DC Board of Pharmacy and Pharmaceutical Control Update

Patricia M. D’Antonio, RPh, MS, MBA, CGP
Executive Director, Board of Pharmacy
Program Manager, Pharmaceutical Control

May 30, 2015
Organization

- Health Regulation Licensing Administration Board of Pharmacy

- Pharmacist - Authority to Immunize
- Pharmacist Detailers
- Pharmacist Intern
- Pharmacist Technicians (Bill Passed; regulation pending)
Board of Pharmacy

• The mission of Board of Pharmacy is to protect and improve the public health through the efficient and effective regulation of the practice of Pharmacy and Pharmaceutical Detailing; through the licensure of Pharmacist, Pharmaceutical Detailers and Pharmacy Interns.

Daphne Bernard, PharmD
Chairperson

5
Pharmacist
(1 Space Vacant)

2
Consumer
Pharmaceutical Control Division

- Conduct routine and complaint driven inspections of pharmacy operations of health facilities
- Investigate reports of contaminated or suspect drugs or improper distribution of controlled substances
- Investigate unusual or suspicious reports in drug supply or in the handling of the drug by the professional
Regulated Facilities Include:

- Pharmacies
- Animal Clinics
- Controlled Substance Registration for Professionals
- Research Training Institutions
- Wholesalers/Distribution
- Cultivation Centers
- Fire/EMS
- Medical Examiner
- Substance Abuse Treatment Programs
- Animal Clinics
- Dialysis Center
- Substance Abuse Treatment Programs
- Animal Clinics
Liaison Role

Food and Drug (FDA)

Drug Enforcement Administration

District Government

Consumer Protection Agency

Health and Human Services

And others involving regulatory control matters related to medications
Pharmacy Law and Regulations

DC Code Title 47, Section 2885.01 Pharmacy

Federal Law
Code of Federal Regulations (CFR) 21, Part 1
Section 1300 - Drugs

DC Code Title 48, Section 701-901
Pharmacy related laws
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Other Regulations of Interest

- Hospital
- Health Care and Community Residence
- Pharmacy
- Nursing Facilities
- Group Homes
Where can I find this?

- DC Municipal Regulations and DC Register
  www.dcregs.dc.gov
  – Subscribe
  – My favorites
- DC Board of Pharmacy webpage
  – http://doh.dc.gov/bop
- DC Pharmaceutical Control webpage
  – http://doh.dc.gov/pcd
What’s New?

- Collaborative Practice
- Pharmacy Technician
- Prescription Drug Monitoring Program
- Reporting Fraudulent Prescriptions
- Center for Rational Prescribing
Collaborative Practice

- Collaborative Care Expansion Amendment Act of 2012 passed in May 31, 2013
- Regulations pending from Board of Pharmacy and Board of Medicine
- Voluntary written agreement
- Between a licensed pharmacist and a licensed physician or another health practitioner with independent prescriptive authority
Collaborative Practice

- Defines the scope of practice between the licensed pharmacist and licensed physician, or other health practitioner,
  - Licensed by a District health occupation board

- Initiation, modification, or discontinuation of a drug therapy regimen
Collaborative Practice Agreements

- Establish policies and procedures for approving, disapproving, and revoking collaborative practice agreements.
Collaborative Practice Agreements

- Specification of the drug therapy to be provided and any tests that may be necessarily incident to its provision;
- Conditions for initiating, modifying, or discontinuing a drug therapy; and
- Directions concerning the monitoring of a drug therapy and the conditions that would warrant a modification
- Establish policies and procedures for approving, disapproving, and revoking collaborative practice agreements.
Pharmacy Technician

A high School Diploma or Equivalent

Or Has passes a board-Approved examination that proves competency

17 years of age

Pharmacy Technician Amendment Act Passed July 19, 2013
Technician Training Programs

(i) A national, regional, or state accredited pharmacy technician training program recognized by the Board;

(ii) A pharmacy technician program at a college or university that is accredited by an accrediting body recognized by the Secretary of the United States Department of Education or the Council on Postsecondary Accreditation.

