

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

Conference Call Number 888-670-3525
Conference Code 9259887749

December 5, 2013
9:00 a.m.

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
Michelle Renae Mendez, DO, Physician

DBPR Staff:

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

Call to Order and Introductions: Gary Cacciatore, Chair

- TAB 1: Approval of Minutes –August 15, 2013 Meeting
- TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD
1. Federal Legislation – Discussion Only
- TAB 3: Executive Director's Report – Reginald Dixon
1. Rules Report
2. Medical Marijuana
- TAB 4: Other Business
1. Finalize 2014 Meeting Dates

Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Drugs, Devices and Cosmetics

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

DATE AND TIME: December 5, 2013, 9:00 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: The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047

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: The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, 850.717.1800. 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).

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.

**Draft Meeting Minutes
Department of Business and Professional Regulation
Drug Wholesale Distributor Advisory Council**

**August 15, 2013
9:30 a.m.**

The meeting was called to order by the Chair, Mr. Cacciatore.

Roll call taken by Dinah Greene:

The following members were present:

Mr. Cacciatore, Mr. Brecko, Mr. Ellis, Mr. Barnes, Ms. Ungru, Mr. Brock, Mr. Mahoney and Mr. Garcia.

Mr. Ayotte was absent.

Tab 1: Approval of Minutes

Motion by: Scott Brock to approve the May 16, 2013 meeting minutes. Seconded by Joe Brecko – Motion Carried

Tab 2: Chair's Report – Gary Cacciatore

1. Federal Legislation – Liz Gallenagh – Healthcare Distribution Management Association

Ms. Gallenagh provided a briefing on the federal legislation currently in process.

(For more information on this topic please visit the Division website for the audio recording.)
<http://www.myfloridalicense.com/dbpr/ddc/index.html>

Tab 3: Executive Director's Report – Mr. Reggie Dixon

1. Rules Report

Mr. Dixon provided an update on the rules report.

The rule was noticed and the department sent the proposed language to the industry asking for comments or concerns.

The department received two comments from the industry and they were included in your meeting material. The department will be working with those individuals for proposed language.

After further review and discussion from the council no action was taken.

2. Senate Bill 284 – School Emergencies

This bill allows both public and private schools to purchase epinephrine.

The department has been working with the Department of Education and Department of Health how to implement this language.

Mr. Dixon stated each school is assigned a unique number from the Department of Education. The wholesaler will be able to use that number in place of a Florida license number. This will only be for the purchase of epinephrine. No other drugs should be ordered.

3. Senate Bill 50 – Public Meetings

This was put on the agenda for informational purposes only.

4. Office Update

Mr. Dixon gave a briefing on the board office and some of the things for the future.

- Applications available with the on line portal for submission
- Had some suggestions from industry on the personal information statement
- Legislative suggestions have been reviewed and considered

Mr. Dixon stated that the Department is looking to make some enhancements to the Controlled Substance Reporting system in the future.

Tab 4: Other Business`

Mr. Cacciatore asked the council members to review the proposed meeting dates for the 2014 calendar. The council will vote on these dates on the December conference call.

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

Motion by: Mr. Brock to adjourn the meeting, seconded by Mr. Mahoney. Meeting adjourned.

Ken Lawson, Secretary

Rick Scott, Governor

RULES REPORT

To: Drug Wholesale Distributor Advisory Council

From: Reginald D. Dixon, Director

Date: November 25, 2013

Re: Division Rulemaking (rev. 11/25/13)

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

Rule #	Title	Purpose	Current Action	Next Action
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.	Rule withdrawn	Re-notice for Development
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.	Rule withdrawn	Re-notice for Development
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.	Rule withdrawn	Re-notice for Development
61N-1.015	Licensing, Application, Permitting	Rearrange the rule and to incorporate the new DDC application forms	Language is being drafted by staff.	Notice of Development
61N-1.018	Fees	Specify fee for restricted Rx drug distributor – blood establishment permit; and for device product registration.	Notice of Development filed	Notice of Rulemaking
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.	Notice of Development filed	Notice of Rulemaking

CONSTITUTIONAL AMENDMENT PETITION FORM

Note:

- All information on this form, including your signature, becomes a public record upon receipt by the Supervisor of Elections.
- Under Florida law, it is a first degree misdemeanor, punishable as provided in s. 775.082 or s. 775.083, Florida Statutes, to knowingly sign more than one petition for a candidate, a minor political party, or an issue. [Section 104.185, Florida Statutes]
- If all requested information on this form is not completed, the form will not be valid.

