND COSMETICS

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

IN RE: BILLS PENDING IN LEGISLATIVE
COMMITTEES THAT IMPACT THE DIVISION

-----/

DBPR
WORKSHOP

The above-entitled panel convened via conference
call on the 8th of February 2016, commencing at 8:30
a.m., EST.

Reported by:
JESSICA RENCHEN
Court Reporter

1 Council Members:

- 2 GARY CACCIATORE, CHAIR
- STEVE MAYS
- 3 SCOTT BROCK
- DEAN ELLIS
- 4 WILLIAM MAHONEY
- PATRICK BARNES
- 5 JEENU PHILLIPS
- ARLENE ELLIOTT

6

DBPR Staff:

7

- REGGIE DIXON, DIVISION DIRECTOR
- 8 DINAH GREENE
- REBECCA BURNETT

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

TELEPHONIC PROCEEDINGS

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

MR. CACCIATORE: My name is Gary Cacciatore from Cardinal Health. I serve as chair for the Drug Wholesale Distributor Advisory Council, and I'd like to call this meeting to order via conference call. And I'll start with asking Dinah to do a roll call, please.

MS. GREENE: Okay. Gary Cacciatore?

MR. CACCIATORE: Here.

MS. GREENE: Patrick Barnes?

MR. BARNES: Here.

MS. GREENE: Steve Mays?

MR. MAYS: Present.

MS. GREENE: Michelle Mendez? Bill Mahoney?

MR. MAHONEY: Here.

MS. GREENE: Scott Brock?

MR. BROCK: Here.

MS. GREENE: Peter Hart? Jeenu Phillips.

MR. PHILLIPS: Present.

MS. GREENE: And Arlene Elliott?

MS. ELLIOTT: Present.

MS. GREENE: Okay, Mr. Chair.

MR. CACCIATORE: Thank you, Dinah. It looks like we have a quorum. Just a couple housekeeping items: If you can keep your phones on mute -- not

1 on hold so we don't get music, but just on mute --
2 it'll help these conference calls go a lot more
3 smoothly.

4 This is a special meeting that we've called
5 in between our normally quarterly meetings, which
6 the next one's going to be on, I believe, February
7 25th. The purpose of this meeting is you go
8 through pending legislation. We felt like -- some
9 of the council members felt like waiting until
10 February 25th given what's going on with the
11 legislative process, and the calendar would be too
12 late. So it'll give the council members an
13 opportunity to provide to them -- to the
14 Department on some pending legislation.

15 Just as a reminder, let me read through the
16 Drug Wholesale Distributor Advisory Council's
17 role. The council shall review this part, being
18 chapter 499, and the rules adopted to administer
19 this part annually to provide input to the
20 Department regarding all proposed rules
21 administered in part, make recommendations to the
22 Department to improve the protection of the
23 prescription drugs and the public health, make
24 recommendations to improve coordination with other
25 states regulatory agencies and the federal

1 government concerning the wholesale distribution
2 of drugs, and make recommendations to minimize the
3 impact of regulation of the wholesale distribution
4 industry while ensuring protection of the public
5 health.

6 So as you'll see in your agenda we've got
7 five bills that are on the agenda. My guess is
8 the first one's going to be the one that's going
9 to take up the most amount of time. So what I'd
10 like to do is maybe turn it over to Mr. Dixon and
11 let him give an overview of the status of these
12 rules -- I mean, of this legislation and then
13 we'll discuss each one.

14 I think, given the time constraints that we
15 have, what I'd like to do is, you know, rather
16 than going line by line on some of these items, if
17 the council members can try to focus their
18 comments and any recommendations and any motions
19 they want to make, as far as recommending what the
20 Department do with legislation, keep those
21 recommendations at a high level and not -- and
22 let's not do a line-by-line analysis of these
23 bills. We're not going to have time to do that.

24 So Reggie, does that work for you?

25 MR. DIXON: Yes, sir. Mr. Chair, if you

1 didn't mind, what we might be able to do is start
2 with some of the other bills first and then come
3 back to Tab 1 and Tab 2, because Tab 1 and Tab 2
4 are essentially the same.

5 MR. CACCIATORE: Right.

6 MR. DIXON: We can start with 3, 4, 5, and
7 then come back, if that would put -- you'll spend
8 most of the time on 1 and 2 and you can go ahead
9 and knock out 3, 4, and 5 if you want to.

10 MR. CACCIATORE: My only concern is I want to
11 make sure we get to 1 and 2. I don't want to get
12 bogged down with 3, 4, and 5, though, so.

13 MR. DIXON: Whatever works for you is what
14 we'll do. I didn't know how you wanted to work
15 through it.

16 MR. CACCIATORE: I mean, 1 and 2 are
17 basically the same, just the house and senate
18 version, basically. So let's do 1 and 2 first,
19 and like I said, if we run out of time, I'd rather
20 run out of time and not discuss 3, 4, and 5 so.

21 MR. DIXON: Okay. Tab 1 and 2 is a bill.
22 Tab 1 is Senator Grimsley and the other one is
23 with Representative Plakon. Both of these bills
24 have already gone through the first committee
25 stop. They're both scheduled to come to the

1 second committee stop. I think the House Bill's
2 this afternoon and the Senate Bill is tomorrow.

3 The basis of these bills is one, to bring
4 forward a statute in compliance with the DQSA and
5 DSCSA and two, to try to implement some of the
6 suggestions that we have gotten from the industry
7 over the past couple of years and some of the
8 ideas that we've had here in the agency over the
9 last couple of years. It kind of streamlines some
10 of the stuff that we're doing as well as to
11 hopefully save the industry some money on what
12 they're doing, as far as licensing and permitting
13 and that kind of a thing.

14 So I guess what we can do is I can start off
15 by giving you a brief overview of the sections, if
16 you'd like. The first section basically, kind of,
17 amends the definitions. We eliminate some
18 unnecessary definitions. We kind of get rid of
19 some of the references to "pedigree," change some
20 of those to "transaction history, information, and
21 statement."

22 And then we try to implement some of the
23 definitions or (inaudible) in the definitions.
24 With respect to the exceptions to the definition
25 of wholesale, we try to incorporate those into our

1 definition section to try to get a little bit more
2 (inaudible) to what we're doing.

3 Section 2 is on page -- Section 2 is on page
4 25. Section 2 basically updates some of the
5 prohibited section -- the prohibited act sections
6 to basically say -- where it used to be
7 "pedigree," we basically did "transaction history,
8 information, and statement" to try to bring those
9 along. The same thing with section 3, you know,
10 to the extent that it is no longer "pedigree."
11 It's "transaction history, information, and
12 statement." So we try to just do a change in
13 those.

