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

Conference Call Number 888-670-3525
Conference Code 9259887749

December 11, 2014
9:30 a.m.

Council Members:
Gary Cacciatore, Pharm.D., J.D., Chair.
Primary Prescription Drug Wholesalers
Mike Ayotte, Vice Chair, Retail Pharmacy
Steve Mays, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Jenn Unguru, Agency for Health Care Administration
Dean Ellis, Secondary Prescription Drug Wholesalers
William Mahoney, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Michelle Renae Mendez, DO, Physician
Jeenu Phillips - Board of Pharmacy

DBPR Staff:
Reggie Dixon, Director,
Division of Drugs, Devices and Cosmetics Program
Ken Lawson, Secretary
Tim Vaccaro, Deputy Secretary
Renee Alsobrook, Compliance Manager
Dinah Greene, Controlled Substance Reporting
Rebecca Burnett, Regulatory Supervisor
Amy Bennett, Office Manager

Call to Order: Gary Cacciatore, PharmD., J.D., Chair

TAB 1: Approval of Minutes – August 14, 2014

TAB 2: Chair’s Report – Gary Cacciatore, PharmD, JD
1. 2015 Meeting Dates

TAB 3: Executive Director’s Report – Reginald Dixon
1. Secondary Wholesalers

TAB 4: Other Business
Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics

The Division of Drugs, Devices and Cosmetics announces a telephone conference call to which all persons are invited.

DATE AND TIME: December 11, 2014, 9:30 a.m.
PLACE: Conference call number: 1(888)670-3525, conference code 9259887749
GENERAL SUBJECT MATTER TO BE CONSIDERED: General Business.

A copy of the agenda may be obtained by contacting: Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800, Dinah Greene.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800, Dinah Greene. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800, Dinah Greene.
DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL
Draft Meeting Minutes
August 14, 2014
9:30 a.m.

9:30 a.m. Call to Order by Gary Cacciatore, Chair
The meeting was called to order by the Chair.

The following members were present:
Steve Mays, Scott Brock, Dean Ellis, Bill Mahoney, Patrick Barnes, Michelle Mendez, Gary Cacciatore, Jenn Unguru. Mike Ayotte was absent.

TAB 1: Approval of May 15, 2014 Meeting Minutes

Motion by: Mr. Brock made a motion to approve, Seconded by: Mr. Ellis.
Motion Carried

TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD
Mr. Cacciatore stated elections for a Chair and Vice-Chair was discussed at the last meeting. I will open the nominations for chair by any of the council members.

Mr. Barnes asked don’t we currently have a Vice Chair.

Mr. Cacciatore stated we do have a vice chair but it is not a succession type of position. The Vice Chair takes over if the Chair is not able to attend the meetings.

Mr. Ellis nominated Mr. Cacciatore for Chair and Seconded by Mr. Mahoney.
Motion carried.

Mr. Cacciatore stated nominations for Vice-Chair are now open.

Mr. Ellis nominated Mike Ayotte and seconded by Mr. Brock. Motion Carried.

TAB 3: Executive Director's Report – Reginald Dixon
1. Rules Report:

Mr. Dixon stated nothing has changed with rules since the last meeting. The Division has been focusing on the DQSA and the Medical Gas legislation.

Mr. Cacciatore asked Mr. Dixon what has to be completed by October 1.

Mr. Dixon stated the Division is working on creating a Part 3 for Chapter 499 regarding Medical Gas instead of amending Chapter 499.
Mr. Dixon stated starting October 1, medical gas manufacturer and wholesale permits that were limited to the state of Florida will now be allowed for out of state. The division has been reviewing applications for any changes that need to be made. Updating the website and putting in place any system changes.

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 on FDA.

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

Mr. Dixon stated one of the issues to be resolved is in the DQSA it addresses finished dose products and not active pharmaceutical ingredient (API).

Mr. Dixon stated the way Chapter 499 is written right now it has API and the companies who wholesale API would have to pass a pedigree. The division has to put some work into that. It will be a policy call from the Secretary on if API is even a prescription drug.

Mr. Ellis stated that the Department has an opportunity to help small business in the State of Florida with the bond amount.

Mr. Dixon stated under the DQSA you only have one bond for every state you do business in.

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 the Division had discussed adding a modifier to the website. The division will research and provide a response at the next meeting.

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 the department would not be opposed to 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.

Mr. Cacciatore stated perhaps we wait until the federal guidelines come out before we suggest a committee.
2. **Controlled Substance Reporting**

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

Mr. Dixon stated there are issues with the CSR when trying to perform audits. The way legislation was written, there are entities that have one of the 5 permits that are required to report and have a DEA number. But they don’t sell controlled substances so they don’t have to report.

The department is in the process of rebuilding the CSR and the goal is for January 2015 to actually have something in place.

The division will be able to search on what drug was sent to a certain pharmacy. Hopefully be able to get accurate audit reports once complete.

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. Unger. Meeting was adjourned.
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<td>May 14, 2015</td>
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Council Members:<br>Please have any agenda items for discussion to our office by the agenda deadline above.<br><br>If you should have any questions pertaining to this matter, please contact me at 850-717-1802.<br><br>Thanks Dinah
Licensee Details

Licensee Information
Name: MCKESSION CORPORATION (Primary Name)
MCKESSION DRUG COMPANY (DBA Name)
Main Address: 4836 SOUTHRIDGE BLVD
MEMPHIS Tennessee 38141
License Mailing:
LicenseLocation: 4836 SOUTHRIDGE BLVD
MEMPHIS TN 38141
County: UNKNOWN

License Information
License Type: Out-of-State Prescription Drug Wholesale Distributor
Rank: Out of FL-Whole
License Number: 232406
Status: Current
Licensure Date: 08/18/2011
Expires: 08/31/2015

Special Qualifications
Qualification Effective
Pending certificate print 08/19/2011
Publicly Held Corporation 06/21/2011
Primary Wholesaler 07/06/2011

View Related License Information
View License Complaint
Licensee Details

Licensee Information
Name: MASTERS MEDICAL, INC. (Primary Name)
MASTERS SPECIALITY PHARMA (DBA Name)
Main Address: 2275 S.W. 66TH TERRACE
DAVIE Florida 33317
County: BROWARD
License Mailing:

LicenseLocation: 2275 S.W. 66TH TERRACE
DAVIE FL 33317
County: BROWARD

License Information
License Type: Prescription Drug Wholesale Distributor
Rank: Rx Drug Whislr
License Number: 221
Status: Current
Licensure Date: 01/13/1995
Expires: 01/31/2015

Special Qualifications
Qualification Effective
Renewal certificate print failure
01/07/2011
Closely Held Corporation 01/06/2011
Secondary Wholesaler 01/07/2010

View Related License Information
View License Complaint

1940 North Monroe Street, Tallahassee Fl. 32399 :: Email: Customer Contact Center :: Customer Contact Center : 850.487.1395

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*Pursuant to Section 455.275(1), Florida Statutes, effective October 1, 2012, licensees licensed under Chapter 455 F.S. must provide the Department with an email address if they have one. The emails provided may be used for official communications with the licensee. However email addresses are public records. If you do not wish to supply a personal address, please provide the Department with an email address which can be made available to the public. Please see our Chapter 455 page to determine if you are affected by this change.

https://www.myfloridalicense.com/LicenseDetail.asp?SID=&amp;id=0E2E998AF320369.. 12/1/2014
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License Master Report
Department of Business and Professional Regulation
State of Florida