CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE
DEPARTMENT OF STATE
DIVISION OF PROFESSIONAL REGULATION

TELEPHONE: (302) 744-4500
FAX: (302) 739-2711
WEBSITE: WWW.DPR.DELAWARE.GOV

PUBLIC MEETING NOTICE:	**CONTROLLED SUBSTANCE COMMITTEE**
DATE AND TIME:	**Wednesday, May 25, at 9:00 a.m.**
PLACE:	**Buena Vista, Second Floor Conference Room, 661 S. DuPont Highway, New Castle, Delaware 19720**
APPROVED:	August 24, 2011

MEMBERS PRESENT

Howard Simon, R.Ph, Pharmacy Representative, Chair
Mark Hanna, Public Representative
Bonnie Wallner, R.Ph., Pharmacy Representative
Philip Kim, M.D., Medical Representative
Luis Garcia, Jr., DPM, Podiatric Representative, Vice President
David W. Dryden, R.Ph., J.D., Director Office of Controlled Substances

MEMBERS ABSENT

Michael Kremer, DMD, Dental Representative, President
Robert Flanagan, DVM, Vet Representative
Ann Dominick, APN, Nursing Representative
Stephen Ruggles, PA-C, PA Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

Patricia Davis-Oliva, Deputy Attorney General
Judy Letterman, Administrative Specialist III

ALSO PRESENT

Jean Chiquoine
Cheryl Heiks
Debbie Hamilton
Geoffrey Christ

CALL TO ORDER

Mr. Simon chaired in Dr. Kremer's absence and called the meeting to order at 9:00am.

REVIEW AND APPROVAL OF MINUTES

A motion was made by Mr. Kim, seconded by Mr. Garcia, to accept the minutes as presented. The motion was unanimously carried.

PRESIDENT'S REPORT

No report.

UNFINISHED BUSINESS

Controlled Substance Regulation Hearing

The hearing for the proposed amendments to the Controlled Substance Regulations was held beginning at 9:40 AM.

- The Committee determined that the security inclusion requirements as amended above would be enforced for new and remodeled pharmacies. These standards would similarly be enforced when diversion for a particular established pharmacy warrants these inclusions.
- The Committee agreed that identification should be obtained at the time of controlled substance prescription pick up.
- The Committee agreed with the inspectional changes and the drive through window amendments.

A motion was made by Ms. Wallner, seconded by Dr. Kim, to accept the amendments as proposed. The motion was unanimously carried.

NEW BUSINESS

Registrant Application Reviews

There were no applications to review.

DIRECTOR'S REPORT

Case/Diversion Review

Mr. Dryden reviewed the controlled substance panel consent order of Alan Seltzer issued May 31, 2011.

Prescription Monitoring Program (PMP) Review

Mr. Dryden reported that the RFP for the bidding of PMP vendors was posted. The vendors interested had met for a question and answer session. The pharmacist position was posted and interviews were being scheduled.

National Disposal

Mr. Dryden reported that the national drug disposal event that was scheduled on April 30, 2011 from 10am to 2pm was a success.

Notice of Inspection Form

Mr. Dryden reported that the "Notice of Inspection" form utilized by OCS has been used during inspections.

Controlled Substance e-Prescribing

Although e-prescribing of controlled substances has been approved, federal Drug Enforcement Administration (DEA) authorities do not expect practitioners and pharmacies to be able to use

controlled substance e-prescriptions until the summer of 2011 because policies, procedures and software are being developed. As we receive further federal updates on e-prescribing controlled substances, we will post the information on the website.

Current Event Review

Mr. Dryden provided a handout of the following topics of current events:

- *Stakeholders Share Information About Fighting Internet Drug Outlets at Senate Committee Hearing*
- *FDA Requests Unapproved Drugs to be Seized from Manufacturer by US Marshals*
- *DEA Emergency Scheduling of Synthetic Cannabinoids*
- *PMP Interconnect*
- *FDA Releases Draft Guidance for Industry Regarding Medication Guides*
- *FDA Takes Action Against Unapproved Prescription Cough, Cold, and Allergy Products*
- *NASCSA Forum Site*
- *FDA prompts removal of unapproved drugs from market*
  FDA Advises US Consumers Regarding Potassium Iodide and Warns About Unapproved Products
- *Bill to Increase Penalties on Pill Mills Introduced to US House*
- *Opioids Now Most Prescribed Class of Medications in America*
- *NASCSA Breaking News - NASPER Funding Update*
- *New ONDCP Prescription Drug Abuse Plan*
- *Expired Product Use*
- *FDA warns companies to stop making MRSA claims for over-the-counter products*
- *Surgeon General Requests Input on Prescription Drug Abuse*
- *DEA Prescription Drug Take-Back Days Part of White House Plan to Fight Abuse*
- *White House Unveils Plan at reducing Prescription Drug Abuse*

COMMITTEE REPORTS

Medical Examiner's Report

No report.

DEA Report

No report.

Substance Abuse Report

No report.

Law Enforcement Report

No report.

Regulatory Committee Report

No report since regulatory amendments were already discussed.

Legislative Committee

Mr. Dryden reported that the Medical Marijuana Bill has passed and been signed into law by Governor Markell. The law requires that the Division of Public Health will be responsible. Mr.

Dryden asked whether the Office of Controlled Substances would be responsible for registering the distribution centers since this drug is considered a schedule I controlled substance. Ms. Davis-Oliva will review the associated laws regarding this issue.

INSPECTION REPORT

Mr. Dryden reported that the office has been very busy with controlled substance inspections. They are seeing registrant applications for facilities associated with Buphenorphine and Methadone for addiction.

COMMITTEE CORRESPONDENCE

No report.

OTHER BUSINESS BEFORE THE BOARD

No report.

PUBLIC COMMENT

There was no public comment.

EXECUTIVE SESSION

No executive session was needed.

NEXT SCHEDULED MEETING

The next meeting will be held on Wednesday, August 24, 2011 at 9:00 a.m.

ADJOURNMENT

A motion was made by Mr. Simon, seconded by Ms. Wallner, to adjourn the meeting. The motion unanimously carried. The meeting adjourned at 11:00 a.m.

Respectfully submitted,

David W. Dryden, R.Ph., J.D.