14 Section 4 -- and these were kind of the same
15 thing. Most of the stuff, like I said, when we
16 saw it -- if it was "pedigree" to accept that the
17 "transaction history, information, and statement"
18 replaced "pedigree" -- we just swapped those out.
19 So you'll see a lot of those.

20 In Section 5, one of the things that we
21 wanted to do in Section 5 was to try to -- you
22 know -- to continue to come -- make us conform
23 with the DQSA. But we also had the opportunity
24 here to do some things that we actually thought
25 would be beneficial. The first one we did in here

1 was we created a nonresident prescription drug
2 repackaging permit, but some of those are on the
3 line. If you are outside of the State of Florida
4 and you were repackaging -- meaning, you weren't
5 necessarily making the product but you were really
6 repackaging -- some of those folks ended up
7 getting wholesale distributor permits.

8 And so we saw an opportunity here to go ahead
9 and create a nonresident repackaging permit, which
10 would allow those folks to actually get a permit
11 doing exactly what it is that they were doing and
12 also to kind of comply with the DQSA, would allow
13 companies -- I can think of one company that can
14 now be a repackaging permit as opposed to a
15 wholesale distributor permit. So we thought that
16 would be beneficial. We also tried to -- we gave
17 ourselves -- or we think (inaudible) is to give
18 the Department the authority to issue a -- what's
19 called a virtual manufacturer permit and a
20 nonresident virtual manufacturer permit.

21 Over the course of the last couple of years
22 we've saw an increase in the number of people who
23 were prescription drug manufacturers, but what
24 they were actually doing was they, themselves, did
25 not actually make the product. So they would

1 contract with other folks to make the product and ¹⁰
2 that kind of thing. But some of those folks were
3 being required to -- well, they're required to get
4 a manufacturer permit, but the permit actually had
5 some physical -- some facility requirement. And
6 to the extent that those folks were never
7 manipulated in the drug actually receiving the
8 product, they had some physical requirements that
9 were probably unnecessary. So we thought that
10 would be a good opportunity to eliminate some of
11 those requirements for those individuals.

12 Let's see. We did make some -- we tried to
13 make some changes to deal with the DSCSA with
14 regard to licensing where there's a requirement
15 that if you're licensed, if you're a distributor
16 from the state in the (inaudible) that requires
17 you to either have a state resident license or a
18 federal license. So we went ahead and
19 incorporated those provisions as well and tried to
20 change our statutes to meet that.

21 Let's see. We did go through, like I said,
22 and tried to remove all references to pedigree.
23 We did make a change -- one of the big issues that
24 came up in the last couple years is dealing with
25 (inaudible), how companies would -- who received

1 API in limited quantities. We had a real
2 difficulty trying to come up with defining limited
3 quantities.

4 I know a lot of you guys will participated in
5 those rule hearings. And so when we had the
6 opportunity to we went ahead and removed that
7 language so that "limited quantities" language is
8 not in there anymore. We did put some
9 requirements for, you know, what kind of
10 documentation labeling you would have on there now
11 that you're not going to have limited quantities.

12 Let's see. We did (inaudible) provision to
13 hopefully help out rural hospitals. In Florida we
14 have what's called a rural hospital where you have
15 entities who serve a dispersed population where
16 this facility is the only option for health care
17 and emergency trauma care in that area. The
18 thought was to kind of relax some of the
19 requirements for them so they can repackage for
20 their own comment on facilities.

21 I think when we did the (inaudible) about
22 nine or ten of these facilities in the entire
23 state. And based on the very small quantities of
24 drugs they were using, we thought that that would
25 be appropriate to place that in their -- in

1 Section 5.

2 Section 6, that deals with a lot of the
3 licensing requirements and case requirements.
4 Many of you guys are aware that Chapter 465 was
5 amended to require certain entities to have the
6 new sterile compounding permit. What we wanted to
7 do in this provision is to insure that we can
8 still issue a manufacturing permit to those
9 (inaudible) pharmacies as well as the pharmacy --
10 retail wholesale distributor permit to community
11 pharmacies. So we went ahead and just put some
12 language in there to address that.

13 With the wholesales we realize that the
14 wholesaler permits were expiring every year and
15 depending on when you got your permit, that meant
16 that some companies were always in a constant
17 state of renewing permits, taking pictures,
18 submitting personal information statements. So
19 what we did was we put in some language in there
20 that would allow the Department to issue up to a
21 four-year license with the thought being that the
22 Department will probably issue a two-year license.

23 And what that would also do is it relaxes the
24 picture requirement. Instead of having a picture
25 every 30 days, I mean, it's 180 days. So that's

1 basically one picture or two pictures a year. It
 2 also allowed entities or offices where the person
 3 who makes a statement has not changed to simply
 4 sent us the affidavit with the prior one without
 5 having to go through a whole bunch of other
 6 things.

7 It allowed the Department to accept
 8 electronic fingerprints. I know you guys have
 9 been fingerprinting -- you had to deal with
 10 issues. I know you had to use fingerprint rolls
 11 and all that other stuff and they'll send the card
 12 in. Well, now we hopefully will allow people to
 13 simply just go get their fingerprint scanned and
 14 then submit those fingerprints into the Department
 15 through a live-scan vendor, which will save time
 16 and hopefully (inaudible).

17 We did remove the requirement that the
 18 Department actually sent out a renewal application
 19 was removed, but the Department is now required to
 20 send out renewal notifications to everybody. One
 21 of the things we also allowed the Department to do
 22 is they made it clear that, you know, you've got
 23 the renewal, that certain entities -- that all
 24 entities can now practice issuing this renewal in
 25 on time.

1 There was an issue with non-wholesalers as to
 2 whether or not they can continue to practice
 3 because the statute didn't specifically say that
 4 they could practice. So when this goes into
 5 effect, this will clarify that all entities
 6 permitted by us, if they get their renewal
 7 submitted timely that they can continue to
 8 practice.

9 Let's see. We did change some language with
 10 regard to what was required when it comes to --
 11 you know, we removed the language regarding
 12 secondary wholesalers -- secondary and primary
 13 wholesalers. Some information -- some of the
 14 financial information that was required to be
 15 submitted, we changed some of that.

16 And also addressed the bond issue for those
 17 entities. Under the DSCSA, you either have to
 18 have one bond for all your establishments in your
 19 company, so we tried to make this part to comply
 20 with it. And to the extent that you may -- if you
 21 had sales of prescription drugs less than \$10
 22 million, it reduced the bond and according to the
 23 way that the DSCSA had. So we tried to fix that
 24 part of it.

