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**DEPARTMENT OF BUSINESS AND  
PROFESSIONAL REGULATION  
DRUG WHOLESALE DISTRIBUTOR  
ADVISORY COUNCIL**

**MAY 10, 2018**

**8:30 A.M. - 9:41 A.M.**

**FLORIDAYS RESORT/ORLANDO  
12562 INTERNATIONAL DRIVE  
ORLANDO, FLORIDA**

**REPORTED BY:**

**HEATHER HOWARD, COURT REPORTER  
NOTARY PUBLIC/STATE OF FLORIDA**

1        **BOARD MEMBERS PRESENT:**

2        STEVE MAYS, CHAIR  
3        JEENU PHILLIPS, VICE CHAIR  
4        MICHAEL MONE  
5        SCOTT BROCK (TELEPHONIC)  
6        ARLENE ELLIOTT (TELEPHONIC)  
7        DEAN ELLIS  
8        PATRICK BARNES  
9        PETER HART  
10       JENNIFER GOLDMAN

11       **DBPR STAFF:**

12       DREW WINTERS, DIVISION DIRECTOR  
13       RENEE ALSOBROOK, COMPLIANCE MANAGER  
14       DINAH GREENE, GOVERNMENT OPERATIONS CONSULTANT

15       **COURT REPORTER:**

16       Heather Howard, American Court Reporting  
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P R O C E E D I N G S

May 10, 2018

8:30 a.m.

(The May 10th, 2018 DBPR Drug Wholesale Distributor Advisory Council meeting was called to order, after which the following took place:)

CHAIR MAYS: Good morning, everyone. This is Steve Mays. I'd like to call this meeting of the Drug Wholesale Distributor Advisory Council to order.

Before we get started, we have a court reporter in the room, I see. Right? Okay. Good. Couple of things. Those of you members in the room, you will -- if you're going to speak, you'll have to hold your microphone button on while you're speaking. It's not one of those -- all of these are not touch and forget. So you have to hold it down while you're speaking.

For everyone -- and also for those in the room and everyone on the line, please make sure that if you're going to ask a question or make a comment, please identify yourself by giving us your name.

And for anyone on the phone, please mute

1 your line when you're not speaking so we don't  
2 pick up a lot of background noise or anything  
3 like that. But please do not put us on hold.

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

6 MS. GREENE: Yes, sir.

7 Steve Mays.

8 CHAIR MAYS: Present.

9 MS. GREENE: Jeenu Phillips.

10 DR. PHILLIPS: Present.

11 MS. GREENE: Michael Mone.

12 MR. MONE: Present.

13 MS. GREENE: Scott Brock.

14 MR. BROCK: Here.

15 MS. GREENE: Arlene Elliott.

16 MS. ELLIOTT: Present.

17 MS. GREENE: Dean Ellis. (No response.)

18 Jeffrey Tuller -- is out.

19 Patrick Barnes.

20 MR. BARNES: Here.

21 MS. GREENE: Peter Hart.

22 MR. HART: Present.

23 MS. GREENE: And Jennifer Goldman. (No  
24 response.)

25 We have a quorum.

1 CHAIR MAYS: Thank you.

2 I want to start the meeting off, as usual,  
3 by reading the goals of the Council as stated in  
4 Chapter 499 of the Florida Statutes.

5 The Council shall review this part and the  
6 rules adopted to administer this part annually,  
7 provide input to the Department regarding all  
8 proposed rules to administer this part, make  
9 recommendations to the Department to improve the  
10 protection of the prescription drugs and public  
11 health, make recommendations to improve  
12 coordination with other states' regulatory  
13 agencies and the federal government concerning  
14 the wholesale distribution of drugs, and make  
15 recommendations to minimize the impact of  
16 regulation of the wholesale distribution  
17 industry while ensuring protection of the public  
18 health.

19 So we have no items under the chair's  
20 report today, but you'll see, under Tab 1 you'll  
21 find the meeting transcript from our February  
22 15th meeting.

23 And I now want to turn it over to  
24 Mr. Winters. And I think he's got a couple of  
25 introductions to make.

1           MR. WINTERS: Thank you, Mr. Chair. Again,  
2           Drew Winters, Director for the Division of  
3           Drugs, Devices and Cosmetics.

4           Yes, just for a quick moment there's a  
5           couple people that I would like to recognize in  
6           the audience since they're not usual attendees  
7           for us.

8           First, I'd like to recognize Robin Smith,  
9           our Deputy General Counsel for the business side  
10          with the Department of Business and Professional  
11          Regulation. She has taken the opportunity to  
12          come down and be with us today and take part not  
13          only in the council meeting, but also the  
14          subsequent proceedings we have for this  
15          afternoon.

16          We want to thank her for her help and all  
17          the great leadership she provides for us in the  
18          Office of the General Counsel. So.

19          And then also I'd like to recognize  
20          Mary Mayleben. She's our Enforcement Program  
21          Administrator and one of our hard workers in the  
22          field and provides a lot of oversight and  
23          management skill that we desperately need out in  
24          the field.

25          And we want to recognize her. She is a

1 great asset to the Division and she had the  
2 opportunity to come over and meet the council  
3 today as well. So I want to recognize them.

4 And then you will hear from two gentlemen  
5 as well that are sitting in the front row. We  
6 have Andrew Janecek and Alex Bosque from our  
7 Division Bureau of Education and Testing.  
8 They'll be here to provide an informational  
9 presentation on our CDR examination, but I want  
10 to recognize them as well and their efforts and  
11 time to come down here and talk to us.

12 So with that I'd just like to recognize  
13 those individuals in the room so that you're  
14 aware of who they are and where they're at. So  
15 thank you all for attending today.

16 And, Mr. Chair, with that, if you'll allow,  
17 I guess I'll go ahead and move into my rules  
18 report at this point in time. As, under Tab 2,  
19 which is the Division Director's Report, Letter  
20 A, the -- under Tab 2 you'll note in your  
21 council agenda, we have the most current rules  
22 report.

23 As we'll go through these, the first two  
24 are application for device manufacture and  
25 application for limited prescription drug

1 veterinary wholesale distributor permit. Again,  
2 those are under development right now inside of  
3 our office. We're trying to finalize the  
4 language for those and we will be moving forward  
5 with the development once we get the language  
6 finalized.

7 On 61N-2.018, the application for  
8 restricted drug distributor blood establishment  
9 permits, I'm happy to note that we have that  
10 noted as submitted for rule adoption, but that  
11 is actually effective today. So it is  
12 officially adopted and we can put that as one  
13 more that's going to the green list that's  
14 behind this.

15 The next ones are 61N-2.019, the restricted  
16 drug charitable organization and the 2.020  
17 application for restricted drug distributor  
18 destruction permit. Again, those are noted  
19 right now as responding to the JAPC letter. We  
20 did respond to that letter.

21 In addition, we have been able to resolve  
22 those items with the Joint Administrative  
23 Procedures Committee and I'm happy to report  
24 that we've asked for certification from the  
25 Joint Administrative Procedures Committee and

1 anticipate filing that for adoption with  
2 Department of State when we get back tomorrow.

3 So, again, moving forward with those two  
4 items.

5 The next three on the application, again,  
6 the 2.021, 2.022 and 2.023 are application for  
7 restricted drug distributor government programs  
8 permit, our restricted drug healthcare entity  
9 permit and our restricted drug distributor  
10 institutional research permit.

11 Those are also -- the language is under  
12 development. I am happy to say that we have the  
13 language pretty much set for those and will be  
14 able to start moving forward, but we have not  
15 moved those just yet, but the language inhouse  
16 is pretty much ready to go.

17 The next one on our rules report is  
18 61N-2.024. Again, that is our application for  
19 restricted drug distributor reverse distributor.  
20 And, again, I'm happy to report that we have  
21 resolved all items with the Joint Administrative  
22 Procedures Committee and asked for certification  
23 so we can file those when we return to the  
24 office on Friday. So that one, as well, will be  
25 moved for adoption and complete.

