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: May 16, 2013, 9:30 a.m.

PLACE: Conference call number (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 32399-1047 or (850)717-1800.

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 32399-1047 or (850)717-1800. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, (800)955-8771 (TDD) or (800)955-8770 (Voice).

For more information, you may contact: Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047 or (850)717-1800.

AGENDA

Department of Business and Professional Regulations
DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL
Conference Call

May 16, 2013
9:30 a.m.

Conference Call Number 1-888-670-3525
Conference Code 925-988-7749

Council Members:

Gary Cacciatore, Pharm.D., J.D., Chair, Primary Prescription Drug Wholesalers
Mike Ayotte, Vice Chair, Retail Pharmacy
Albert Garcia, Board of Pharmacy
Joseph Brecko, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Jenn Ungru, Agency for Health Care Administration
Dean Ellis, Secondary Prescription Drug Wholesalers
William Mahoney, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Physician- Vacant

DBPR Staff:

Reggie Dixon, Executive Director,
Drugs, Devices and Cosmetics Program
Ken Lawson, Secretary
Mike Walker, Deputy Secretary
Robert Jernigan, Compliance Manager
Dinah Skrnich, Controlled Substance Reporting
Rebecca Burnett, Regulatory Supervisor
Amy Bennett, Office Manager

Call to Order and Introductions: Gary Cacciatore, Chair

TAB 1: Approval Meeting Minutes February 12, 2013

TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD
1. Federal Pedigree

TAB 3: Executive Director's Report – Reginald Dixon
1. Rules Report
2. Office Use Compounding Rule
3. Final Order Allegations
4. 2013 Legislative Update

TAB 4: Other Business

Drug Wholesale Distributor Advisory Council Meeting
February 12, 2013
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. Mahoney, Mr. Barnes, Mr. Brock, Ms. Ungru. Mr. Garcia was available by phone.

A quorum was present

Tab 1: Approval of August 16, 2012 Meeting Minutes

The minutes were approved after suggested corrections were made.

Motion by: Mr. Brecko and seconded by Mr. Brock to approve the minutes.
Motion Carried.

Tab 2: Chair's Report: Gary Cacciatore, Chair

Mr. Cacciatore gave a brief statement to the council in regards to Federal Pedigree. No action was taken.

Tab 3: Controlled Substance Reporting- Dinah Skrnich
Ms. Skrnich gave a brief report on the graph that was provided to the council in the agenda material.

Mr. Jernigan gave a brief statement for future plans with the controlled substance reporting and audits. No action was taken.

Tab 4: Executive Director's Report – Reginald Dixon

Mr. Dixon gave a brief report on the office and accomplishments in the past year.

- Risk based inspections to date 47 inspections have been completed.
- Meetings with industry – 43 different groups on licensing or disciplinary matters
- Compliance questions and emails between Rob and I we have handled 582 issues.
- Changes to applications will be on going process. No action was taken.

1. Language Borrow and Loan-

Mr. Dixon presented language to the council that was provided by Mike McQuone of Florida Society of Health System Pharmacist and Patrick Barnes for Borrow and Loan process. After discussion, No action was taken.

2. Cancer Drug Donation Program

Mr. Dixon provided an update on how many participants are now registered with the program and the department is strategizing on how to increase donor participation. No action was taken.

3. Rules

Mr. Dixon informed the council that 61N-1.012 Returns rule has been certified for adoption will become effective on March 4, 2013. No action was taken.

4. Meningitis

Mr. Dixon informed the council that there are letters included in the agenda material for informational purposes only. No action was taken.

5. CSR Auditing

Mr. Dixon informed the council the department wants to perform a 100% audit of the companies that are not reporting. The department has developed a form letter to be sent asking for certain information about distributions from companies. The program office is working with the enforcement team on developing discipline guidelines or penalty ranges that will be fair. No action was taken.

6. DDC 2013 Legislative Report

Mr. Dixon informed the council this was a legislative report the department was required to do by January 2013. No action was taken.

Mr. Cacciatore commented that the report was very well done and commends the department.

Mr. Cacciatore asked if the council could get a summary of the most common types of problems the inspectors seeing in the field and what type of disciplinary cases are being handled by the program office.

Mr. Dixon stated that the office would provide some information to the council.

TAB 5: Compounding Update- Albert Garcia- Chair - Board of Pharmacy
Mr. Garcia informed the council that the Board of Pharmacy approved and emergency rule requiring immediate notification, via survey, by pharmacies of their compounding activities and inspections. The survey was required to be completed by Dec. 11, 2012.

The committee discussed several options for the future some of the highlights included.

- Accrediting of compounding pharmacies by outside agency.
- All compounding pharmacies to complete an annual Continuing Education class.
- Inspectors to be trained on what to look for when inspecting these types of pharmacies.