25 We did -- we tried to address the fact that

1 there's a requirement under the DSCSA for
2 inspection. So we put that language in there to
3 allow for inspection and also to allow the
4 Department to accept inspections from third
5 parties who may be accredited, like any VP or
6 other accrediting entities who might be doing
7 inspections.

8 Let's see. That's most of the information in
9 that section. Let's see. The next section dealt
10 with -- let's see. The next section we dealt with
11 was the Agency for Health Care Administration.
12 That was something that was captured by the House
13 staff. I know there was a provision in good faith
14 to remove the stuff about pedigree so they took
15 that out in Section 7.

16 Section 8 deals with record keeping. We had
17 some questions that come up with that. But
18 basically the DSCSA and the DQSA neither one of
19 those had record-keeping requirements regarding
20 active pharmaceutical ingredient or the
21 prescription drugs that were not specifically
22 excluded. That posed a problems for people who's
23 a distributor in Florida in the sense that if the
24 DSCSA didn't specifically exclude you or exclude
25 that prescription drug for that active

1 pharmaceutical ingredient, which it didn't, then
2 those individuals distributed into Florida or
3 distributors in Florida would now have to have
4 full pedigree for those products.

5 So the thought was not to require pedigree
6 but to require that basic record keeping that most
7 companies would do anyway to the extent that you
8 ship something to someone, you got to send them an
9 invoice, you got to send them a receipt that says
10 what they paid and what they were getting, and the
11 person felt obligated to receive and keep it. So
12 we didn't think that was particularly onerous, so
13 that's what that provision (inaudible).

14 Section 9 deals with the product
15 registration. We wanted to make sure, for those
16 of you who are in the state and you register
17 products, you realize that you have a rolling
18 registration process that could be quite
19 frustrating. Because sometimes your actual
20 manufacturing permit expired one point and your
21 products could be expiring at any moment during
22 the course of that year.

23 So the thought process here was to allow
24 products as well as the manufacturing permit to
25 (inaudible) those licenses with the thought being

1 two years from now. If we implement this, two
2 years from now everybody will have the same rule
3 period, so that if I'm a manufacturer, my permit
4 as well as those products that are registered
5 under that permit will be all lined up. So we
6 thought that was a good idea.

7 The next one's dealing with inspection. That
8 was just some cleanup language because that
9 provision was moved somewhere else under 499.051.
10 Let's see. And that removed "pedigree."

11 Section 13. Section 13 is a section that
12 deals with the Department's ability to issue
13 citations. What the thought process was here --
14 and I think we may have mentioned this before in
15 one of the earlier council meetings -- was we
16 think that this is an opportunity to give the
17 person an intermediate step before we actually
18 take enforcement action.

19 So if we go out and do an inspection and we
20 find issues, we're going to give people a warning.
21 We're going to say, "Hey, look. You need to fix
22 this, you need to -- blah, blah, blah. So we'll
23 give them a letter, a notice of inspection, or
24 whatever we call it now. We'll give that to you.

25 If we come back out a year later, a year and

1 a half later and you're still having some of the
2 same issues, well, I think the idea was to them
3 being able to issue a citation, address those
4 issues that haven't been resolved, addressing new
5 issues that we may find. And that way we don't
6 have to go through an enforcement proceeding where
7 now you get an administrative complaint filed
8 against you or a you get a notice of violation
9 filed against you.

10 To get a citation, which is not -- which
11 doesn't have to be reported to other states, so
12 you don't have the kind of bouncing around from
13 different states that you get sometimes. Every
14 now and then you'll see one where Florida may have
15 taken discipline against someone in 2009 and then
16 now I'm getting a report that you've been
17 disciplined by Colorado in 2013 and the underlying
18 discipline is something from New York, which was
19 based on something from North Carolina, which is
20 based on our original discipline in Florida.

21 So we thought that if we had a
22 nondisciplinary citation that had a monitoring
23 aspect to it or an remedial aspect to it that that
24 would allow folks to -- and get someone's
25 attention but still allow them the opportunity to

1 address the issue without having a full
2 enforcement proceeding.

3 Section 14, (inaudible) 499.82. Section 15,
4 (inaudible) pedigree. Section 16, which was all
5 pedigree, so we eliminated that. Section 17 was
6 updating some cross-references. Section 18 is the
7 same. Section 19 was updating a bunch of
8 cross-references in the criminal/felony section.
9 Section 20 -- I think 20 did the same thing and
10 Section 21 (inaudible).

11 MR. CACCIATORE: Thank you for the overview,
12 Reggie. I really appreciate it. This is
13 Gary Cacciatore again. What I'd like to do then
14 is open up discussion to any council members who
15 would like to make comments on HB 1211.

16 I know this is a really extensive bill, and I
17 just want to say: I want to compliment the
18 Department for their efforts to get this bill
19 introduced and moving. It encompasses a lot of
20 topics that we've talked about for a long time,
21 and I know I appreciate the efforts to give the
22 industry some relief on some of the administrative
23 issues and (inaudible) issues that we've talked
24 about for a long time. And then just the process
25 of just trying to match the Florida Legislation

1 with the Federal Legislation. It's a huge
2 undertaking. So I appreciate all the efforts that
3 the Department made in that regard.

4 From my perspective, I think -- I'm speaking
5 on behalf of Cardinal Health -- we're generally
6 supportive of this bill. We do have a couple of
7 concerns to some technical issues and need to be
8 addressed. But what I'd like to do is open it up
9 to the other council members and have them provide
10 any comments first.

11 MR. PHILLIPS: Hi. This is Jeenu Phillips.

12 MR. CACCIATORE: Yes, Mr. Phillips, go ahead.

13 MR. PHILLIPS: Thank you, Gary. So line
14 2372, around the -- I guess, the wholesale
15 distributor regarding the number of units.

16 MR. DIXON: Which bill are you looking at?

17 MR. PHILLIPS: House Bill 1211.

18 MR. DIXON: Okay.

19 MR. PHILLIPS: It's on page 92, I believe, of
20 House Bill 1211.

21 MR. CACCIATORE: Yes.

22 MR. PHILLIPS: Okay. I thought one of our
23 discussions here was around trying to get this
24 language eliminated. Is this something that the
25 legislature is not interested in?

1 MR. DIXON: I think one of the other bills
2 actually does that. The bill by -- I want to say
3 Senator Bean that -- I'm not sure if that bill has
4 gone anywhere. But I know Senator Bean had a
5 bill. I think he had a bill that actually
6 eliminated that language and so that bill was
7 going to run separately.

8 I apologize. We don't have it. But I know
9 there was another bill out there that talked about
10 eliminating that language.