1           Our 61N-2.025, the application for retail  
2 pharmacy wholesale distributor permit. That is,  
3 again, the language for our application is under  
4 development, but I am happy to report that we  
5 have got most of that draft finalized and we're  
6 simply waiting to move forward with that through  
7 the process.

8           The next one is your 61N-2.026, the  
9 application for third party logistic provider.  
10 Again, that one is one that we have noted on  
11 your report as responding to a JAPC letter. I'm  
12 happy to report we filed response to that and  
13 Dinah has already provided a request to JAPC to  
14 certify that for adoption and anticipates filing  
15 that for adoption with Department of State on  
16 May 11th, when we return, tomorrow.

17           The next two on the list, the application  
18 for veterinary prescription drug retail  
19 establishment and application for veterinary  
20 prescription drug wholesale distributor permit.  
21 Again, those are under development, but I am,  
22 again, happy to say that we have got most of the  
23 language finalized for that and it's in its  
24 final stages before we move forward with the  
25 rulemaking process.

1           And so we look forward to giving those in  
2 the process and moving at the next council  
3 meeting.

4           And then the final ones on your list, the  
5 61N-2.029, the application for change of mailing  
6 address. We have that noted as submitted for  
7 adoption. I am happy to say that that is  
8 effective today. So, again, that one is  
9 complete and adopted.

10           The application for name change is in the  
11 same status. It is actually been provided to  
12 Department of State and has an effective date as  
13 of today, as well as the application for  
14 physical location change. So those are all  
15 effective today and adopted.

16           And then the final items for us, as noted,  
17 61N-2.032 and 2.033, the application for  
18 certificate of free sale and application for  
19 certified designated representative. Both of  
20 those are adopted and effective.

21           So we'll have quite a few of them moving  
22 from this report onto the larger list of those  
23 that we've already approved and adopted. And  
24 so, with the hard work of specifically my staff,  
25 but I want a special thanks to Ms. Dinah Greene

1 for all of her efforts to move those through the  
2 system.

3 They take a lot of steps and she's done a  
4 great job at manning the helm on those. So a  
5 big thanks to her.

6 So we are getting very close to our final  
7 goal, which is to have all our applications  
8 adopted and complete and inside of the Florida  
9 Administrative Codes. So that's going to be a  
10 great accomplishment when we get that done.

11 So, again, a thank you to all the staff,  
12 but especially Dinah. And I recognize our  
13 Office of General Counsel staff, including  
14 Ms. Robin Smith, who does a lot to review these  
15 things as we move through the process.

16 So with that I'll turn it over for any  
17 questions or concerns that you may have as far  
18 as we've got with the rule development or the  
19 report as provided to you.

20 Hearing no questions, I'll move forward  
21 with the Director's Report. At this point in  
22 time, we're going to go to Letter B under Tab 2.  
23 And that is going to be our presentation from  
24 the Bureau of Education and Testing regarding  
25 our certified designated representative.

1 I'll turn it over to, again, the Chief of  
2 the Bureau of Education and Testing, Mr.  
3 Andrew Janecek and his staff member,  
4 Alex Bosque, who is our test development person  
5 inside of the bureau.

6 So, again, gentlemen, thank you very much  
7 for coming down today and we'll look forward to  
8 a good presentation.

9 MR. JANECEK: Good morning.

10 UNIDENTIFIED SPEAKER: Morning.

11 UNIDENTIFIED SPEAKER: Good morning.

12 MR. JANECEK: Well thank you so much. It's  
13 good to see you all this morning. I think this  
14 is my first time with the opportunity to visit  
15 your council, so thanks for all you do and thank  
16 you, Director Winters, for providing this  
17 opportunity.

18 Ms. Dinah, are you going to click for us?

19 MS. GREENE: I am.

20 MR. JANECEK: Okay. Perfect. We can go  
21 ahead and move in.

22 A quick overview of our bureau. Again, I'm  
23 Andy Janecek. I have the privilege of serving  
24 as the Chief of Education and Testing for DBPR.  
25 We are a service bureau within the Department so

1 we serve your customers and your candidates, but  
2 we also serve you.

3 So we help you specifically with the  
4 development and maintenance of your CDR  
5 examination. And then we monitor the contract  
6 with our outside vendor, Pearson VUE, to  
7 actually administer that examination to  
8 candidates.

9 Aside from that, we do a lot of things  
10 within the Agency. We serve the divisions of  
11 real estate; certified public accounting; drugs,  
12 devices and cosmetics; and, a number of  
13 professional boards and regulatory bodies within  
14 the Division of Professions. Everything from  
15 the asbestos licensing unit to the Board of  
16 Cosmetology down to the Board of Veterinary  
17 Medicine and everything in between.

18 Our bureau is established in 455 of Florida  
19 Statutes and we've been charged with assisting  
20 the divisions and the boards and the bureaus  
21 with protecting the public. So we do that by  
22 working with you to make sure we have strong and  
23 measurable examinations.

24 Within our bureau is the Examination  
25 Development and Administration Unit, that's

1 Alex's shop. That unit, again, is responsible  
2 for developing, maintaining and scoring  
3 examinations. We ensure that the examinations  
4 are valid and reliable.

5 These things can be challenged in court, so  
6 we want to make sure that they're strong and  
7 that the content is well-maintained. We also  
8 want to make sure that your licensees, your  
9 candidates are meeting those minimum competency  
10 thresholds.

11 This unit schedules candidates, we report  
12 grades, we conduct post-examination reviews. A  
13 number of the professions allow failing  
14 candidates to review the questions and answers  
15 that they missed to better prepare them for when  
16 they take the exam again.

17 We manage the examination administrations  
18 themselves. Most of our administrations are now  
19 handled through computer-based testing at  
20 Pearson VUE test sites. However, we still have  
21 a few professions that use a paper and pencil  
22 format and we administer those exams throughout  
23 the state.

24 We also monitor the national examinations  
25 and contracts. And in this case, the contract

1 that involves CDR or the CDR exam is a contract  
2 with Pearson VUE for the administration.

3 I think I covered this slide already, but,  
4 again, we assisted, back in 2011, when the --  
5 when your program was transferred from DOH to  
6 DBPR. We helped with that implementation. We  
7 also work with you to provide ongoing  
8 maintenance for your examination items.

9 We publish a candidate information booklet  
10 on the website and keep that up-to-date. That  
11 helps candidates understand what to expect when  
12 they schedule their exams. It also includes a  
13 content breakdown so they know which areas to  
14 study.

15 Again, we defend those examinations when  
16 challenges arise. And we really, overall, just  
17 do our best to make sure we're meeting your  
18 needs and helping you all meet your objections.

19 I mentioned our partnership with Pearson  
20 VUE. We do hold a contract with Pearson VUE,  
21 which is an international testing provider.  
22 They do not actually handle any of the content  
23 for your exam. That's handled inhouse.

24 We're fortunate here in Florida, I think,  
25 our bureau might be the only -- the only state

1 agency in Florida and probably one of the few  
2 remaining throughout the country that maintains  
3 an inhouse psychometrics program. So we're very  
4 proud of that. We handle a lot of the updates  
5 and maintenance to the exams right inhouse.

6 So go back one more time, Ms. Dinah,  
7 please.

8 The nature of that contract with Pearson  
9 VUE really picks up after your office approves a  
10 candidate for the CDR exam. So once that  
11 candidate is approved, an authorization file is  
12 sent overnight to Pearson VUE. Pearson VUE then  
13 contacts that candidate and lets them know that  
14 they're eligible to schedule an exam through  
15 their test sites.

16 So they -- at that point they are customer  
17 service for your candidates. Candidates will  
18 contact Pearson VUE directly or go online,  
19 contact them by phone, and actually make that  
20 reservation, choose their testing location and  
21 choose an available date and time.

22 Pearson VUE registers those candidates.  
23 Pearson VUE provides grade reports before the  
24 candidate leaves the test site, which is very  
25 nice. And Pearson VUE also helps us with

1 examination reviews.

2 You'll see there at the test site map,  
3 there are a number of test sites in Florida.  
4 And this is where our partnership with Pearson  
5 VUE becomes very special. If we were still  
6 administering this on our own, it would be very  
7 hard to have that many test sites in Florida.