There were other discussions this is just a quick highlight of things that were discussed. The committee will be meeting to discuss this further in the future.

TAB 6: HB 517 Communication – Patrick Barnes

Mr. Barnes presented the following to the council for HB 517.

1. Hospitals under common control are allowed to repackage drug products under HB517.
2. This includes repackaging bulk products to unit dose form. Examples are bulk tablets to unit dose and liquids to unit dose.
3. HB 517 allows a hospital to pick refills for automated dispensing cabinets and distribute them to other hospitals under common control.
4. The hospital that is repackaging or filling the automated dispensing refills must have a Restricted Prescription Drug Distributors permit.
5. A letter must be sent to the Department giving a 30 day notice of the start date.

Mr. Dixon stated he would like to have time to review it further before giving a response. Mr. Barnes stated that he would be fine with doing a conference call to discuss.

TAB 7: 2013 Meeting Dates

Motion by: Mr. Brecko to approve the 2013 meeting dates, second by Mr. Barnes.
Motion Carried

TAB 8: Other Business

Motion by: Mr. Brock to adjourn the meeting, second by Mr. Brecko.
Motion Carried.

Florida Department of Business & Professional Regulation

Division of Drugs, Devices and Cosmetics
1940 North Monroe Street
Tallahassee, Florida 32399-1047
Phone: 850. 717.1800
Fax: 850.414.8240

Ken Lawson, Secretary

Rick Scott, Governor

RULES REPORT

To: Drug Wholesale Distributor Advisory Council

From: Reginald D. Dixon, Director

Date: May 8, 2013

Re: Division Rulemaking (rev. 5/7/13)

The following chart is a summary of the Division's current rulemaking efforts.

Rule #	Title	Purpose	Current Action	Next two Actions
61N-1.001	General Regulations; Definitions	Clear up the definitions of certain terms, as well as to define "limited quantities" as used in ss. 499.01(3) & (4), F.S.	Language drafted	1. DBPR approval 2. OFARR approval
61N-1.012	Records of Drugs, Cosmetics and Devices	Set forth recordkeeping requirements for Florida manufacturers engaging in "limited quantities" of Rx drugs obtained from non-Florida licensed entities.	Language drafted	1. DBPR approval 2. OFARR approval
61N-1.013	Prescription Drugs; Receipt, Storage and Security.	Set forth Rx drug storage requirements for Florida manufacturers engaging in "limited quantities" of Rx drugs obtained from non-Florida licensed entities.	Language drafted	1. DBPR approval 2. OFARR approval
61N-1.015	Licensing, Application, Permitting	Rearrange the rule and to incorporate the new DDC application forms	Language is being drafted by staff.	1. Complete initial draft. 2. DBPR approval
61N-1.018	Fees	Specify fee for restricted Rx drug distributor – blood establishment permit; and for device product registration.	Language drafted	1. DBPR approval 2. OFARR approval
61N-1.023	Restricted Prescription Drug Distributor Permits; Special Provisions	Create/set forth the restricted Rx drug distributor permit; identify Rx drugs these permits can distribute per s. 499.01(2)(g)1.c., F.S.	Language is being drafted by staff.	1. Complete initial draft. 2. DBPR approval

64B16-27.700 Definition of Compounding.

"Compounding" is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent; and shall specifically include the professional act of preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S. The term also includes the preparation of nuclear pharmaceuticals and diagnostic kits incident to use of such nuclear pharmaceuticals. The term "commercially available products," as used in this section, means any medicinal product as defined by Sections 465.003(7) and (8), F.S., that are legally distributed in the State of Florida by a drug manufacturer or wholesaler.

(1) Compounding includes:

(a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.

(b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.

(c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.

(2) The preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding and is not within the practice of the profession of pharmacy, except that the supply of patient specific compounded prescriptions to another pharmacy under the provisions of Section 465.0265, F.S., and Rule 64B16-28.450, F.A.C., is authorized.

(3) Office use compounding, "Office use" means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy. A pharmacist may dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with this section provided:

(a) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration date of the drug;

(b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;

(c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

(d) The pharmacy and the practitioner enter into a written agreement. The agreement shall specifically provide:

1. That the compounded drug may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity;

2. That the practitioner shall include on the patient's chart, medication order, or medication administration record the lot number and the beyond-use-date of any compounded drug administered to the patient that was provided by the pharmacy;

3. That the practitioner will provide notification to the patient for the reporting of any adverse reaction or complaint in order to facilitate any recall of batches of compounded drugs.