11 MR. CACCIATORE: I believe the SB 7038, which
12 is Tab 5 in there, includes the elimination of
13 that language.

14 MR. DIXON: Oh, I'm sorry. It was not
15 Senator Bean; it was (inaudible). That's what it
16 was; it was (inaudible).

17 MR. ELLIS: Gary, this is Dean Ellis. It's
18 on page 2 of that bill.

19 MS. GREENE: It's on page 2 of the bill.

20 MR. ELLIS: And Jeenu, to your question, that
21 other bill, just eliminates that language. It
22 doesn't modify it. HB 1211, changes it from 5,000
23 7,500. So those bills will have to be reconciled
24 somehow. I guess the way it eliminates the
25 language would probably take precedent. But, you

1 know, one bill could go through and one may not.

2 MR. PHILLIPS: Right. Yeah, because that was
3 my concern. Because I did recognize that there
4 there was another bill but to delete that language
5 but then I didn't know how that conflict would get
6 resolved.

7 MR. CACCIATORE: Mr. Dixon, do you have any
8 history on the change, just increasing the 7,500?
9 Was that a compromise or was that something
10 that --

11 MR. DIXON: The 7,500, I believe, came
12 from -- it was an amendment from -- I want to say
13 it was an amendment that was proposed to the bill
14 sponsor. The bill sponsor (inaudible) amendment
15 was in there. We both have indicated to those
16 folks who have inquired that did not know whether
17 that 7,500 -- that change from 5,000 to 7,500 was
18 based on (inaudible) data.

19 We've always said that kind of that our
20 (inaudible) that would mean that the number is
21 meaningless. (Inaudible) or something like that,
22 that's something that you all have (inaudible)
23 for.

24 MR. CACCIATORE: Okay. Any other comments
25 from other council members?

1 MR. MAHONEY: This is Bill Mahoney from the
2 (inaudible).

3 MR. CACCIATORE: Yes, Mr. Mahoney, go ahead.

4 MR. MAHONEY: I'm wondering what the rationale
5 is for taking Florida out of sync with the federal
6 statute on active pharmaceutical ingredient. Why
7 do we segregate and require more (inaudible) than
8 is required in the federal statute?

9 MR. DIXON: This is Reggie. I think the
10 issue with regards to the pharmaceutical
11 ingredient is that -- if we didn't make any
12 changes, we would have had those changes to the
13 statute that -- without making changes, we
14 probably would not have been able to remove the
15 pedigree requirement. Because right now -- and
16 there are lot of entities that didn't
17 necessarily -- I think -- were aware that right
18 now, as Florida Law is saying, we're preemptive on
19 product as product is defined.

20 Product does not include (inaudible). And so
21 if we wanted to -- which we don't. If we want to,
22 we could roll into everybody's facility who
23 distributes API and ask them for -- and ask
24 them -- require that the recipient actually get a
25 full pedigree. And so what we wanted to do was to

1 eliminate the requirement of pedigree to be passed
2 with respect to active pharmaceutical ingredient.

3 But with the thought process being that we're
4 not trying to track this all the way back to it's
5 origin. We're just trying to figure out and make
6 sure that you, as an entity that is purchasing
7 active pharmaceutical ingredient that you just get
8 basic information from the entity that immediately
9 sales to you. So if I bought a 50 gallon drum of
10 raw hydrocodone, I'm going to have an invoice, I'm
11 going to have the license number that shipped it
12 to me, I'm going to have the address that it came
13 from, and I'm going to have like a (inaudible).
14 So I'm going to have basic records.

15 And so I think that to the extent that
16 there's no tracking of active pharmaceutical
17 ingredient, I don't think -- I don't think that
18 that's something that would -- I think the state
19 has the best interest in (inaudible).

20 And I'm sorry. There's somebody -- someone
21 has the microphone a little close to their face
22 and it's making a loud noise. I hope that
23 answered the question. I don't know if you got
24 all of the answer.

25 MR. MAHONEY: I think it did. I think the

1 concern is that -- I guess I'm gathering that
2 you're saying that the collection of this
3 information is not going to be onerous. But to
4 me, it seems like there are a lot of products that
5 are distributed to, let's say, hospitals in the
6 administration of the various products, which are
7 both products and API.

8 I'm just hoping that we don't have to overly
9 document things that are in the course of
10 individual administration or in pedigree or
11 something like pedigree with the TH and the --

12 MR. CACCIATORE: And Mr. Mahoney, this is
13 Gary Cacciatore, and Reggie, I think -- and maybe
14 (inaudible) -- but I think what the concern is --
15 I think, Mr. Dixon, that the intent is probably
16 correct that you want the API to have basic
17 record-keeping requirements, but I think part of
18 the concerns -- at least from my perspective --
19 seems to be that including that in certain places
20 in this bill seems to imply that you're going to
21 have to do the full transaction information for
22 API.

23 It seems like to me it would be clearer if
24 it's not include at all when it's talking about
25 the rest of the bill. And maybe there's a

1 separate section that talks about -- okay, this is
2 what we do for API and these are the
3 record-keepings for API and remove it from the
4 rest of the sections of the bill.

5 That's kind of the impression that I got as I
6 went through this. As I was reading through it,
7 at first, it seemed to me like it was implying
8 that you need the transaction information for the
9 API, just not the intent. I'm not sure it's clear
10 the way it's written.

11 Maybe there's other people that's out there
12 that could provide very specific language that
13 would clarify that. But I just wanted to make
14 sure that the bill sponsors and the Department is
15 open to considering, you know, some changes that
16 would help clarify that if that truly is the
17 intent. If that's the only intent, I think the
18 industry would probably be comfortable with that.
19 Any other comments on that?

20 MR. DIXON: I mean, we're definitely open
21 to -- any suggestions, anything we get, I mean,
22 we'll look at it. Like I said, the only
23 responsibility -- the only particular requirement
24 that we thought was -- is this like -- yeah
25 (inaudible). If I buy something online and they

1 ship it to my house -- you know, I get a box with
2 my product in it, it's got kind of an invoice with
3 it, it's got like -- it's got a package slip in
4 there telling me what's included, and I know where
5 it came from and I know where it shipped from.

6 I think that's the only -- that was the
7 intent of this. You guys know that 499 is kind of
8 a hodgepodge. It's different. You know, it
9 doesn't look like everything was written at one
10 time. And so I think that -- I think the struggle
11 on it was to try to make sure that we didn't
12 include too much, and that really was the intent,
13 was just to say, look, if you're shipping API into
14 Florida, then your recipient needs to just have
15 basic record-keepings that will come along with
16 anything else that they purchase.