8 And this is just Florida. Pearson VUE has  
9 test sites all over the country and beyond. I  
10 recently was speaking with a candidate -- I  
11 don't believe he was CDR, but a candidate from  
12 Ontario, who was testing right in Ontario. So  
13 that relationship is very helpful.

14 All right. Just to give you some volume  
15 numbers -- I know it's hard to read on the  
16 screen -- our program with Pearson VUE is  
17 divided into separate programs. So we've pulled  
18 out our largest -- our largest testing bases.  
19 That's electrical, construction, real estate.  
20 Those kind of stand alone in their numbers.

21 You can see -- and it's a little small for  
22 me, but we go into the tens of thousands of  
23 exams administered for some of those professions  
24 throughout the year.

25 The block you see in the upper left that

1 says Professions, that's basically everyone  
2 else. So that includes CDR numbers as well as  
3 barber numbers and cosmetology numbers,  
4 auctioneer numbers, other professions that have  
5 exams administered by the Department.

6 So I just want you to see that we are  
7 actually -- we're pumping out a lot of exams  
8 each year.

9 This slide shows you some numbers  
10 specifically related to CDR between 2014 and  
11 2018. You can see your candidate counts. You  
12 can see your pass and fail rates. You'll note  
13 that that's divided by first-time test takers,  
14 then folks who take the test more than once and  
15 then the overall statistics.

16 I will say, a lot of times the pass rates  
17 can be alarming. When you see that -- if you  
18 look in 2018, you've got an average pass rate  
19 that's below 40 percent. And that can sometimes  
20 be alarming.

21 But one thing we did notice, particularly  
22 as we transitioned more of the exams to a  
23 computer-based format and made them a little bit  
24 more accessible, we see that people tend to take  
25 them before they might be ready to kind of prep

1           them so they know, you know, what to look  
2           forward to.

3           So when we were doing an exam, for example,  
4           if we use construction, the old version of the  
5           construction exam was administered six times a  
6           year and that was it. So I think you saw, at  
7           that point, that a lot more people would wait  
8           until they knew they were ready and then they  
9           would go take the exam.

10          Through our partnership with Pearson VUE,  
11          you can take the exam one week, reschedule it,  
12          take it again the next week. It's much more  
13          frequent and it's available more often. So we  
14          see that candidates will tend to go in kind of  
15          before they're ready to get a feel for it.

16          And so sometimes that pass rate may go down  
17          because of that. There's a number of reasons,  
18          but I will just say, you see that low number,  
19          don't let that on its own worry you necessarily.

20          Out-of-state testing volume. Again, it's  
21          really great to us that Pearson VUE provides us  
22          with the opportunity to test candidates  
23          out-of-state. If they're prepping to relocate  
24          to Florida or getting involved in operations  
25          within our state, they can actually test from

1 where they are.

2 So this is just a breakdown for you so that  
3 you can see how many people in 2017 actually  
4 took advantage of out-of-state testing. For  
5 electrical and construction, you know, the  
6 industry is up and folks are coming to Florida,  
7 so you can see that there was a relatively high  
8 percentage of those folks testing out-of-state.

9 This one's a little tight. This shows you  
10 the out-of-state testing metrics for the CDR  
11 exam. It looks like the highest there might be  
12 Tennessee, you know, so you can see that even  
13 with CDR you have folks who are taking this at  
14 sites outside of our state -- state boundaries.

15 In military testing volumes, we're very  
16 pleased, at the Department, to be able to  
17 provide service to members of the armed forces  
18 and folks coming out of military service.

19 So Pearson VUE actually makes available  
20 testing locations on military bases and within  
21 military facilities. So we're very proud of  
22 that. You can see that, for some of our  
23 programs, I don't believe CDR has gone this way  
24 yet, but we've had military members taking our  
25 examinations in Japan, Dubai, Qatar, Bavaria. So

1 all over the -- all over the globe they're  
2 taking Florida exams to prep to get -- to get  
3 into our state, rather. So that's a very nice  
4 thing.

5 I don't believe any CDR candidates have  
6 taken advantage of this yet, but Pearson VUE  
7 even has a testing facility on the USS Abraham  
8 Lincoln. So those folks can actually go to a  
9 test site on their ship and take a Florida exam,  
10 if that's what they need to do. So that's a  
11 nice thing to offer.

12 With that I will go ahead and introduce and  
13 pass the mic over to Alex Bosque, who's the  
14 manager of the Examination Development and  
15 Administration Unit, to give you a little bit  
16 more specifics about the history of your exam  
17 with DBPR and where we would like to see things  
18 to in the future with your help.

19 MR. BOSQUE: Good morning. It's a pleasure  
20 to be here with you all. As Mr. Janecek said,  
21 my name's Alex Bosque. I'm the manager over the  
22 Exam Development and Administration Unit.

23 Just wanted to provide you a little bit of  
24 history of the exam. What I have or the  
25 knowledge that I have about the history.

1 I know that in 2003 the exam was developed  
2 by the Department of Health in 2003 and it was  
3 first administered in April of 2004. It's  
4 designed to be a laws and rules exam. It covers  
5 areas that may get someone in trouble or when  
6 they're handling the products. So it's pretty  
7 specific. The scope of the test is just the  
8 laws and rules and we'll see those areas in a  
9 minute.

10 It transferred over to us in 2011 and it  
11 was -- started to be administered by Pearson VUE  
12 at that point. Prior to that, I believe, they  
13 were using Prometric for the Department of  
14 Health, but the history I have is that it was  
15 delivered via computer-based testing also.

16 There's some indication that initially,  
17 maybe in '04, it was paper and pencil every  
18 other month, but haven't been able to verify  
19 that a hundred percent. But the maintenance  
20 they did on the exam is similar to us.

21 They had -- they had an annual exam review  
22 and update and they followed the same  
23 psychometric or exam development procedures that  
24 we would inhouse and that transitioned to us.

25 The model we use for your exam is we review

1 the exam yearly, look to see how the questions  
2 are performing, but an actual subject matter  
3 expert review, unless we see something out of  
4 the ordinary, takes place every 18 months to two  
5 years and mostly because of the volume that  
6 you're -- that you're dealing with.

7 The last update that we had for your exam  
8 was in October of 2016 and that went into  
9 production October 2016, about six -- we worked  
10 on it for about six months prior to that.

11 Before we talk a little bit more about the  
12 exam, let's look -- if we can see our slides --  
13 my eyes -- I'm getting old. I'll be 53 this  
14 month, so I'm a little bit taxed there.

15 But the score that you have to get on the  
16 test is 75 percent. There's 40 scored items on  
17 the exam. And that means you have to answer 30  
18 questions correctly and the candidates are  
19 afforded 90 minutes to take the exam for the 40  
20 questions. It's currently a closed book  
21 examination or they don't take their reference  
22 with them.

23 Those are the area -- the content areas  
24 that we're currently covering and the  
25 percentages. And if you go to the next slides,

1 it shows you the areas of law that we're  
2 covering and it's -- and it's fairly specific.  
3 So I've been told by our exam development person  
4 that the -- and our research associate, that  
5 this exam -- the questions are pretty complex  
6 material, but considering that we publish the  
7 information in such specificity, it's a little  
8 surprising when Mr. Janecek talks about the pass  
9 rates that we see.

10 See them in the 35 or not even 40 for the  
11 -- for the first time test takers. I would hope  
12 that candidates are preparing a little bit  
13 better up front. So I have some thoughts on  
14 that.

15 First, we want to make sure that our exams  
16 that we put out are, you know, balanced and  
17 proper and reliable and we're confident that  
18 that's the case. So then we want to see, well,  
19 why aren't the candidates performing as well.

20 And some of the suggestions we -- that I  
21 have -- we'll go to the next slide here, which  
22 is -- we're going to do a review again of the  
23 questions in the fall of this year. What we --  
24 what I've noticed over the years is that it's  
25 just left in the hands of our team and we have a

1 little bit of trouble recruiting subject matter  
2 experts or folks that actually hold the  
3 certificate.

4 So we'd like to see if the Council has any  
5 thoughts on helping us recruit some folks either  
6 from the Council or certificate holders that may  
7 want to participate in reviewing the questions.

