**Drug Wholesale Distributor Advisory Council Meeting**
**February 16, 2012**
**Draft Meeting Minutes**

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

Roll Call taken by Dinah Skrnich.

The following council members were present:
Mr. Cacciatore, Mr. Ayotte, Mr., Brecko, Mr. Ellis, Mr. Garcia, Mr. Mahoney, Mr. Barnes, Ms. Elliott., Mr. Brock.

The following council members were absent: Dr. Walker

A quorum was present

**Tab 1. Approval of December 6, 2011 Meeting Minutes**
**Motion by:** Mr. Barnes and seconded by Mr. Ayotte to approve the minutes. Motion Carried.

**Tab 2: Returns:**
Mr. Cacciatore stated that he added this to the agenda for review and to reintroduce the language for the return rule and asked the department to move forward with noticing the rule for development.

Mr. Dix stated when this was discussed before language was presented allowing returns for the chain pharmacies to return to the chain pharmacy warehouses without any time limit because it was within their own system and control. They also received the drugs with direct purchase pedigree so there was no way to create a full pedigree if they need to be redistributed.

Mr. Dix stated the rule has language regarding "a shipment" being returned he suggested that the department may want to add different language because you may not want to return a whole shipment.

Mr. Ayotte asked could we do a rule to define shipment.

Mr. Dixon stated he can research this and come back with language for the council to review.

**Motion by**: Mr. Barnes recommended the department begin rule making for 61N-1. 012(3) (f) Returns, seconded by Mr. Brock motion carried.

**Tab 3: Federal Pedigree Legislation**

Mr. Cacciatore stated this is a standing item on the agenda to monitor the federal legislation.

Mr. Ayotte stated there is a tremendous amount of work going on with this. After the recent notification on the counterfeit Avastin, the cancer drug there will be a more strong and robust movement for this legislation.

Mr. Cacciatore stated perhaps by the next meeting a bill will be introduced for the council to review.

**Tab 4: Executive Director's report**

Mr. Dixon introduced the DDC attorneys Kathryn Price and Bart Moore to the Council.

Mr. Dixon gave and update to the council on follow up issues from the stakeholder list:

a. Trade secret data
b. List of wholesaler licensees
c. Blood Establishment
d. Bond Requirement
e. Compounding
f. Pedigree Authentication
g. Common Control

Mr. Dixon provided the council with an update to the legislative session.

**Senate Bill 1006**

The proposed bill creates a license by endorsement, which would only be issued if the applicant demonstrated compliance with the "requirements of this chapter and holds a valid drug wholesale distribution license or permit from another state." The effective date of the bill is July 1, 2012. There is a companion bill for this House Bill 751 that has more language. The department will continue to follow this through the legislative process.

**House Bill 751**

The proposed bill amends Chapter 499, Florida Statutes modifying existing restrictions on the limited distribution of active pharmaceutical ingredients to Florida to licensed prescription drug manufacturers, and restrictions on prescription drug distributions to licensed prescription drug manufacturers and researchers. The proposed bill revises certain definitions and organizes the various exceptions to licensure in Chapter 499, Florida Statutes into a single subsection.

One of the amendments was if a wholesaler has out sourced the receipts of payments to a payment center. The department made suggestions to the language for distribution to include a payment center under that license.

Mr. Kahan stated in the discussion of API back in 2010 there was discussion regarding research and development use of API and the amount or quantity that could be purchased.

Mr. Dixon stated it does not resolve the amount issue but it does open up the sources of where the API could be obtained.

Mr. Kahan inquired if anything was being done now to address this?

Mr. Dixon stated to his knowledge nothing but the department could do research and bring it back to the next meeting.

**House Bill 475**

The bill exempts certain blood establishments from requirements to be permitted as a prescription drug manufacturer and to register products and authorizes DBPR to adopt rules regarding distribution of prescription drugs by blood establishments.

Mr. Cacciatore asked if this bill passes will the Department have to develop a list of approved drugs that they can distribute under this permit.

Mr. Dixon stated that is correct.

**Rules Report:**

Mr. Dixon advised the council that the DDC rules have been transferred to the department. Mr. Dixon suggested to the council that we start fresh for any rule changes the council suggests from this point forward.

The council agreed.

Mr. Dixon stated the DDC rules formerly under 64F-12 have now been transferred to 61N-1. The Department of State was accommodating with letting the department keep the actual rule numbers.

**Process Improvements**

Mr. Dixon stated that the program office wanted to share the goals and objectives for the year with the council. Two major goals for this year for DDC are to: 1.) Increase program efficiency and 2.) Improve program effectiveness.

These goals will be met by employee training, risk based inspections, balancing the territory inspection maps and performance measures.

Mr. Dixon stated we are testing risk based inspections in the field now. What this means is the low risk licenses where you there less likely to be diversion of drugs are inspected less frequently and the higher risk facilities are inspected on a more frequent basis. There has been some positive feedback from the industry.

Mr. Dixon stated in regards to the Controlled Substance Reporting there is a letter in your agenda packet for you to review and approve that will be mailed to the industry.

Mr. Ellis asked if the letter had been mailed yet.

Mr. Dixon stated it had not been mailed because the office wanted to let the council review it before being mailed.