17 If you buy a book or something, you get basic
18 information. That's kind of the thought. The
19 thought was not transaction information, history,
20 and statement at all.

21 MR. CACCIATORE: This is Gary Cacciatore,
22 again. And Mr. Dixon, I appreciate that. I think
23 that's very helpful. Because in order to get this
24 to match with the federal law since the API is not
25 included in the federal law, the concern was that

1 the API manufacturers are not going to be prepared
2 to go through the whole DSCSA requirement.

3 So I think it's helpful to know that you're
4 not requiring that and requiring some record
5 keeping I think is a reasonable approach. I just
6 want to make sure that it's not implied that the
7 whole tracking requirements are in place.

8 Let me go through a couple of minor things.
9 I know I said I didn't want to go line by line,
10 but I want to point out a couple of things. On
11 page 9 of the bill, this is in the definition
12 section around line pages 220 to 226, these are
13 really key definitions, distribute or
14 distribution. One concern I have there, it
15 doesn't talk about what you're distributing. It
16 seems like the word "prescription drug" should be
17 in there somewhere. See how it approaches
18 delivery or receipt of what? So I don't know if
19 that's just an oversight.

20 Then line on lines 224 to 226, my initial
21 concern was you were deleting that language,
22 which, you know, might require an invoicing office
23 or billing office. Would we include it as a
24 distribution? But then I think I saw later on, on
25 line 671 to 673, that section was just moved. So

1 that's part of the difficulty with trying to read
2 these legislations. You think things are being
3 eliminated but they're actually just being moved.
4 So I think that's okay.

5 But I think it's important to really define,
6 you know, the sales, distribution, trade,
7 delivery, handling, storage, or receipt of what
8 we're actually talking about here. And I realize
9 Chapter 489 is about prescription drugs, but we
10 need to verify that.

11 A couple of other things: I was a little
12 concerned with the language on page 74, lines 1910
13 and 1914. My concern there, it says -- it sites
14 the FDA and then it says, "or another governmental
15 entity charged with the regulation of good
16 manufacturing practices related to wholesale
17 distribution."

18 I don't like the term "good manufacturing
19 practices," even though it says, "related to
20 wholesale distribution," because wholesale
21 distributors are not subject to good manufacturing
22 practices, and it's just seems like the wrong
23 terminology to me. I would say another
24 governmental entity charged with the regulation of
25 wholesale distribution. You might want to take

1 the distribution practices (inaudible).

2 But the use of GMPs seems wrong there online
3 1910, 11, and then 14. Now, it could be
4 interpreted to GMP as related to distribution.
5 But to me, the GMPs are only for manufacturing.
6 So that's just kind of a technical issue.

7 And then I had one other question related
8 to -- you mentioned the virtual manufacturer,
9 Mr. Dixon.

10 MR. DIXON: Uh-huh.

11 MR. CACCIATORE: And if you could remind me
12 what section that was in. I can find it here. I
13 believe it's line 913, around there. 911 to 918,
14 I just wanted to point out -- I'm not sure this
15 was intentional or not -- on line 911, it says,
16 "The Department shall adopt rules for issuing a
17 virtual nonresident prescription drug
18 manufacturing permit to a person who engages in
19 the manufacture of prescription drugs but does not
20 make or take physical possession of the
21 prescription drug."

22 My concern is if they're not taking physical
23 possession of the drugs, how can they be engaged
24 in manufacture. If you look at the definition of
25 manufacture, it only talks about physical

1 manipulation of the drug. It seems like you're
2 not covering anybody there then. The intent was
3 to take someone who's not doing any physical
4 manipulation of the drug, then you would need to
5 delete the words "who engages in the manufacture."
6 Or am I reading that wrong?

7 MR. DIXON: I think you may be reading it a
8 little too closely in a sense that right now, we
9 have a number of folks who have manufacturer
10 permits who do not touch the product at all.

11 MR. CACCIATORE: Right.

12 MR. DIXON: The product is manufactured for
13 them by someone else, is labeled by them -- by
14 someone else for them to distribute themselves
15 under their own label. So we're trying to create
16 a way for those folks to distribute their product
17 without having to have all the physical
18 requirements of a facility, because a lot of times
19 those folks are essentially -- they're almost like
20 brokers but not.

21 MR. CACCIATORE: So what you're saying is
22 those people would not be licensed then?

23 MR. DIXON: No. We're saying that they are
24 licensed, but if we don't make this change,
25 they're going to have to comply with the physical

1 requirements of a manufacturer.

2 MR. CACCIATORE: Okay. I mean, I'll go
3 through and read that again. I don't see how you
4 can be a virtual manufacturer if it requires you
5 to be engaged in a manufacturer when a personal
6 manufacturer is not engaged in the manufacture of
7 a drug. But maybe I'm just reading that wrong so.

8 MR. DIXON: Let's look at it -- let's put it
9 this way: If we do anything different, you're
10 going to have some folks that can't get a permit.

11 MR. CACCIATORE: Right. Okay. Well, if they
12 haven't raised the issue, then I won't worry about
13 that then. Okay.

14 All right. Any other items that want to be
15 raised with this particular bill before we move on
16 to the next one with the council members?

17 Reggie, could you explain, maybe, the -- I
18 guess --- you said this is going to the committee
19 tomorrow you think?

20 MR. DIXON: This one actually goes to the
21 committee later on this afternoon.

22 MR. CACCIATORE: This afternoon, okay.

23 MR. DIXON: Right. This one will be going
24 to -- give me one second. It goes to the
25 government operations appropriations subcommittee.

1 Today it is on the calendar from 3:00 to 5:00 with
2 a number of other bills.

3 MR. CACCIATORE: Okay. So I want to
4 encourage anyone who's got any other concerns or
5 amendments they'd like to see to this bill to make
6 sure they attend that.

7 Any other comments on this bill before we
8 move on to the next one? Any comments from any
9 public members that are on the call?

10 MR. JORDAN: Hi. This is Guy Jordan with
11 PFizer. I have a question.

12 MR. CACCIATORE: Go ahead.

13 MR. JORDAN: Under Section 8, dealing with
14 the record keeping. Reggie, does this section
15 apply to manufacturers? I know one of our
16 attorneys had a question about this fifth point
17 with the financial information being one of the
18 requirements. He said that that's expressly not
19 required under the DQSA.

20 MR. DIXON: So let me ask the question this
21 way: Are you saying if you are a manufacturer
22 sitting in Florida or licensed by Florida and you
23 get a truck full of API, should you be required to
24 keep records that say this is who I got it from,
25 this is the amount, this is the (inaudible), and

1 this is how much I paid for it? If that's the
2 question, then the answer to that question is yes.