8 Another thing we've done recently is up --  
9 we've updated our candidate information booklet.  
10 It's not a major update, but what we did is that  
11 we made links to the laws and rules so they  
12 don't have -- the candidates don't have to go  
13 search for them.

14 And in addition, it's not up on the web  
15 yet, but we're -- our research associates  
16 compiled all the laws and rules that we're  
17 covering into one booklet in a pdf that  
18 candidates can pull up off the web so they don't  
19 have to go out to the federal code and the  
20 Florida code and try to find them themselves.

21 They're going to be able to pull it up and  
22 I'm hopeful that that will be a source that they  
23 can use to study. That's on our Bureau of  
24 Education and Testing website. It'll be linked  
25 through your Division's page.

1           But we want to make sure it's visible and  
2 we have to -- we're going to put some thought to  
3 see that that information gets out there to the  
4 entities or organizations that are looking to  
5 have, you know, folks get the certificate and  
6 pass and work.

7           So we'd like to see some thoughts on  
8 getting that information. I think that  
9 component, then getting the candidates to  
10 prepare properly is probably key.

11           We do notice the behavior that was  
12 described before. The fee to test is about a --  
13 it's \$50. It's not very much. Candidates,  
14 they're busy they're working, they just jump in  
15 there to see what it's like and a lot of times  
16 they haven't done the preparation.

17           And I know that sounds like deflecting it  
18 to the individual, but they do have some  
19 responsibility to prepare and we notice this not  
20 just in your profession. The landscape  
21 architects, we were talking about their exam.  
22 They used to have to reapply if they failed our  
23 Florida portion. That was done away with. They  
24 pay much less.

25           Those students have taken a national. They

1 study a whole lot. When they come to our exam,  
2 they're like, I'm just going to pay the -- I  
3 think it's about \$20 or so that they have to pay  
4 to take the test. And we notice that the pass  
5 rate had gone down just because of the behavior  
6 that they saw, well, if I fail I don't have to  
7 reapply, I can just go and pay another \$20 and  
8 retest.

9 So not only do we want to get more  
10 involvement from the Council and from some  
11 certified drug representatives, but we also want  
12 to try to get them this information of the  
13 candidate information booklet and the laws and  
14 rules. Make it as easy for them to prepare for  
15 the examination.

16 And with that said, the exam is, you know,  
17 is the Council's, so we're also -- that's key.  
18 Any involvement or anybody -- I know you all  
19 have busy schedules, but anybody that there's  
20 not a conflict of interest with what you're  
21 managing, we're more than -- more than welcome  
22 to assist us in the review and we can set that  
23 up through Mr. Winters' office.

24 So we're open for any questions if you all  
25 have --

1 CHAIR MAYS: Any questions from Council  
2 members?

3 MR. MONE: Mr. Chairman?

4 CHAIR MAYS: Mr. Mone?

5 MR. MONE: So when you give 90 minutes for  
6 40 scored questions -- 40 scored items, how many  
7 people actually use all 90 minutes?

8 MR. BOSQUE: I don't have that information.  
9 I can get it for you. I suspect that not many  
10 do. Usually most candidates finish about a  
11 half-hour early. Forty scored questions they --  
12 they could finish under an hour, I mean.

13 But I can get you the information.

14 MR. MONE: So and a couple other things.  
15 So have we ever thought about how robust is the  
16 item pull?

17 MR. BOSQUE: We have about 250 items  
18 available.

19 MR. MONE: Two-hundred-and-fifty scored  
20 items?

21 MR. BOSQUE: Yes, sir.

22 MR. MONE: Okay. Do you have any in  
23 pretest?

24 MR. BOSQUE: No, we're not currently  
25 pretesting any. We haven't written any.

1 MR. MONE: So do you ever --

2 MR. BOSQUE: Well, let me --

3 MR. MONE: -- ever put any pretest items in  
4 the examination?

5 MR. BOSQUE: No, we have not. Not since we  
6 took it and both in the practice of health was  
7 not either we would -- we kind of rate the -- if  
8 we -- this last go-round there were a few new  
9 items, but we kind of rated the difficulty of  
10 the item and put it in production and then took  
11 a look to see how --

12 MR. MONE: How it scored?

13 MR. BOSQUE: Right. Yeah.

14 MR. MONE: How it performed.

15 MR. BOSQUE: Yeah. It's -- I mean we do  
16 have enough candidates if we -- if we wrote a  
17 significant amount of new items we could -- we  
18 could do the pilot testing.

19 We do do it in other -- in our other exams,  
20 but we haven't done it on your exam.

21 MR. MONE: Have there ever been  
22 considerations to increasing the number of  
23 items? So when you've got 40 scored items, you  
24 can only get 10 wrong, right?

25 MR. BOSQUE: That's correct.

1           MR. MONE: Have we thought about increasing  
2 the number of items given -- and you'd have to  
3 do the study to figure out how long they take to  
4 perform on each item, but you might be able to  
5 make some new metrics associated with increasing  
6 the number of items, thereby decreasing the  
7 sensitivity of each item.

8           Because I went and did the math. So you've  
9 got 11 items on -- you end up with 11 items on  
10 product integrity, 10 on records, five on  
11 inspections and then they work their way down in  
12 terms of the number of items.

13           So are we able to do an analysis of how  
14 many items in each of these categories we have  
15 to know what items we need to write to so that  
16 we might be able to increase the number of total  
17 scored items, add some pretest items and  
18 decrease the sensitivity of any person missing  
19 one -- because the significance of missing one  
20 or two items becomes -- is truly significant on  
21 a pass/fall basis.

22           Have we thought about doing any of that?

23           MR. BOSQUE: We have not done it, but we  
24 can certainly explore it for you. We -- pretty  
25 much the exam is as it was developed by the

1 Department of Health with the 40 items and  
2 because of the limited resource of consultants  
3 we haven't really looked if there's any other  
4 areas that need to be covered or expanding.

5 But we can certainly get you a breakdown of  
6 the pool and the number in each content area.

7 The other thing we could do is, you know,  
8 we could do a cut score study and see if -- your  
9 test, we don't scale it. It's a straight 75  
10 percent. But we could look to see and adjust  
11 for difficulty in that way also.

12 I'll leave it -- in a nutshell that's how  
13 the -- what we could do. But I'm pretty sure,  
14 just like a lot of the certification exams, the  
15 Department of Health, they didn't go through a  
16 cut score. They just picked 75 percent.

17 If we could -- if we could scale your exam,  
18 we could probably look at the forms and adjust  
19 for the difficulty that way. What I'm saying  
20 there is, the raw score on -- are we -- we put  
21 out the forms and they're pretty close in  
22 difficulty, but one may be slightly more  
23 difficult than another.

24 So we can -- we can adjust it by scaling a  
25 score and a scale is more like when you take an

1 SAT or some of the other national exams you may  
2 be familiar with. They report it out on a  
3 scale, but you never know exactly how many  
4 questions you needed to answer.

5 We may have one of your test in production  
6 that you -- that you have to answer 29 questions  
7 and that's a pass. Another one may be a 30 or a  
8 31 overall or lower. I mean we do that for some  
9 of our programs.

10 So but those are some good ideas that  
11 you're suggesting. I'm not sure increasing the  
12 number of items completely adjusts the  
13 difficulty 100 percent, but it could -- it could  
14 help a little bit.

15 We can also, if anybody's interested in  
16 coming, we can show you all the -- we have  
17 statistics on each question and there may be  
18 some that you all -- even though they're good  
19 questions, you may think that they're too  
20 difficult.

21 It's also a challenge when you're doing the  
22 laws and rules to come up with a robust item  
23 bank because some of the areas are -- I'm not as  
24 familiar with your actual areas, but there's  
25 only so much you can write from an area. So

1 those are some challenges.