Your name _____

Please print name as it appears on your Voter Information Card

Your residential street address _____

City _____ Zip _____ County _____

Voter Registration Number _____ OR Date of Birth _____

I am a registered voter of Florida and hereby petition the Secretary of State to place the following proposed amendment to the Florida Constitution on the ballot in the general election:

BALLOT TITLE: Use of Marijuana for Certain Medical Conditions

BALLOT SUMMARY: Allows the medical use of marijuana for individuals with debilitating diseases as determined by a licensed Florida physician. Allows caregivers to assist patients' medical use of marijuana. The Department of Health shall register and regulate centers that produce and distribute marijuana for medical purposes and shall issue identification cards to patients and caregivers. Applies only to Florida law. Does not authorize violations of federal law or any non-medical use, possession or production of marijuana.

ARTICLE AND SECTION BEING AMENDED OR CREATED: Article X, Section 29

Full text of proposed constitutional amendment is as follows:

ARTICLE X, SECTION 29. Medical marijuana production, possession and use.—

(a) PUBLIC POLICY.

(1) The medical use of marijuana by a qualifying patient or personal caregiver is not subject to criminal or civil liability or sanctions under Florida law except as provided in this section.

(2) A physician licensed in Florida shall not be subject to criminal or civil liability or sanctions under Florida law for issuing a physician certification to a person diagnosed with a debilitating medical condition in a manner consistent with this section.

(3) Actions and conduct by a medical marijuana treatment center registered with the Department, or its employees, as permitted by this section and in compliance with Department regulations, shall not be subject to criminal or civil liability or sanctions under Florida law except as provided in this section.

(b) DEFINITIONS. For purposes of this section, the following words and terms shall have the following meanings:

(1) "Debilitating Medical Condition" means cancer, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), hepatitis C, amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, multiple sclerosis or other conditions for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient.

(2) "Department" means the Department of Health or its successor agency.

(3) "Identification card" means a document issued by the Department that identifies a person who has a physician certification or a personal caregiver who is at least twenty-one (21) years old and has agreed to assist with a qualifying patient's medical use of marijuana.

(4) "Marijuana" has the meaning given cannabis in Section 893.02(3), Florida Statutes (2013).

(5) "Medical Marijuana Treatment Center" means an entity that acquires, cultivates, possesses, processes (including development of related products such as food, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to qualifying patients or their personal caregivers and is registered by the Department.

(6) "Medical use" means the acquisition, possession, use, delivery, transfer, or administration of marijuana or related supplies by a qualifying patient or personal caregiver for use by a qualifying patient for the treatment of a debilitating medical condition.

(7) "Personal caregiver" means a person who is at least twenty-one (21) years old who has agreed to assist with a qualifying patient's medical use of marijuana and has a caregiver identification card issued by the Department. A personal caregiver may assist no more than five (5) qualifying patients at one time. An employee of a hospice provider, nursing, or medical facility may serve as a personal caregiver to more than five (5) qualifying patients as permitted by the Department. Personal caregivers are prohibited from consuming marijuana obtained for the personal, medical use by the qualifying patient.

(8) "Physician" means a physician who is licensed in Florida.

(Continues on next page)

(9) "Physician certification" means a written document signed by a physician, stating that in the physician's professional opinion, the patient suffers from a debilitating medical condition, that the potential benefits of the medical use of marijuana would likely outweigh the health risks for the patient, and for how long the physician recommends the medical use of marijuana for the patient. A physician certification may only be provided after the physician has conducted a physical examination of the patient and a full assessment of the patient's medical history.

