

1 **DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL**  
2 **Draft Meeting Minutes**  
3 **August 14, 2014**  
4 **9:30 a.m.**  
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7 **9:30 a.m. Call to Order by Gary Cacciatore, Chair**

8 The meeting was called to order by the Chair.  
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10 The following members were present:

11 Steve Mays, Scott Brock, Dean Ellis, Bill Mahoney, Patrick Barnes, Michelle Mendez, Gary  
12 Cacciatore, Jenn Ungru

13 Mike Ayotte was absent.  
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15 **TAB 1: Approval of May 15, 2014 Meeting Minutes**

16 **Motion by:** Mr. Brock made a motion to approve, Seconded by: Mr. Ellis.  
17 Motion Carried  
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20 **TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD**

21 Mr. Cacciatore stated we discussed elections for a Chair and Vice-Chair at the  
22 last meeting. I will open the nominations for chair by any of the council  
23 members.  
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25 Mr. Barnes asked don't we currently have a Vice Chair.  
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27 Mr. Cacciatore stated we do have a vice chair but it is not a succession type of  
28 position. The Vice Chair takes over if the Chair is not able to attend the meetings.  
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30 Mr. Ellis nominated Mr. Cacciatore as Chair for another year. Seconded by Mr.  
31 Mahoney. Motion carried.  
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33 Mr. Cacciatore stated nominations for Vice-Chair are now open.  
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35 Mr. Ellis nominated Mike Ayotte seconded by Mr. Brock. Motion Carried.  
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39 **TAB 3: Executive Director's Report – Reginald Dixon**

40 **1. Rules Report:**  
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42 Mr. Dixon stated nothing has changed with rules since the last meeting. The  
43 Division has been focusing on the DQSA and the Medical Gas legislation.  
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45 Mr. Cacciatore asked Mr. Dixon what has to be done by October 1.  
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47 Mr. Dixon stated the Division is working on creating a part 3 for Chapter 499  
48 regarding Medical Gas instead of amending Chapter 499.  
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Mr. Dixon stated beginning October 1 the medical gas manufacturer and wholesaler permits that were limited to the state is now going to be allowed for out of state. Making sure applications are up to date and we have systems in place.

Mr. Cacciatore asked Mr. Dixon if he had any knowledge of when the Federal Guidelines will be coming from FDA.

Mr. Dixon stated he has not had any notification.

Mr. Dixon stated we have met with legislative staff and department staff in regards to DQSA. We are compiling a list of the changes that need to be made to Chapter 499.

Mr. Dixon stated one of the issues that need to be resolved is DQSA only talks about finished dose products and not active pharmaceutical ingredient.

Chapter 499 speaks to API, the companies who wholesale API would have to pass a Florida pedigree. This is the way the statute reads right now. The Division has to work on that and part of it will be policy call from the Secretary on if API is even prescription drug.

Mr. Ellis stated that we have an opportunity to help small business in the State of Florida with the hundred thousand dollar bond.

Mr. Dixon stated under the DQSA talks about bonding but you only have to have one for every state you do business.

Mr. Ellis stated but the state will have the option to change that amount depending on the sales. I feel that is a great opportunity for small business. I think we need to discuss this and perhaps talk to other small businesses.

Mr. Ellis also stated we need to identify the primary and secondary from the website. In light of the federal legislation a secondary needs to know who the primary wholesalers are.

Mr. Dixon stated that we were working on adding a modifier to the website.

Mr. Cacciatore suggested that we put together a committee to help with the re-write of Chapter 499 in regards to DQSA.

Mr. Dixon stated that the department would not be opposed to that having a committee to help in the rule making process for the DQSA. Some of you may have in-site to what other states are doing.

Mr. Dixon stated the Federal regulations were supposed to be out by November. That probably will not happen.

Mr. Cacciatore stated perhaps we wait until the federal guidelines come out and the election is over.

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**2. Controlled Substance Reporting**

Mr. Dixon provided a report to the council from the Controlled Substance Reporting.

Mr. Dixon stated the issues we have with this system and trying to perform audits. The way the legislation is drafted, there are entities that may have one of the permits that are required to report and have a DEA number. But they don't have to report because they don't deal in Controlled Substances.

The division is trying to figure out a way to automate it, to create a list to work from for the audits.

Our department is rebuilding the CSR and the goal is for January to actually have something in place.

The system will be able to show you what you uploaded. The division will be able to search on what drug was sent to a certain pharmacy. These are things we are working on with the CSR.

**3. HD Smith Declaratory Statements**

Mr. Dixon stated the Declaratory Statements were provided to the council as informational purposes only.

**TAB 4: Other Business**

Motion by Mr. Brock seconded by Ms. Ungru. Meeting was adjourned.