2 But we welcome the opportunity, definitely,  
3 to make -- to make improvements.

4 MR. MONE: And I will apologize. I had  
5 volunteered to do this and my time got away from  
6 me, but Drew and I talked --

7 MR. BOSQUE: Yeah.

8 MR. MONE: -- and I'll find a time to come  
9 down and work with you all on some of these  
10 thoughts. -

11 MR. BOSQUE: Our pleasure. We'll get it  
12 prepared for you and we'll get all the  
13 statistics and we'll get the counts of the item  
14 bank and the, you know the content area, where  
15 each one is classified to, and let you look  
16 through it and that's really -- from the history  
17 that I saw, it's been some departmental folks  
18 for the most part, even with health.

19 They initially may have had some input, but  
20 so that's no excuse, I mean, but --

21 MR. MONE: And if you would, send me the  
22 confidentiality agreement before I come look at  
23 it because if Renee wrote it, I really want to  
24 make sure I read it carefully.

25 MR. BOSQUE: It's only a one-pager, so, you

1 know --

2 MR. MONE: Okay.

3 MR. BOSQUE: But I think with your -- with  
4 your ideas, Mr. Mone, and some of the inputs and  
5 putting some of this information out -- I've  
6 observed that since it came over our department  
7 -- I can only speak for DBPR, but it seems that  
8 the information booklet and the laws and rules  
9 are a little bit buried and maybe candidates  
10 aren't finding them.

11 So just maybe if we can do an outreach to  
12 the -- to the industry and get that out and that  
13 would be -- that would be another step.

14 So in combination we can, hopefully, see  
15 the, you know, more certificate holders that get  
16 out there and working.

17 Now maybe some of you are just as happy  
18 that they're not. You know, there is a point to  
19 the exam that we want them competent. So, you  
20 know, at a certain point it is what it is, but  
21 we do want to improve.

22 So definitely.

23 MR. WINTERS: And, Mr. Chair, well,  
24 actually, I'll defer to Renee real quick. I  
25 know she wanted to --

1 MS. ALSOBROOK: Renee's chomping at the bit  
2 because I'm the one that goes out and  
3 investigates the competence of these CDRs.

4 In 2016, I as well as one of my inspectors  
5 who is a CDR, and Division Director Dixon, were  
6 integrally involved with the revisions that  
7 occurred in October of 2016. So the exam at  
8 that point was quite old and the questions were  
9 quite old and the chapter -- the statute had  
10 changed multiple times and the examination  
11 booklet was quite old.

12 So I think that the current test and the  
13 examination booklet is much better than it was,  
14 but obviously needs some work. The key,  
15 however, to the testing questions is what  
16 happens in the field and what we find as  
17 violations.

18 So regardless of what you decide you want  
19 to do with the questions, please be mindful of  
20 what actually happens in the field. And most of  
21 you are involved with wholesale distribution and  
22 you're quite cognizant of what goes on in the  
23 business.

24 Be mindful of what, however, we're finding  
25 as violations. Many of these CDRs are not

1 located in legitimate companies who want to do  
2 right. They're hired by illegitimate companies  
3 who don't want to do right. And they want these  
4 CDRs to be there just so they can get a license.

5 And we find that in multiple, multiple  
6 cases where the CDRs aren't present, they aren't  
7 in management positions and they are not  
8 educated enough to control the businesses or  
9 provide education and consultations for the  
10 business.

11 So it is very, very important that the CDRs  
12 who achieve their registrations through this  
13 testing actually do know what's going on in  
14 these businesses.

15 And as was indicated by the division  
16 director and Alex, you saw, it's not many rules  
17 and laws to read. I mean it's a couple little  
18 sections of 21CFR and Chapter 499. So if you  
19 can't get that, how are you going to be able to  
20 provide the consultation, etcetera that are  
21 required of a truly legitimate wholesale  
22 distribution business?

23 It's the difference between being a drug  
24 dealer and a prescription wholesale -- a  
25 prescription wholesale distribution business.

1 So that's the purpose of the CDR as articulated  
2 in the statute when they were put in place.

3 So just be mindful of that when you adjust  
4 these questions up and down and you reduce the  
5 number of questions that you have in certain  
6 areas.

7 MR. WINTERS: And, Mr. Chair, I want to  
8 take a moment now that I've given her a chance  
9 -- Renee a chance to make sure she got her  
10 statement in.

11 I wanted to address a couple items that I  
12 think is important because I think that we've  
13 got kind of what I would call a two-front item.  
14 One of the things that as the division director  
15 and working with the Council that I've wanted to  
16 do is to ensure that the testing, the material  
17 and other items is up-to-date.

18 And, two, that we're doing what we can to  
19 improve the administration of that test. I  
20 think our Bureau of Education and Testing does  
21 lot of great strides to work on our tests and to  
22 work with a very good company, Pearson VUE, as  
23 you saw, to provide the test in multiple  
24 locations so that they have an opportunity in a  
25 wide range of areas so that access is there.

1           The next thing is just to ensure, as we've  
2 worked on -- we've worked on the booklet to make  
3 sure it's improved. Website updates. And we'll  
4 continue to make sure that we address those.

5           One of the other things we've done is to  
6 try and remove some of the items that we thought  
7 were causing concern inside of the industry  
8 that, what I would call unnecessary items where  
9 we've expanded. And I'm happy to say that, as  
10 we talked with the Council previously, that to  
11 expand the amount of time someone has to take  
12 and pass the examination. That has been  
13 implemented as of April.

14           We have gone ahead and extended from six  
15 months to 18 months so people are not spending a  
16 lot of time just trying to reapply because they  
17 weren't able to complete and pass it in six  
18 months.

19           We found that it, again, the benefit just  
20 didn't outweigh the general cost, so we moved  
21 that to 18 months, giving them three times as  
22 long to pass it. And that is in place. So  
23 anybody that applied for and has been approved  
24 for the exam as of April 1 will have 18 months.

25           So, again, some just general improvements

1 as far as the administration of the exam.

2 I think the other point that we've made and  
3 I think Councilman Mone made a great point, and  
4 made -- had some great questions. And I think  
5 the -- it just brings to the point that, with  
6 the help of the Council and some additional  
7 expertise, that, again, we can start bringing a  
8 little bit into focus those questions.

9 I think that Alex said, and just to kind of  
10 put a point to it, we have a lot of data that  
11 can be used and brought to bear on an  
12 improvement to this exam. And hopefully, as you  
13 said, with some of those additional ideas that  
14 we can take that data and make a much better  
15 examination.

16 And we welcome that opportunity. And I  
17 know with the expertise that Mr. Mone brings, I  
18 think that that's going to be great. I think  
19 that what we have seen is that we have a great  
20 bit of expertise inside of our staff with the  
21 help of Chief Alsobrook, our inspectors that are  
22 on there. Dr. Vu would be one particular, I  
23 believe, was involved quite frequently.

24 And they brought a lot of great expertise,  
25 but we welcome the opportunity to see some

1 additional expertise on the other side that's  
2 inside of the industry. And that's going to be  
3 a welcome addition.

4 So, again, I think that with that kind of  
5 moving forward I look forward to it and I think  
6 that our staff, when we go to having Mr. Mone  
7 come, is going to bring that to bear. And then  
8 we'll be able to also reach out.

9 When we do go for the further examination  
10 overhaul that's coming up in the fall, if we can  
11 identify some additional individuals it would be  
12 helpful to bring in. Again, they will have to  
13 be able to sign confidentiality agreements, but  
14 to let them come in and give some more industry  
15 input, along with our current staff to, again,  
16 allow that.

17 I think we're going to see a much better  
18 improvement of the exam. So, again, we welcome  
19 that. So.

20 CHAIR MAYS: Go ahead, Mr. Phillips.

21 DR. PHILLIPS: Thank you.

22 So I understand that the testing time is 30  
23 days if the -- if the candidate fails the  
24 original test to retest, correct?

25 MR. BOSQUE: That's my understanding, yes.

1 DR. PHILLIPS: So any consideration, I  
2 guess from an integrity standpoint, so that the  
3 candidate isn't just taking the test multiple  
4 times just to be able to pass it after taking it  
5 a few times of extending that time.

6 Or is that a standard -- do you know if  
7 that's a standard across all tests? Maybe to go  
8 to 60 days or 90 days.

9 MR. BOSQUE: It's not a standard. With a  
10 test like this it's kind of common practice.  
11 Some would say that 30 might be a little bit too  
12 long of a wait, just because they -- the time  
13 that they take to be, you know, certified and  
14 get their certificate.