(10) "Qualifying patient" means a person who has been diagnosed to have a debilitating medical condition, who has a physician certification and a valid qualifying patient identification card. If the Department does not begin issuing identification cards within nine (9) months after the effective date of this section, then a valid physician certification will serve as a patient identification card in order to allow a person to become a "qualifying patient" until the Department begins issuing identification cards.

(c) LIMITATIONS.

- (1) Nothing in this section shall affect laws relating to non-medical use, possession, production or sale of marijuana.
- (2) Nothing in this section authorizes the use of medical marijuana by anyone other than a qualifying patient.
- (3) Nothing in this section allows the operation of a motor vehicle, boat, or aircraft while under the influence of marijuana.
- (4) Nothing in this law section requires the violation of federal law or purports to give immunity under federal law.
- (5) Nothing in this section shall require any accommodation of any on-site medical use of marijuana in any place of education or employment, or of smoking medical marijuana in any public place.
- (6) Nothing in this section shall require any health insurance provider or any government agency or authority to reimburse any person for expenses related to the medical use of marijuana.

(d) DUTIES OF THE DEPARTMENT. The Department shall issue reasonable regulations necessary for the implementation and enforcement of this section. The purpose of the regulations is to ensure the availability and safe use of medical marijuana by qualifying patients. ~~It is the duty of the Department to promulgate regulations in a timely fashion.~~

(1) Implementing Regulations. In order to allow the Department sufficient time after passage of this section, the following regulations shall be promulgated no later than six (6) months after the effective date of this section:

- a. Procedures for the issuance of qualifying patient identification cards to people with physician certifications, and standards for the renewal of such identification cards.
- b. Procedures for the issuance of personal caregiver identification cards to persons qualified to assist with a qualifying patient's medical use of marijuana, and standards for the renewal of such identification cards.
- c. Procedures for the registration of Medical Marijuana Treatment Centers that include procedures for the issuance, renewal, suspension, and revocation of registration, and standards to ensure security, record keeping, testing, labeling, inspection, and safety.
- d. A regulation that defines the amount of marijuana that could reasonably be presumed to be an adequate supply for qualifying patients' medical use, based on the best available evidence. This presumption as to quantity may be overcome with evidence of a particular qualifying patient's appropriate medical use.

(2) Issuance of identification cards and registrations. The Department shall begin issuing qualifying patient and personal caregiver identification cards, as well as begin registering Medical Marijuana Treatment Centers no later than nine months (9) after the effective date of this section.

(3) If the Department does not issue regulations, or if the Department does not begin issuing identification cards and registering Medical Marijuana Treatment Centers within the time limits set in this section, any Florida citizen shall have standing to seek judicial relief to compel compliance with the Department's constitutional duties.

(4) The Department shall protect the confidentiality of all qualifying patients. All records containing the identity of qualifying patients shall be confidential and kept from public disclosure other than for valid medical or law enforcement purposes.

(e) LEGISLATION. Nothing in this section shall limit the legislature from enacting laws consistent with this provision.

(f) SEVERABILITY. The provisions of this section are severable and if any clause, sentence, paragraph or section of this measure, or an application thereof, is adjudged invalid by any court of competent jurisdiction other provisions shall continue to be in effect to the fullest extent possible.

DATE OF SIGNATURE

X

SIGNATURE OF REGISTERED VOTER

Include below the name and address of paid petition circulator if one was used to obtain signature (Section 106.19(3), F.S.)

Name of paid circulator (if applicable)

Address

RETURN TO:

People United for Medical Marijuana
Post Office Box 560296
Orlando, FL 32856

For official use only: Serial number 13-02
Date approved 7/10/2013

Proposed 2014 Council Meeting Dates

February 20, 2014- Face to Face

May 15, 2014- Conference Call

August 14, 2014 Face to Face

December 11, 2014- Conference Call