(e) The pharmacy shall maintain readily retrievable records of all compounded drugs ordered by practitioners for office use. The records must be maintained for a minimum of four (4) years and shall include:

1. The name, address and phone number of the practitioner ordering the compounded drug for office use and the date of the order;

2. The name, strength, and quantity of the compounded drug provided, including the number of containers and quantity in each;

3. The date the drug was compounded;

4. The date the compounded drug was provided to the practitioner;

5. The lot number and beyond use date.

(f) The pharmacy shall affix a label to any compounded drug that is provided for office use. The label shall include:

1. The name, address, and phone number of the compounding pharmacy;

2. The name and strength of the preparation of a list of active ingredients and strengths;

3. The pharmacy's lot number and beyond-use-date;

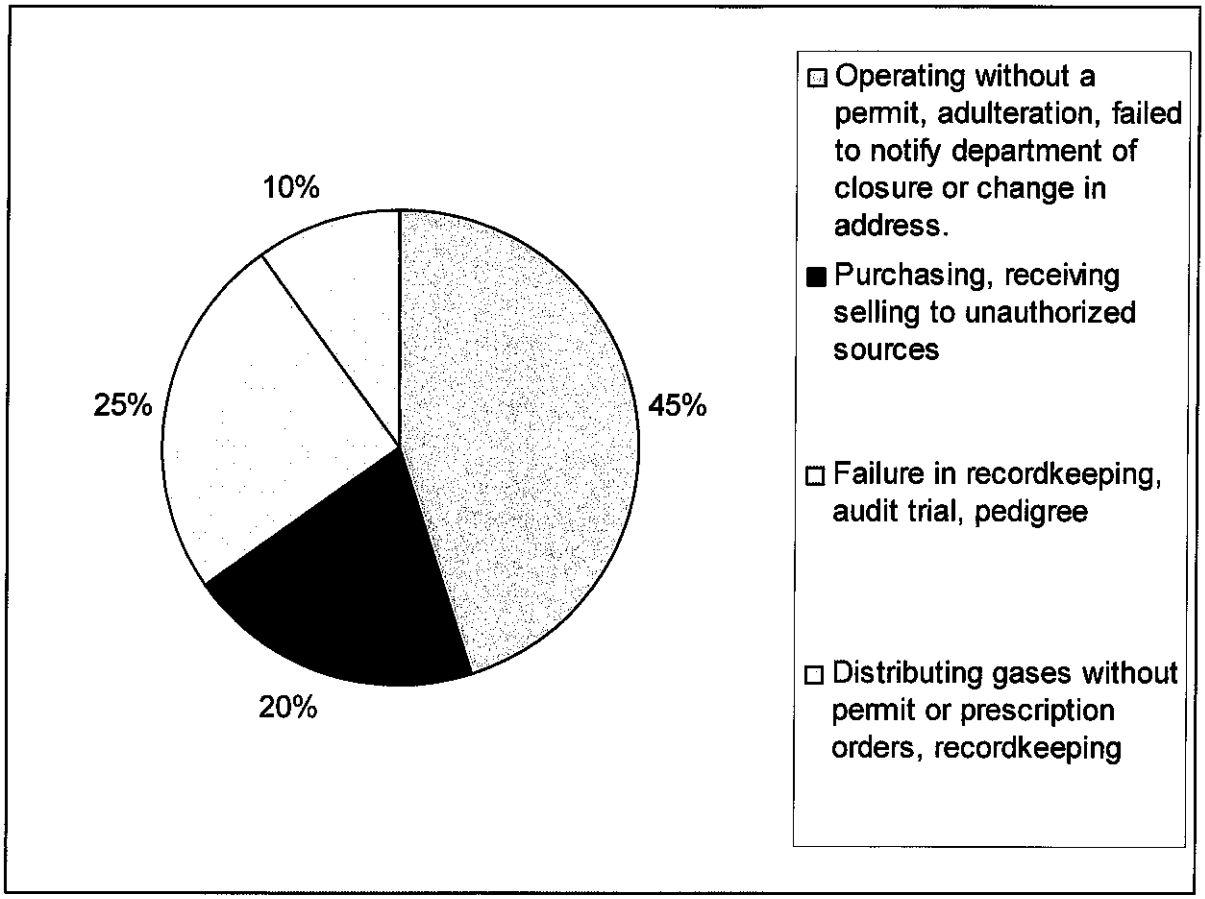
4. The quantity or amount in the container;

5. The appropriate ancillary instructions such as storage instructions, cautionary statements, or hazardous drug warning labels were appropriate; and

6. The statement "For Institutional or Office Use Only – Not for Resale," or if the drug is provided to a veterinarian the statement "Compounded Drug."

Rulemaking Authority 465.005 FS. Law Implemented 465.003(12), 465.0155, 465.0265 FS. History–New 10-1-92, Formerly 21S-27.700, 61F10-27.700, 59X-27.700, Amended 11-2-03, 10-7-08, 3-21-13.

DIVISION OF DRUGS, DEVICES AND COSMETICS
CASE ALLEGATIONS



DIVISION OF DRUGS, DEVICES AND COSMETICS
ALLEGATIONS BY PERMIT TYPE