Drug Wholesale Distributor Advisory Council Meeting
December 5, 2013
Draft Meeting Minutes

9:00 a.m. Call to Order by Gary Cacciatore, Chair

Roll Call taken by Dinah Greene.

The following council members were present:
Mr. Cacciatore, Mr. Barnes, Mr. Ayotte, Mr. Ellis, Mr. Brock, Mr. Mahoney, Mr. Barnes, Mr. Garcia, Dr. Mendez, Ms. Ungru.

Mr. Cacciatore welcomed Dr. Mendez to the council representing the physician member.

A quorum was present:

Tab 1: Approval of August 15, 2013 Meeting Minutes

Motion by: Mr. Brock to approve the minutes, seconded by Mr. Barnes.
Motion Carried.

Tab 2: Chair's Report- Mr. Gary Cacciatore

1. Federal Pedigree –

Mr. Cacciatore informed the council that the Federal legislation Drug Quality and Security Act has passed.

Mr. Cacciatore stated he would like to open the floor to the council members for comments or questions regarding the legislation.

Mr. Ayotte stated the bill has a federal pre-emption and my concern is we need to await the department's review of the legislation. I don't think anyone has done that research yet to see if there is a need for legislation to repair or fix the statutes or rules.

Mr. Cacciatore stated timing is going to be crucial for this federal legislation.

Mr. Barnes stated he would like to know how soon the department will have the review completed.

Mr. Cacciatore stated he would like to provided and overview of the legislation.

- **Serialization**: Beginning 4 years from enactment, manufacturers shall serialize each package and homogeneous case of prescription drug product distributed within the United States. Wholesale distributors may not accept product unless it has been serialized starting in 6 years, dispensers starting 7 yrs. from enactment.
- **Lot traceability**: Beginning Jan 1, 2015 (manufacturers) through July 2015 (dispensers), prior to or at the same time as product changes ownership, companies need to provide or receive transaction information, history and statements for products in a single document (paper or electronic), Beginning 4 years from enactment, this information needs to be exchanged electronically.
- **Item-level track and trace**: Beginning 10 years from enactment, transaction information and statements shall be exchanged starting at point of manufacture, in a secure, interoperable electronic manner, for all products at the unit level including the standardized numerical identifier.
- **Verification**: Beginning Jan 1, 2015, manufacturers shall have systems in place to verify potentially illegitimate product, including validation of applicable transaction histories and information.
- **Requests for Information**: Manufacturers shall provide transaction information, history and statements for potentially suspect or illegitimate product that is subject to an investigation or recall initiated by a Federal or State official not later than 1 business day or 48 hours total elapsed time after receiving the request.
- There are specific nuances or exemptions that affect companies in different ways depending on segment, product, etc.

Mr. Cacciatore stated the federal law is modeled after the Florida law and very similar. It will still require transaction data, transaction history and transaction statement. This is similar to the Florida pedigree.

Dr. Mendez asked if this is for legend drugs, veterinary drugs or controlled substances.

Mr. Cacciatore stated it is for human drugs and all prescription drugs not just controlled substances. There are exemptions for specific products and they are listed in the legislation.

Mr. Cacciatore stated he would like for Mr. Dixon to provide some feedback on behalf of the Department.

Mr. Dixon stated the department has all resources reviewing the legislation.

Mr. Dixon stated on a policy perspective we should with-in a short time period be able to determine what previsions of Chapter 499 will be affected. How we as an agency will implement those changes. What training we would have to provide to the inspectors.

Mr. Cacciatore asked Mr. Dixon if it would be possible for the Department to publish some informal guidance on the legislation for the industry.

Dr. Mendez asked Mr. Dixon if any research had been done on what other states are doing for implementing this new legislation.

Mr. Dixon stated the department has been doing some research on having some informal industry training. Perhaps schedule another council meeting to discuss the legislation.

Mr. Cacciatore suggested that Mr. Dixon request a special meeting of the council once the review was complete.

Mr. Cacciatore stated if there are no further comments we will move on to Tab 3.

TAB 3: Executive Director Report- Reginald Dixon

1. Rules Report

Mr. Dixon provided a briefing on the rules report.

61N-1.001 Definitions (limited quantities) – Rule withdrawn –
Re-noticed for development
61N-1.012 Records – Rule withdrawn – Re-noticed for development
61N-1.013 Storage – Rule withdrawn- Re-noticed for development
61N-1.018 Fees – Notice for development – Noticed for rulemaking
61N-1.023 Drug Distributor permits – Notice for development – Notice for rulemaking
No action was taken

Mr. Cacciatore asked if the council can be notified when the department withdraws or notices a rule.

Mr. Dixon stated the department will make note of that.

2. Medical Marijuana
   Informational purposes only. No action was taken.

TAB 4: Other Business

1. Finalized 2014 Meeting Dates

   There was a conflict with the February meeting date. New proposed dates will be discussed.

Motion by Mr. Ellis to adjourn, seconded by Mr. Garcia. Meeting was adjourned.