(iii) An employer-based pharmacy technician training program recognized by the Board that includes within a one-year period a minimum of 160 hours of training, including theoretical and practical instruction; or

(iv) A pharmacy technician program that meets the guidelines of the American Society of Health-System Pharmacists, is licensed by the District of Columbia Educational Licensure Commission, and has certified to the Board its intent to pursue accreditation upon becoming eligible to do so.
Pharmacy Technician

• Grandfather Clause
• Defines the roles of ancillary personnel
• Addresses supervision responsibilities of a pharmacist
• Regulations pending Board of Pharmacy
  – Informal Comments June, 2014
  – Monitor communications and DC Register for Proposed Regulations
Pharmacy Technician

Define the role of ancillary personnel
Address supervision responsibilities of pharmacist
Regulations pending Board of Pharmacy
- Informal Comments June 2014
- Monitor communications and DC Register for Proposed Regulations

Grandfather Clause
Prescription Drug Monitoring Program

- Improve District’s ability to identify & combat prescription drug diversion
- Enhance patient care by assuring legitimate use of controlled substances
- Equips health care practitioners with an automated information system to verify controlled substance prescriptions
- Allows participating PMPs across the United States to be linked

www.doh.dc.gov
Prescription Drug Monitoring Program

- Stakeholder meeting on Draft Legislation
  - February 2012

- Legislation introduced in City Council
  - September 2012

- Committee on Health Hearing
  - July 2013

- Legislation passed
  - February 2014

- Draft regulations expected to be ready
  - Fall 2014

- Briefing at Board of Medicine Symposia on Use of ER/LA Opioids
  - September 2014

- PCD to conduct stakeholders meeting to share draft regulations
  - Fall 2014
Prescription Fraud Reporting

**Purpose:** To standardize a process for handling reports of loss, theft, and forgery of prescriptions

- Stolen prescription pads in physician offices and clinics
- Pharmacies receiving fraudulent prescriptions

**Reporting Forms:**
- Located on PCD Website
- Practitioner
- Pharmacy

Educational resources for practitioners and pharmacies
Prescription Fraud Reporting

- PCD receives notification:
  - Contact complainant for additional information.
  - Advise to file a report with Metropolitan Police Department (MPD).
  - Complete ALERT letter to District Pharmacies and PCD contacts.
  - Follow up with MPD.
  - Generate a memorandum for appropriate Board(s).
  - Complete the Forged/ Stolen Prescription.
Findings on Inspection/Survey

- Failure to Document administrative CSII substances
- Medication Administration Records (MARs) not consistently reflecting administration

Failure to Conduct CSII Audit as Indicated

Cleaning procedures for IV Room

Using Single Dose Vials for Multi-Use
Compounding

Preparation, mixing, assembling packaging, or labeling of a drug or device

result of a practitioner’s prescription drug order or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing

in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns
Manufacturing

Any packaging or repackaging of the substance or drug; labeling or relabeling of any drug package or container to further distribution from the original place of manufacture to the person who makes final delivery, distribution, or sale to the ultimate consumer or user.
Center for Rational Prescribing

DCRx

information about medications and other therapeutic options to physicians and healthcare professionals

non-commercial, independent continuing education, along with access to other educational resources

choosing treatments based on the best-available evidence and benefits that outweigh harms

free to DC licensed healthcare professionals

Topics for 2015

• Generic Drugs: Myths and Facts
• Drug Approval Process
• Medical Marijuana (pending)
Board of Pharmacy and Pharmaceutical Control Websites

- Application
- AwarRx
- Policy Statement
  - Dual Responsibility and Dispensing Errors Drug Abbreviations
  - Changes to a CII Prescription
- Laws and Regulations
- Safe Disposal for Consumers
- Meeting Agenda/Minutes
- Adverse Event Reporting Form
MMP Regulatory Process

DC Medical Marijuana Program

- Patients
- Cultivation Centers
- Caregivers
- Dispensaries
- Physicians
300.5 Medical marijuana shall not be administered by or to a qualifying patient anywhere other than:

(a) The qualifying patient’s residence, if permitted; or
(b) At a medical treatment facility when receiving medical care for a qualifying medical condition, if permitted by the medical facility.
Board of Pharmacy Meeting

First Thursday of every even month

(Feb, Apr, June, Aug, Oct, Dec)
9:30am
899 North Capitol Street, NE
2nd Floor Conference Room

Open to the Public