3 MR. JORDAN: Okay. But if it's just in the
4 shipping of our products that we manufacture, not
5 API, are we -- if the federal law doesn't require
6 financial documentation, then can Florida require
7 that information or does this section not relate
8 to that?

9 MR. DIXON: I mean, I'm not sure who your
10 lawyer is, and I'm not sure how familiar they are
11 with the differences between what Florida requires
12 for not -- and I guess the easiest way for me to
13 explain it -- because I've had this conversation
14 with a couple of folks -- the DQSA and the DSCSA
15 specifically address product as that term is
16 defined.

17 That term is very specific as to what is
18 included in tracking and tracing. The DSCSA goes
19 through and it also excludes certain product or
20 certain nonproduct from the tracking and tracing
21 requirement. It does not -- active
22 pharmaceutical, I believe -- I think I even did
23 (inaudible) not appear in the DSCSA, if I'm
24 correct and it does not apply to it and it does
25 not exempt API. So as it stands right now,

1 Florida should require -- Florida could require
2 full pedigree for (inaudible).

3 MS. GREENE: Someone's got music playing.

4 MR. DIXON: So I think to the extent that
5 Florida could require much more extensive record
6 keeping on API but Florida is saying that if you
7 purchase API --

8 MR. CACCIATORE: Please don't put us on hold
9 whoever just did that. Thank you.

10 MR. DIXON: Yeah. Whoever just put us on
11 mute or put us on hold, you got music on hold so
12 it interrupted the phone call. But I'm sorry,
13 Mr. Jordan.

14 So the API -- the DSCSA does not address API
15 at all and so to the extent that someone in
16 Florida is receiving API, the thought process is
17 that you should -- or if you're licensed by us --
18 that you should have minimum record keeping. I
19 think once you talk to your folks -- I don't know.
20 I don't think there's anything in that statute
21 that you would not already have.

22 MR. JORDAN: Okay. Let me ask you: By
23 striking the word "wholesale" on line 2316, does
24 that -- and it just says, "distributors of
25 prescription drugs and API," does that basically

1 eliminate manufacturers or are we not considered
2 because we're not a distributor of our own
3 product?

4 MR. DIXON: It's my understanding that under
5 the DSCSA, the manufacturers -- the transactions
6 where a manufacturer actually distributes their
7 own product is no longer considered a wholesale
8 distribution.

9 MR. JORDAN: Okay.

10 MR. CACCIATORE: Okay. This is
11 Gary Cacciatore, again. Any other comments from
12 the public?

13 All right. I have one other question,
14 Mr. Dixon, I just wanted to ask. On page 23, on
15 lines 574 to 576, this is in the section that has
16 all the following activities, I think, are
17 exemptions from wholesale distribution. And it's
18 talking about the distribution of prescription
19 drug for emergency medical reasons, and it
20 includes by a retail pharmacy to another retail
21 pharmacy (inaudible) temporary shortage.

22 It adds the language for purposes of the
23 subparagraph on drug shortage not caused by a
24 public health emergency does not constitute an
25 emergency medical reason. Is that just a

1 clarification of current interpretation by the
2 Department or what's the purpose of that section?

3 MR. DIXON: To be honest with you, that was
4 not a change that the Department made.
5 Legislative staff thought that that was a better
6 wording than Section 2. The intent from what I
7 can understand was not to change any of what No. 2
8 said, but that's words made by someone in the
9 legislative staff.

10 Because before -- before it basically said,
11 "The sale, purchase, or trade of prescription drug
12 or an offer to sale, purchase or trade
13 prescription drug for emergency medical reasons."
14 And they put a period there. And then it says,
15 "For the purpose of this (inaudible) medical
16 reasons includes transfer of prescription drugs by
17 retail pharmacy to another retail pharmacy
18 (inaudible)."

19 The language -- they did some rearranging of
20 the language to make -- to, at least in there
21 opinion, make it read better.

22 MR. CACCIATORE: Okay. Thank you for that
23 clarification. And I think I saw this somewhere
24 but now I can't find it, of course. 499.01212,
25 which is the actually pedigree section, isn't

1 there a line somewhere that deletes that entire
2 section?

3 MR. DIXON: Yes, that section -- section --

4 MR. CACCIATORE: I remember reading it but
5 now I can't find it.

6 MR. DIXON: Yeah, these are -- yeah, it's
7 section -- yeah, the entire pedigree section is
8 deleted.

9 MR. CACCIATORE: Yeah. It's just I read a
10 line in this version of it. There's just one line
11 that says that Chapter 499.01212 is deleted, I
12 think is the way -- I thought I saw that
13 somewhere. Am I remembering that correctly?

14 MR. DIXON: Yeah.

15 MR. CACCIATORE: Mine's on page 99, line
16 2552, "Section 499.01212, Florida Statutes, is
17 repealed." That's what I was looking for, okay.
18 Is that not in the other -- in the other bill?

19 MR. DIXON: Yes, it's in the other bill as
20 well.

21 MR. CACCIATORE: It is, okay. Okay. That's
22 kind of fairly important, I believe. Okay. We
23 got a few minutes left. I guess, let's just move
24 on to the other bills that are listed there. And
25 rather than go through a summary of each one, if

1 you just kind of get the high-level review of what
2 those are, Mr. Dixon, and then we'll see if we
3 have any particular comments from the council
4 members.

5 Did the council members have any other
6 recommendations or want to make any motions with
7 regard to HP 1211? Okay. Hearing none, then
8 we'll move on to the other bills.

9 MR. DIXON: Right. Tab 3 is simply a
10 cosmetic product registration bill that was filed.
11 The purpose of this bill was to eliminate the
12 registration of cosmetic products by manufacturers
13 and manufactured cosmetic products in the State of
14 Florida.

15 MR. CACCIATORE: Any council members have any
16 questions or comments regarding the cosmetic
17 registration bills? Okay. And then Tab 5, Bill
18 7038.

19 MR. DIXON: Yeah, 7038 is the only one that
20 is (inaudible) up on that one is the removal --
21 well, is the removal of the product (inaudible) in
22 that language (inaudible) health care practices
23 (inaudible).

24 MR. CACCIATORE: This is Gary Cacciatore. I
25 believe the rest of the bills are related mainly

1 to the prescription drug monitoring program. But
2 I think that language that Mr. Phillips
3 mentioned -- to delete the language regarding the
4 5,000 dosage units is in that bill as well.