15 The 30 days -- the thought behind it is  
16 that they -- it limits our exposure of smaller  
17 item pool, but also candidates do take some time  
18 to prepare. Extending it, I'm not sure, would  
19 have any positive or negative effect.

20 So we -- it varies from program -- some  
21 programs they can test within two days. And,  
22 again, that behavior is not -- our real estate  
23 candidates do that, but, you know, if they don't  
24 change anything in their -- in their preparation  
25 process, then we see that they're not

1           successful.

2           So I wouldn't say that model's good. But I  
3 think 30 is sufficient time behind it. If they  
4 do -- one thing we didn't mention is that your  
5 candidates -- it was brought up on one of our  
6 slides -- but they can review the examinations  
7 Florida provides in their statute and rules for  
8 that opportunity.

9           So that's one thing the candidates can take  
10 advantage of. And if they do review that, that  
11 extends the period a little bit longer. They  
12 have to wait 21 days to test again. So they may  
13 fall within the 30 or a little bit beyond that.

14           But that's another thing we can add to our  
15 -- to our information to make it a little bit  
16 more visible to them. It is on their fail score  
17 report. It does say that they can review. But,  
18 again, I'd have to find the numbers for you to  
19 see how many of your candidates are taking  
20 advantage of that.

21           MR. JANECEK: I seem to recall we looked  
22 and it's a low number --

23           MR. BOSQUE: It's a low --

24           MR. JANECEK: -- requesting reviews --

25           MR. BOSQUE: Yeah. Right.

1 MR. JANECEK: -- of the exams.

2 MR. BOSQUE: So it could be that they're  
3 not interested or they're not -- they're not  
4 aware of what it is, but they would see -- in a  
5 review they would see the questions they missed,  
6 along with the correct answer.

7 And then, you know, I'm not telling --  
8 saying that they should learn the exam, because  
9 they're not going to see the same test again,  
10 but it gives them an opportunity to do that.  
11 And it also gives them a chance to challenge any  
12 questions that they -- that they feel that their  
13 answer is correct and that we're not.

14 But we haven't had any -- we've had very  
15 few challenges via the review process. But  
16 that's another opportunity.

17 To answer your question, I feel 30 days is  
18 sufficient and usually it's asked the opposite  
19 way, not wanting to extend it. I think  
20 extending it would just slow down the  
21 certification process and it's not -- it's not  
22 going to change -- I doubt that it would change  
23 their behavior or improve the performance, if  
24 that's where you question's --

25 CHAIR MAYS: This is Steve Mays. I think,

1 probably to your point, I'm sure there's  
2 probably distributors where maybe they only have  
3 one person that could meet the qualifications to  
4 take the exam, especially a smaller distributor.  
5 So I would think they would want to accelerate  
6 that time, if anything, to try to retake that  
7 exam.

8 MR. BOSQUE: I think you're at a -- you  
9 know, that's really up to what you all -- I  
10 think you're at a good spot with that 30 days to  
11 let them see that they, you know, prepare and  
12 take it seriously and get their certificate.

13 To shorten it may encourage them -- more  
14 behavior that's not conducive to -- either  
15 they're trying to learn the exam or so forth. I  
16 think -- I think the 30's a good -- especially  
17 since we've extended it to 18 months that they  
18 can -- they can take the exam.

19 DR. PHILLIPS: I think the only reason I  
20 mention that is because, at the beginning of the  
21 presentation, you mentioned the number of people  
22 who might have -- who might be taking it and you  
23 might see lower or increased failed rates in the  
24 beginning just because they're testing the exam.

25 So in this case, by having a longer period,

1 it forces them to really want to pass the first  
2 time.

3 CHAIR MAYS: Any other questions from  
4 Council members?

5 MR. HART: This is Peter Hart. I'd like to  
6 defer over to the enforcement side of this.

7 Do you see that 30 day timeframe showing up  
8 as an issue?

9 MS. ALSOBROOK: Councilman Hart, I don't.  
10 I think the 30 days is a good timeframe.

11 I think what we need to look at is, is the  
12 exam too hard. And when Council member Mone  
13 looks at I think we'll have a good idea if it's  
14 too hard.

15 MR. WINTERS: The other thing is, just from  
16 a -- the Division side, I have -- unless they're  
17 contacting directly Bureau of Education and  
18 Testing, in talking with a lot of the candidates  
19 for the CDR exam I have not heard, in the  
20 timeframe that I've been here, and I haven't  
21 received any information from our processing  
22 manager, Rebecca Burnett, that we're getting any  
23 particular kickback on that 30 days.

24 So I think that right now, based on the  
25 information we've got, I think the 30 days is a

1 good number. It seems to be, obviously, the  
2 integrity is maintained. We're not seeing a  
3 massive jump on the second time takers and we're  
4 not receiving a lot of reports that people are  
5 being prevented from taking the exam and causing  
6 problems.

7 Like I said, I got much more calls on,  
8 okay, it's been six months, what do I do now.  
9 You know, how do I do this and I've got to  
10 submit this over. That was -- that was more the  
11 call that we were getting, which is one of the  
12 reasons why we focused on that, to get that  
13 process improvement.

14 But, again, as Renee said, and what I'm  
15 saying is, that number seems to be overall  
16 working and we don't -- like I said, we're not  
17 seeing an item on either side that would kind of  
18 raise that.

19 Although, again, as Dr. Phillips mentioned,  
20 you always take into consideration the integrity  
21 of the test based on the timeframe between  
22 testings. So, but, again, I think we're looking  
23 right now, based on the information, everything  
24 is generally good with that number.

25 CHAIR MAYS: Any other questions from

1 Council members? Okay.

2 I just -- this is Steve Mays. I, you know,  
3 I'll preface my remarks by saying I've never  
4 taken the exam before. I've been in the  
5 industry over 40 years and I would be very  
6 interested in taking a look at it and being as  
7 helpful as I can be personally, because I would  
8 really like to take a look at it myself.

9 I do -- I have -- I have some mixed  
10 feelings. I think that, you know, we want to  
11 make sure that the people that are representing  
12 distribution centers in the state are -- that  
13 are permitted in the states know what they're  
14 doing and they understand the rules and the  
15 statutes.

16 I think, on the other hand, I look at a lot  
17 of these people -- my concern more about the  
18 pass/fail rate is kind of alarming to see that  
19 many failures. And it's not so much that maybe  
20 the test is too hard, but I'm concerned that,  
21 you know, typically these people are still going  
22 to be in there operating that business, even  
23 though they didn't pass the test and maybe  
24 someone else has to be the CDR.

25 So I think the education part of it is just

1 as important and, you know, I know -- I know --  
2 and I don't really have a problem with the 75  
3 percent or the number of questions. I mean we  
4 take -- I take exams all the time with my  
5 company internally. Code of ethics exams and a  
6 lot of other things. And you're typically have  
7 to go through some extensive training first and  
8 then you've got to basically pass up to 90  
9 percent of the questions to pass.

10 So, having said all that, I think I  
11 understand, too, you know, from looking at some  
12 of our folks, they're typically a, you know, a  
13 distribution center manager and they've got a  
14 day job they've got to do and they've got  
15 families to go home to and they're not  
16 professional -- they're not professionals and  
17 they're not full time students.

18 So I know it's difficult for them to do a  
19 lot of the in depth studying. And I'm not  
20 making excuses for people that fail the test,  
21 but I think it would be good, you know,  
22 especially for Mr. Mone to take a look at it and  
23 make sure that we've got -- the questions are  
24 real world questions in how to, you know,  
25 operate a pharmaceutical distribution center in

1 compliance with the laws and statutes and in a  
2 real world.

3 And, you know, I think that if it's fair I  
4 don't, you know, we want people, you know, our  
5 bottom line is we want to have a safe and secure  
6 supply chain and we don't want to have issues  
7 out there with bad players that are -- that are  
8 representing distribution centers and operating  
9 them.

