

DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL

February 27, 2014
9:00 a.m.

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

The following members were present: Mike Ayotte, Steve Mays, Scott Brock, Jenn Ungru, Dean Ellis, Bill Mahoney, Patrick Barnes, and Michelle Mendez

Mr. Gary Cacciatore and Albert Garcia were available by phone.
A quorum was present.

Introduction: Mr. Cacciatore introduced the new council member Steve Mays, Prescription Drug Wholesale member.

Mr. Dixon presented a plaque to Mr. Joe Brecko the retiring member from the council.

Mr. Brecko thanked the council for their leadership over the years. It was my pleasure to serve on the council and work with a very diverse group of people.

TAB 1: Approval of December 5, 2013 Meeting Minutes

Mr. Barnes stated his name was listed twice on the members present.

Motion by: Mr. Ellis to approve the minutes, Seconded by: Mr. Brecko.
Motion Carried

TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD

Mr. Cacciatore stated he would like to defer the time to Mr. Dixon and focus on the Drug Quality and Security Act.

TAB 3: Executive Director's Report – Reginald Dixon

1. Rules Report:
 - a. Mr. Dixon gave a briefing on the rules report.
 - b. Mr. Dixon provided a status update on the Department.
 - c. Mr. Dixon provided a briefing on some proposed legislation for medical gas and medical marijuana.

No action was needed on these items.

2. Drug Quality and Security Act

Mr. Dixon stated he needed to make some disclaimer comments before we start this discussion.

Chapter 120 deals with rule making and any statement of general applicability something that applies to a section of people that would be applicable to them have to be done in rule making.

Any statements made today that fit that category we will need to do rule making, final orders, declaratory statements or petition for variance and waiver. The discussions we have today will be informational purposes only.

The purpose of this was to set national standards. We know what the intent of the federal law was and we know what 499 says and now we have to make sure we are not requiring anything more than what the DQSA has.

Track and Trace – To the extent that the federal law requires you right now to provide information to those people in your distribution stream regarding tracing your products. Florida will not require you to do anything more than you are already required to do.

Florida's pedigree requirements are really high. As we back away from enforcing those pedigree requirements we expect companies to comply with the federal requirements that are already in place.

Mr. Ellis stated he would like to clarify this because it is huge impact for secondary wholesaler. As it relates to pedigrees and where that pedigree begins can you comment on that?

Mr. Dixon stated what we are encouraging industry to do is file a petition for declaratory statement. The department will meet with you and discuss your business model and come up with a solution.

If there are other businesses with similarly aligned business models the answer to the question will help them.

This would be published on the website and other people in the industry could view it and

Mr. Cacciatore stated the ultimate goal is to protect the public. I think this is a move in the right direction. It's just getting through the transition period.

Motion By: Mr. Ellis that the council recommends that the Department do whatever is necessary to ensure a bill amending Chapter 499 to be consistent with Drug Quality Security Act and the federal law that has passed. Seconded by Mr. Ayotte. Motion carried.

Steve Fishbach- Safecor – Does the agency view those broad definitions of wholesale distribution and exclusions of wholesale distribution as part of the track and tracing pre-emption given that of the requirements of tracking and tracking of products.

Mr. Dixon stated to the extent of DQSA and the federal allows certain transactions to occur which may not have been previously allowed. We are not going to interpret 499 to prohibit those transactions.

TAB 4: Compounding / Outsourcing Facility – Albert Garcia, R. Ph., MHL

Mr. Garcia provided an update to the council on the Florida Board of Pharmacy. The Board performed a survey on the compounding pharmacies in the state.

11% of pharmacies were doing some sort of compounding

68% of them were in Florida

32% were non resident

We created a rule 64B-28.800 Requiring all pharmacy permit that were compounding to get this permit.

We have held several workshops and incorporated a lot of the guidelines of USP 797.

Outsourcing facility I think we have some of the same concern as DBPR. We will have to add language to rule for office use compounding. It is important whether it is outsourcing or non-resident that it be compliant with 797.

Dr. Mendez asked if the Board of Pharmacy has gotten any feedback from the Board of Osteopathic or medicine in regards to office use compounding.

Mr. Garcia said there has been some input but the board would like to have much more if possible.

TAB 5: Other Business

Correspondence

1. Product Registration – Scott Harkins- Unit Dose Services

Mr. Dixon stated that Mr. Harkins provided a letter to the department and wanted to bring it to the council.

Mr. Harkins summarized his letter and concern to the council in regards to product registration.

In the case of providing “service only”; we are not taking ownership of the medication, we would request to be exempt from the product registration

process and fees, as we are technically only selling a “packaging service.” I copied Florida law below relating to the topic.

Mr. Dixon stated we have to look at alternatives from an agency perspective. Part of the problem the law is designed with is the thought that a repackager purchases. To the extent that you’re not purchasing but you’re providing a service. We have to figure out a way to adapt to a new business model and it maybe we need to change some of the rules.

Motion: Mr. Cacciatore that we explore and come up or create opportunities for this business model.

Seconded by Mr. Barnes. Motion carried.

Motion to adjourn. Motion by Mr. Ellis and seconded Mr. Ayotte.