Mr. Cacciatore stated he wanted to thank Mr. Dixon for all his efforts and that he thinks this is a good approach with the risk based inspections.

**Senate Bill 1316**

Mr. Dixon stated this bill changes the way inventory is kept for the 340B program. Florida is the only state that requires physical separation of 340B program drugs. This will remove that separate inventory requirement.

Mr. Barnes asked for clarification on a "bill to ship to" arrangement Where a hospital is buying the product (under 340B pricing) and having the inventory replaced at a contract pharmacy that is not on premises of the hospital. When that occurs since the hospital is the title holder of drugs,. is there a pedigree involved in that transaction to the contracted pharmacy?

Mr. Dixon stated he could not answer that question at this time.

Mr. Dixon stated a lot of the issues brought to our attention were the facilities had to order the drug then wait for the drug to come in before you could ship that drug out. You could go ahead and send it out without having to wait. When the legislative bill was reviewed the department did not have any concerns with it.

Mr. Dix stated it is listed under the definition of exemption of wholesale distribution so there is no pedigree requirement.

**Tab 5 Controlled Substance Reporting**

Ms. Grosh provided an update to the council on the controlled substance reporting.

Ms. Grosh reported that this quarter the department wants to start the data entry screen for the smaller companies that only report a small amount of items or have nothing to report. This summer the department is hoping to have the FTP site ready for submitting reports.

Mr. Cacciatore stated he has a question in regard to the industry compliance letter. If a wholesaler does not have a DEA registration number are they required to report?

Mr. Ellis stated according to the letter you have to meet both of those requirements. If you don't meet both then you don't have to report.

Mr. Rodney Bias with PSS World Medical stated he interrupted it the same way. If you have prescription drug wholesale distributor permit you had to report. All of our locations but one don't have DEA license. If the letter is correct it would mean the one location with a DEA license would have to report.

Mr. Dixon stated we are conducting some research on this because there have been some controlled substances in Florida that are not controlled substances by DEA.

Mr. Cacciatore stated I have one more question on corrections. The way corrections are handled for Florida reporting is different then ARCOS is there a reason for that?

Ms. Grosh stated you have to report more information to us then ARCOS, that's why we had to come up with our own correction number independent of ARCOS.

**Tab 6 Other Business**

Mr. Barnes gave a presentation on repackaged products as found in the meeting materials and asked the council to re-review the material and have discussion.

Mr. Dixon asked Mr. Barnes if he is looking for a solution for the hospital to purchase from the wholesaler verses the manufacturer.

Mr. Barnes stated that is correct.

Mr. Dixon stated he is conducting some research on repackaging so he can look into this and bring it back to the council.

Ms. Cacciatore asked if there was any other business.

**Audience Comments:**

Ms. Veronica Clifford presented language to the council in regards to 61N-1.105 Licensing, Application, Permitting.

(11) PERMIT RENEWALS FOR PRESCRIPTION DRUG WHOLESALER, PRESCRIPTION DRUG WHOLESALER – BROKER ONLY, OR OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER.

(a) The program will mail an application for renewal of the prescription drug wholesaler, prescription drug wholesaler – broker only, or out-of-state prescription drug wholesaler permit at least 90 days prior to the expiration date of the permit.

(b) A renewal application that is postmarked within 45 days prior to the expiration date of the permit must include submission of a $100 delinquent fee in addition to the annual permit fee, fingerprint fees, and bond.

(c) File with the department a completed application for a permit using an original Form DH 2124, "Prescription Drug Wholesaler/Out-of-State Prescription Drug Wholesaler Application" effective January 2004.

(d) File with the department an original Form DH 2125, "Personal Information Statement" effective January 2004, for the applicant's manager, next four highest ranking employees that are responsible for prescription drug operations, and all affiliated parties. In the event that there has been no change in any of the items or responses to questions from the Personal Information Statement together with an original affidavit attached thereto which incorporates the Personal Information Statement by reference and states that the information contained therein continues to be true and correct.

Mr. Cacciatore thanked Ms. Clifford for the language and asked if the department had the authority to make the change.

Mr. Dixon stated if the council will vote on this recommendation we can asked the attorneys for an opinion.

**Motion by:** Mr. Cacciatore asked that the language be presented to the department attorneys for review and provide feedback to the council, seconded by Mr. Mahoney. Motion Carried

Ms. Shannon Salimoney with Holland & Knight asked the council to provide some clarification. There are a number of licenses that are available to in-state wholesalers or other types of drug distributors and not a corresponding out of state license. Is there some general policy decision behind that and has the council made any sort of policy recommendation with respect to why there is such a distinction to some of the licensure categories?

Mr. Dixon indicated that he could not speak for the council, but that some of the concern probably pertained to the department's authority to do inspections of licensees that did not reside in this state.

Mr. Cacciatore stated he doesn't recall the Council has having that discussion for a statute change.

Mr. Steve Miller with Air Liquide asked if this would be the forum that his company would use to bring issues to regarding medical gases and any changes regarding rules.

Mr. Dixon indicated that the department would meet with anyone who has any issues or suggested changes to rules.

Mr. Cacciatore asked if there was any further discussion or business.

Meeting adjourned 11:40 a.m.