10 So, having said that, I'll open it up to  
11 questions from any interested parties on the  
12 line.

13 Any other -- any other questions?

14 Okay. Okay. In the back. I'm sorry.

15 Could you identify yourself.

16 MS. HARTSFIELD: Yeah. I'm

17 Shannon Hartsfield of the law firm of Holland  
18 and Knight. I was just curious, is the pass  
19 rate for this exam very different from a pass  
20 rate of other professions? Are there -- is this  
21 one anomalous in any way? Or are the -- are the  
22 pass rates much higher from most other  
23 professions?

24 MR. BOSQUE: Slightly lower. I wouldn't  
25 call it -- call it an anomaly, but it's -- we'd

1 like to see a little bit better performance.

2 MS. HARTSFIELD: Is it the lowest one or  
3 are there other professions that have lower pass  
4 rates?

5 UNIDENTIFIED SPEAKER: We may have to look,  
6 but --

7 MR. BOSQUE: I'd have to look. I'm pretty  
8 sure it's not the lowest. We don't -- it's in  
9 the ballpark with the -- with a few others. But  
10 most of our exams are 40, 50, 60 percent for the  
11 first time test takers.

12 So what we want to do is what Mr. Winters  
13 said. We want to make sure that the forms are  
14 -- we aren't setting the difficulty level too  
15 high, that the material is appropriate and that,  
16 no one test is any more difficult than the  
17 other.

18 And then, from there, we'll see how the  
19 pass rates improve the -- I wouldn't call it an  
20 anomaly either. It's --

21 CHAIR MAYS: And I did have one more  
22 question.

23 Do we provide -- and, again, not seeing --  
24 not having seen any of the materials before, the  
25 booklet or anything, do we provide -- does the

1 Department provide a study guide of sorts to the  
2 -- to the applicant?

3 I think -- I mean I would recommend that we  
4 do that covers all those different areas of the  
5 rules and the statutes. Where they, you know,  
6 something that's not too extensive so they could  
7 understand, you know, these are the main things  
8 that I need to really be concentrating on.

9 MR. JANECEK: That's where that candidate  
10 information booklet comes into play. It does  
11 provide some details there. Now Alex did  
12 mention we did recently create the laws and  
13 rules book that can be downloaded.

14 And our thought was, if it's all packaged  
15 in one nice pdf --

16 CHAIR MAYS: Okay.

17 MR. JANECEK: -- it may be more accessible  
18 to them than having to go find all those  
19 resources separately. So that is available now,  
20 too.

21 MR. BOSQUE: And we can -- we can -- from  
22 Mr. Winters' office we can send out those --  
23 those links to you all if you'd -- if you'd like  
24 to have them, especially the laws and rules.

25 CHAIR MAYS: That would be great. That

1 would be great.

2 I want to thank you two gentlemen for  
3 coming today. I think this has been a very  
4 helpful conversation.

5 MR. JANECEK: Well and it's just the first  
6 one. So we'll make sure to continue this on.  
7 We'll work with Director Winters to kind of  
8 build that team of experts so that we can give  
9 this a good, thorough review.

10 CHAIR MAYS: Okay.

11 MS. ALSOBROOK: You guys are great, but you  
12 do know the requirements of a CDR, right? That  
13 you know the business, you know the laws and  
14 rules, that you're a manager. You're not  
15 supposed to have to spoon feed them to pass the  
16 exam, Chairperson.

17 MR. JANECEK: I'm not touching that.

18 MR. BOSQUE: Thank you all for having us.  
19 We appreciate your time and look forward to  
20 working with you all.

21 CHAIR MAYS: Thank you. Thank you.

22 Mr. Winters, anything else?

23 MR. WINTERS: Not for the CDR examination.  
24 I think that we've hit that a good lick today.  
25 So I think it just shows we've got some work to

1 do, but obviously made some improvements and  
2 we're continuing to soldier forth.

3 And thank the representatives of the Bureau  
4 of Education and Testing, Mr. Janecek,  
5 Mr. Bosque. But with that I'll go ahead and  
6 move forward.

7 We've got one more item, specifically on  
8 the director's report, and that is to provide  
9 you a copy of House Bill 675 that has been  
10 enrolled and signed by the governor and is  
11 passed and is effective now.

12 Excuse me. It will go effective July 1 of  
13 this year and what -- I'm going to give you just  
14 a brief, high level overview of it to give you  
15 some of the main points of what it does.

16 It is a fairly short bill compared to some  
17 of the others we've reviewed so, again, it's not  
18 difficult reading. But just to start, the basic  
19 overview of this is that the House Bill did  
20 create a new Class 3 institutional pharmacy  
21 permit under the Board of Pharmacy.

22 And it did provide not only additional  
23 definitions under 465 with the Board of Pharmacy  
24 and specifically to those would be to adopt a  
25 definition of a central distribution facility

1 and making that part of the Class 3  
2 institutional pharmacy permit. So if there's a  
3 central distribution facility it would be a  
4 Class 3 institutional pharmacy requiring that  
5 permit.

6 It also adopted the definition of common  
7 control, which is on page three of the bill,  
8 which basically adopts a very similar definition  
9 to what we have inside of Chapter 499.

10 The first part that you'll want to look at,  
11 the main issue that I'll draw your attention to,  
12 is the Class 3 institutional pharmacy permit on  
13 page five of your -- of 15 of the bill, starting  
14 on line 78 of the bill as we've provided to you.

15 Again, that gives you the scope of work and  
16 the general licensing requirements for the Class  
17 3 institutional pharmacy permit and the scope of  
18 that, which includes the -- not only to dispense  
19 but, in this case, the most pertinent part for  
20 our discussion, which is the distribution of  
21 prescription drugs that are handled through that  
22 pharmacy permit.

23 It also specifically is for preparation of  
24 prepackaged drug products, which is defined  
25 further on in the bill, which we will address

1 that issue item shortly.

2 But what is does is that it creates that  
3 under the Board of Pharmacy. We had been  
4 working with the Board of Pharmacy to determine  
5 just the normal adoption process, their  
6 implementation of this and the items that  
7 they're going to require of the Class 3  
8 institutional pharmacy applicants in order to do  
9 that.

10 And then working with them as far as  
11 development of how they're going to develop that  
12 permit. Because, in this particular case, this  
13 permit is within their purview. While we have  
14 commensurate permits on our side that currently  
15 exist, the Class 3 institutional pharmacy permit  
16 will be under their development. So they do  
17 have the authority over its strictures and its  
18 development.

19 Again, the Class 3 institutional pharmacy  
20 permit, if you'll look, again, has several items  
21 of requirement that will be, again, implemented  
22 by the Board of Pharmacy that we will look at,  
23 including, specifically, recordkeeping,  
24 preparation, dispensing, prepackaging,  
25 transportation, distribution of additional drugs

1 for their recordkeeping.

2 Then also safe practices, requirement of a  
3 consultant pharmacist responsible for those  
4 services. So that will be handled by the Board  
5 of Pharmacy and their development.

6 Going forward from that the Class 3 permit,  
7 again, tracks with the Class 2 institutional  
8 pharmacy permit, which is currently already in  
9 existence. The difference here is that it will  
10 allow for distribution under that permit.

11 Moving forward to the next page, we'll --  
12 I'll draw your attention to, which is on page  
13 eight. This is the 499 definitions and they  
14 have added a couple of items to the definitions.

15 Under 499.003(39) there's a definition of  
16 prepackaged products. That definition has been  
17 changed under this to allow for the prepackaging  
18 as defined in the statute currently. However,  
19 it adds in there that prepackaging that is  
20 conducted by a Class 3 institutional pharmacy  
21 permit.

22 And it also removes the restriction that  
23 those prepackaged drugs be held in the  
24 establishment in which prepackaging occurred.  
25 That is currently what is required. Now it will

1 allow them to be moved under the pharmacy permit  
2 under the Class 3.

3 The other item that you'll note is that  
4 under the wholesale distribution on page eight  
5 and beginning on line 190 to the bill, there is  
6 an additional exemption put into the definition  
7 of wholesale distribution.