5 As you recall in a previous meeting, the
6 council did pass a motion to support -- I think
7 our motion was to support elimination of that
8 language and use of the federal language. It
9 doesn't include the federal language, but it does
10 accomplish at least removal of the language, which
11 is something I think that the council had
12 recommended. So we'll have to just see what
13 happens with that particular bill.

14 Okay. I appreciate everyone joining this
15 morning. Again, I think it was important for the
16 council to at least touch base on this
17 legislation. This is the first really major piece
18 of legislation that changes 499 since -- I think
19 since I've been on the council actually. And we
20 felt like it was necessary to have this call prior
21 to our February the 25th meeting.

22 We are keeping our February 25th meeting.
23 Hopefully we'll know what's going on with the
24 bills at that time so we can have further
25 discussion at that meeting. And that meeting is,

1 I believe, an in-person meeting in Tallahassee, so
2 I encourage all the council members to try to
3 attend in person if you can.

4 We did not go through any minutes on this
5 meeting because it's a special meeting. We'll
6 cover minutes at the next meeting. Just so the
7 council members know, the purpose of the court
8 reporter is to give an actual recording of the
9 meetings, which kind of eliminates the requirement
10 for formal minutes, and that's kind of how we're
11 going to do that going forward.

12 So with that, I will entertain a motion to
13 adjourn.

14 MR. BARNES: This is Patrick. Mr. Chair, I
15 so move it.

16 MR. CACCIATORE: So moved. Is there a
17 second?

18 MR. PHILLIPS: Jeenu Phillips, I second it.

19 MR. CACCIATORE: A second from Mr. Phillips.
20 Any discussion? Hearing none, all in favor,
21 signify by saying aye.

22 MR. PHILLIPS: Aye.

23 Mr. BARNES: Aye.

24 MR. ELLIS: Aye.

25 MR. MAYS: Aye.

1 MS. ELLIOTT: Aye.

2 MR. CACCIATORE: Meeting is adjourned. Thank
3 you very much everyone, and I will see you
4 February the 25th. Thank you.

5 (Thereupon, the proceedings were concluded at
6 9:30 a.m.)

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

CERTIFICATE OF REPORTER

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

STATE OF FLORIDA)
COUNTY OF LEON)

I, Jessica Renchen, Court Reporter and Notary Public for the State of Florida at Large, do hereby certify that I was authorized to and did stenographically report the foregoing telephonic proceedings; and that the transcript is a true record of the telephonic proceedings within the limits and quality of the telephonic proceedings.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

JESSICA RENCHEN, Court Reporter

\$

\$ 10 [1] - 14 : 21

1

1 [8] - 6 : 3 , 6 : 8 , 6 : 11 , 6 : 16 , 6 : 18 , 6 : 21 , 6 : 22
11 [1] - 30 : 3
1211 [5] - 19 : 15 , 20 : 17 , 20 : 20 , 21 : 22 , 39 : 7
13 [2] - 17 : 11
14 [2] - 19 : 3 , 30 : 3
15 [1] - 19 : 3
16 [1] - 19 : 4
17 [1] - 19 : 5
18 [1] - 19 : 6
180 [1] - 12 : 25
19 [1] - 19 : 7
1910 [2] - 29 : 12 , 30 : 3
1914 [1] - 29 : 13

2

2 [14] - 6 : 3 , 6 : 8 , 6 : 11 , 6 : 16 , 6 : 18 , 6 : 21 , 8 : 3 , 8 :
21 : 18 , 21 : 19 , 37 : 6 , 37 : 7
20 [2] - 19 : 9
2009 [1] - 18 : 15
2013 [1] - 18 : 17
2016 [1] - 1 : 11
21 [1] - 19 : 10
220 [1] - 28 : 12
224 [1] - 28 : 20
226 [2] - 28 : 12 , 28 : 20
23 [1] - 36 : 14
2316 [1] - 35 : 23
2372 [1] - 20 : 14
25 [1] - 8 : 4
2552 [1] - 38 : 16
25th [5] - 4 : 7 , 4 : 10 , 40 : 21 , 40 : 22 , 42 : 4

3

3 [6] - 6 : 6 , 6 : 9 , 6 : 12 , 6 : 20 , 8 : 9 , 39 : 9
30 [1] - 12 : 25
3 : 00 [1] - 33 : 1

4

4 [5] - 6 : 6 , 6 : 9 , 6 : 12 , 6 : 20 , 8 : 14
465 [1] - 12 : 4
489 [1] - 29 : 9

citations [1] - 17:13
clarification [2] - 37:1, 37:23
clarify [3] - 14:5, 26:13, 26:16
cleanup [1] - 17:8
clear [2] - 13:22, 26:9
clearer [1] - 25:23
close [1] - 24:21
closely [1] - 31:8
collection [1] - 25:2
Colorado [1] - 18:17
comfortable [1] - 26:18
commencing [1] - 1:11
comment [1] - 11:20
comments [10] - 5:18, 19:15, 20:10, 22:24, 26:19, 33:7, 33:8, 36:11, 39:3, 39:16
committee [4] - 6:24, 7:1, 32:18, 32:21
COMMITTEES [1] - 1:5
community [1] - 12:10
companies [4] - 9:13, 10:25, 12:16, 16:7
company [2] - 9:13, 14:19
complaint [1] - 18:7
compliance [1] - 7:4
compliment [1] - 19:17
comply [3] - 9:12, 14:19, 31:25
compounding [1] - 12:6
compromise [1] - 22:9
concern [9] - 6:10, 22:3, 25:1, 25:14, 27:25, 28:28:21, 29:13, 30:22
concerned [1] - 29:12
concerning [1] - 5:1
concerns [3] - 20:7, 25:18, 33:4
concluded [1] - 42:5
conference [3] - 1:10, 3:6, 4:2
conflict [1] - 22:5
conform [1] - 8:22
connected [1] - 43:17
considered [2] - 36:1, 36:7
considering [1] - 26:15
constant [1] - 12:16
constitute [1] - 36:24
constraints [1] - 5:14
continue [3] - 8:22, 14:2, 14:7
contract [1] - 10:1
convened [1] - 1:10
conversation [1] - 34:13
coordination [1] - 4:24
correct [2] - 25:16, 34:24
correctly [1] - 38:13
cosmetic [4] - 39:10, 39:12, 39:13, 39:16
COSMETICS [1] - 1:2

GMPs [2] - 30: 2, 30: 5
government [2] - 5: 1, 32: 25
governmental [2] - 29: 14, 29: 24
GREENE [11] - 2: 8, 3: 8, 3: 10, 3: 12, 3: 14, 3: 16, 3:
3: 20, 3: 22, 21: 19, 35: 3
Grimsley [1] - 6: 22
guess [8] - 5: 7, 7: 14, 20: 14, 21: 24, 25: 1, 32: 18,
34: 12, 38: 23
Guy [1] - 33: 10
guys [4] - 11: 4, 12: 4, 13: 8, 27: 7