8 And that is for a hospital that is covered  
9 under Section 340B of the Public Health Services  
10 Act under the federal statute that arranges for  
11 prescription drug whole distributor to  
12 distribute those prescription drugs to code  
13 entities, to act directly as a contract  
14 pharmacy.

15 And that would exempt them from the  
16 necessities to have a restricted drug  
17 distributor permit under 499.012(h).  
18 Specifically what that means is that, if you  
19 have a current or potential governmental  
20 entity's permit under our restricted drug  
21 distributor, if they do not take possession of  
22 the drugs -- the 340B drugs, would rather use a  
23 contract pharmacy that's been approved through  
24 the HRSA requirements and is an approved  
25 pharmacy, they would not need the governmental

1 entity's permit -- the 54 permit as it's  
2 commonly referred to in our office.

3 But the restricted drug distributor,  
4 governmental entity's program, which was created  
5 to allow for the handling of those 340B drugs.  
6 So that would be to allow them, if they are  
7 contracting out, to not need that permit.

8 And, again, the addition, also, of the  
9 Class 3 institutional pharmacy permit is also  
10 added to a exemption from the wholesale  
11 distribution under the new subparagraph X that's  
12 noted on line 198.

13 The next portion that you'll want to look  
14 at is an exemption that's placed into 499.01.  
15 And I'll read it because it's a short paragraph.  
16 It says, "A prescription drug repackager permit  
17 is not required for distributing medicinal drugs  
18 or prepackaged drug products between entities  
19 under common control, which each either hold an  
20 active Class 3 institutional pharmacy permit or  
21 an active healthcare clinic establishment  
22 permit."

23 That's our HCCE permit, as we commonly  
24 refer to it. So, again, what it means is, is  
25 that if you meet the definition of common

1 control and you have both the Class 3  
2 institutional and you're commonly controlled  
3 HCCE, you could move those drugs to those HCCEs.  
4 So, again, that is inside of the statute now.

5 And moving forward, there is also  
6 additional exemptions that are added. If you'll  
7 move to page 13-of-15, there's a item placed on  
8 line 278 of the bill which basically, again,  
9 mimics the previous exemption.

10 It basically, in its verbiage, says, "A  
11 restricted drug distributor permit is not  
12 required for distributing medicinal or  
13 prepackaged drug products between the entities  
14 under common control that hold the Class 3 or an  
15 active healthcare clinic establishment permit."

16 So, again, those entities that have the  
17 Class 3 or the HCCE would allow them to move  
18 those drugs from the Class 3 to the institution  
19 or the HCCE.

20 It does line out a previous exemption which  
21 basically allowed for prepackaged or a  
22 repackager permit not to be necessary in the  
23 event that you met certain criteria. And that  
24 criteria was provided in sub 5.

25 We did look at this. The items that -- in

1 this, again, the prescription drug distributor,  
2 they had to notify us within 30 days, they had  
3 to be under common control, much like the Class  
4 3 and the HCC under the provisions that'll come  
5 into effect July 1 for distributing.

6 In the particular case, the prescription  
7 drug distributor had to meet good manufacturing  
8 practices under both state and federal law and  
9 that they had to maintain the state and federal  
10 recordkeeping laws for the labeling. Excuse me,  
11 the labeling requirements under both state and  
12 federal law.

13 That has now been pulled out of the  
14 statute, which means that in some fashion that  
15 there is more -- a repackager permit would now  
16 be required under those. However, the thought  
17 of these appears to be is that the Class 3  
18 institutional would be the permit that they  
19 would seek if they were going to -- wanting to  
20 continue to do that.

21 For the record, we did research. There  
22 were -- we could not locate a substantial number  
23 of people that had notified us they were even  
24 using this provision. So that impact in and of  
25 itself, the removal, does not appear to be a

1 large impact.

2 I was posed the question and I'll go ahead  
3 and address it, which is, what is the general  
4 impact going to be on the Division.

5 Again, the main impact is going to be the  
6 loss of permits. Entities electing to go to the  
7 Class 3 institutional as opposed to using the  
8 current restricted HCE permit for the healthcare  
9 entity.

10 So that would be the main impact. This --  
11 the other impact would be permits in the  
12 repackager permit and the governmental entities  
13 permit. Again, the potential to see reduction  
14 in those permit types as people elect to use the  
15 exempting language.

16 How much or how many people will elect to  
17 do that is unclear and so we have not put a  
18 specific number on that, only to indicate that  
19 it is an indeterminate impact. How substantial  
20 it will be, we'll wait and see.

21 We have implemented reporting to make sure  
22 that we monitor that for its progress over the  
23 next several years so we can keep an eye on it.  
24 And, like I said, we're looking to those items  
25 to ensure that we at least maintain those.

1           The other thing is, is that it does now  
2           give specific distribution authority under a  
3           pharmacy permit that did not previously exist.

4           So, with that, I'll turn it over. That's,  
5           again, just a large overview. It does not get  
6           into the minutiae, but, again, we can -- if you  
7           have any questions right now we can attempt to  
8           answer those.

9           Or, if not, if at a later time questions  
10          come up, you can, of course, always contact me  
11          with the Division.

12          CHAIR MAYS: Mr. Mone?

13          MR. MONE: Mr. Winters, correct me if I'm  
14          wrong, because it's entirely possible I read  
15          this wrong.

16          The distribution authorization in the -- in  
17          the act is limited to those under common control  
18          and ownership. So it's only going to be those  
19          hospitals and those common controlled clinics;  
20          correct?

21          MR. WINTERS: That is correct. It is --  
22          the language does limit it to that and it limits  
23          it to the entities that are holding the Class 3  
24          or the HCE under common control. So those  
25          elements will be there.

1           The other part that I did not mention  
2 specifically and it is one to note, the  
3 regulation that currently exists -- the  
4 licensing permitting types currently does -- it  
5 remains.

6           So, again, people can maintain the current  
7 structure. It just depends on how many are  
8 going to move to that different type. So, you  
9 know, we keep that in mind. That's why it's in  
10 -- we can't determine the impact of it right  
11 now.

12           CHAIR MAYS: Any other questions from  
13 Council members?

14           MR. ELLIS: Mr. Chairman, this is  
15 Dean Ellis. I'm here.

16           CHAIR MAYS: Better late than never,  
17 Mr. Ellis.

18           MR. ELLIS: It's true. I thought I was  
19 early. Ten o'clock. I'm sorry. So sorry.

20           MR. WINTERS: Well, you know, the  
21 questions, like I said, again, as the Division's  
22 representative and the director's office, I'll  
23 let you know that, again, we know that as we  
24 discuss items on a council meeting that may come  
25 up later. If there's any requests you can

1 always contact me individually. If I can help  
2 or provide additional information that will be  
3 helpful, I'll be certainly -- we're welcome to  
4 -- we offer that open door policy. So please do  
5 reach out.

6 Other than that, that concludes my  
7 director's report for the council.

8 CHAIR MAYS: Any other questions from  
9 council members for Mr. Winters?

10 Questions from interested parties on the  
11 line? Okay.

12 Is there any other business? (No  
13 response.)

14 Okay. Hearing none, do we have a motion to  
15 adjourn?

16 UNIDENTIFIED SPEAKER: Motion to adjourn.

17 CHAIR MAYS: Do we have a second?

18 UNIDENTIFIED SPEAKER: Second.

19 CHAIR MAYS: All in favor say aye. (Board  
20 members responded.)

21 Opposed? (No response.)

22 The meeting is adjourned. Thank you.

23 (The meeting adjourned at 9:41 a.m.)  
24  
25

**C E R T I F I C A T E**

STATE OF FLORIDA )

COUNTY OF ORANGE )

I, HEATHER K. HOWARD, Court Reporter,  
certify that I was authorized to and did report the  
aforementioned May 10th 2018 Department of Business  
and Professional Regulation, Drug Wholesale  
Distributor Advisory Council Meeting, and that the  
transcript is a true and complete record of my notes  
and recordings.

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

DATED this 31st day of May, 2018.

*Heather K. Howard*

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HEATHER K. HOWARD, Court Reporter  
Notary Public, State of Florida  
(electronic signature)

Commission Expiration: 06/17/18  
Commission No.: FF 119444