H

half [1] - 18: 1
handling [1] - 29: 7
Hart [1] - 3: 18
HB [2] - 19: 15, 21: 22
health [5] - 4: 23, 5: 5, 11: 16, 36: 24, 39: 22
Health [3] - 3: 3, 15: 11, 20: 5
HEARING [1] - 1: 9
hearing [2] - 39: 7, 41: 20
hearings [1] - 11: 5
help [3] - 4: 2, 11: 13, 26: 16
helpful [2] - 27: 23, 28: 3
hereby [1] - 43: 7
Hi [1] - 33: 10
hi [1] - 20: 11
high [2] - 5: 21, 39: 1
high-level [1] - 39: 1
history [6] - 7: 20, 8: 7, 8: 11, 8: 17, 22: 8, 27: 19
hodgepodge [1] - 27: 8
hold [4] - 4: 1, 35: 8, 35: 11
honest [1] - 37: 3
hope [1] - 24: 22
hopefully [5] - 7: 11, 11: 13, 13: 12, 13: 16, 40: 23
hoping [1] - 25: 8
hospital [1] - 11: 14
hospitals [2] - 11: 13, 25: 5
house [2] - 6: 17, 27: 1
House [4] - 7: 1, 15: 12, 20: 17, 20: 20
housekeeping [1] - 3: 24
HP [1] - 39: 7
huge [1] - 20: 1
hydrocodone [1] - 24: 10

I

idea [2] - 17: 6, 18: 2
ideas [1] - 7: 8
immediately [1] - 24: 8

mute [3] - 3:25, 4:1, 35:11

N

name [1] - 3:2
necessarily [2] - 9:5, 23:17
necessary [1] - 40:20
need [6] - 17:21, 17:22, 20:7, 26:8, 29:10, 31:4
needs [1] - 27:14
never [1] - 10:6
new [2] - 12:6, 18:4
New [1] - 18:18
next [7] - 4:6, 15:9, 15:10, 17:7, 32:16, 33:8, 4:
nine [1] - 11:22
noise [1] - 24:22
non [1] - 14:1
non-wholesalers [1] - 14:1
nondisciplinary [1] - 18:22
none [2] - 39:7, 41:20
nonproduct [1] - 34:20
nonresident [4] - 9:1, 9:9, 9:20, 30:17
normally [1] - 4:5
North [1] - 18:19
Notary [1] - 43:6
notice [2] - 17:23, 18:8
notifications [1] - 13:20
number [6] - 9:22, 20:15, 22:20, 24:11, 31:9, 33:1

O

obligated [1] - 16:11
OF [6] - 1:1, 1:1, 1:2, 43:1, 43:3, 43:4
offer [1] - 37:12
office [2] - 28:22, 28:23
offices [1] - 13:2
once [1] - 35:19
1 [35] - 5:8, 5:13, 6:22, 7:3, 8:20, 8:25, 9:13,
10:23, 13:1, 13:4, 13:20, 14:18, 15:18, 16:20, 17:
18:14, 20:22, 21:1, 22:1, 27:9, 28:14, 30:7, 32:16,
32:20, 32:23, 32:24, 33:8, 33:15, 33:17, 36:13, 38:
38:25, 39:19, 39:20
one's [3] - 4:6, 5:8, 17:7
onerous [2] - 16:12, 25:3
online [2] - 26:25, 30:2
open [4] - 19:14, 20:8, 26:15, 26:20
operations [1] - 32:25
opinion [1] - 37:21
opportunity [7] - 4:13, 8:23, 9:8, 10:10, 11:6, 17:
18:25
opposed [1] - 9:14

requirement [11] - 10: 5, 10: 14, 12: 24, 13: 17, 15: 23: 15, 24: 1, 26: 23, 28: 2, 34: 21, 41: 9
requirements [12] - 10: 8, 10: 11, 11: 9, 11: 19, 12: 15: 19, 25: 17, 28: 7, 31: 18, 32: 1, 33: 18
requires [3] - 10: 16, 32: 4, 34: 11
requiring [2] - 28: 4
resident [1] - 10: 17
resolved [2] - 18: 4, 22: 6
respect [2] - 7: 24, 24: 2
responsibility [1] - 26: 23
rest [3] - 25: 25, 26: 4, 39: 25
retail [5] - 12: 10, 36: 20, 37: 17
review [2] - 4: 17, 39: 1
rid [1] - 7: 18
role [1] - 4: 17
roll [2] - 3: 7, 23: 22
rolling [1] - 16: 17
rolls [1] - 13: 10
rule [2] - 11: 5, 17: 2
rules [4] - 4: 18, 4: 20, 5: 12, 30: 16
run [3] - 6: 19, 6: 20, 21: 7
rural [2] - 11: 13, 11: 14

S

sale [2] - 37: 11, 37: 12
sales [3] - 14: 21, 24: 9, 29: 6
save [2] - 7: 11, 13: 15
saw [6] - 8: 16, 9: 8, 9: 22, 28: 24, 37: 23, 38: 12
SB [1] - 21: 11
scan [1] - 13: 15
scanned [1] - 13: 13
scheduled [1] - 6: 25
Scott [1] - 3: 16
SCOTT [1] - 2: 3
second [5] - 7: 1, 32: 24, 41: 17, 41: 18, 41: 19
secondary [2] - 14: 12
section [37] - 7: 16, 8: 1, 8: 3, 8: 4, 8: 5, 8: 9, 8: 14: 12: 2, 15: 9, 15: 10, 15: 16, 16: 14, 17: 11, 19: 3, 19: 4: 19: 5, 19: 6, 19: 7, 19: 8, 26: 1, 28: 12, 28: 25, 30: 12, 33: 14, 34: 7, 36: 15, 37: 2, 37: 25, 38: 2, 38: 3, 38: 7
Section [10] - 8: 3, 8: 20, 8: 21, 12: 1, 15: 15, 19: 9, 19: 10, 33: 13, 37: 6, 38: 16
sections [3] - 7: 15, 8: 5, 26: 4
see [17] - 5: 6, 8: 19, 10: 12, 10: 21, 11: 12, 14: 9, 15: 9, 15: 10, 17: 10, 18: 14, 28: 17, 32: 3, 33: 5, 39: 4: 40: 12, 42: 3
segregate [1] - 23: 7
senate [1] - 6: 17
Senate [1] - 7: 2