



District of Columbia Department of Health

Health Regulation and Licensing Administration Board of Pharmacy and Pharmaceutical Control



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Organization

- Health Professions Licensing Administration
 - Board of Pharmacy
 - Pharmacists (1534)
 - Authority to Immunize (164)
 - Pharmaceutical Detailers (1765)
 - Pharmacy Interns (28)
 - Pharmacy Technicians (B19-0293 introduced in City Council in May 2011)

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.
- 7 Members
 - 5 pharmacists
 - 2 consumers (1 space vacant)
 - Beverly Mims, PharmD Chairperson

Pharmaceutical Control Division

- Health Regulation and Licensing Administration – Division of Food, Drug, Radiation and Community Hygiene
 - 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
 - Resident (143)
 - Non-Resident (224)
- Researchers/Teaching Institutions (53)
- Wholesalers/Distributors/Manufacturers (6/751)
- Fire/EMS
- Medical Examiner
- CNMC Emergency Room at UNMC
- Substance Abuse Treatment Programs (6)
- Animal Clinics (16)
- Dialysis Centers (6)
- Ambulatory Surgical Centers (6)
- Controlled Substance Registration for Professionals (7,352)

Liaison Role

Between District and Federal entities:

- Food and Drug (FDA)
- Drug Enforcement Administration (DEA)
- Health Human Service (HHS)
- Consumer Protection Agency
- And others involving regulatory control matters related to medications

Pharmacy Law and Regulations

- DC Code Title 47, Section 2885.01
Pharmacy
- DC Code Title 48, Section 701-901
Pharmacy related laws
- Federal Law
 - Code of Federal Regulations (CFR) 21, Part 1
 - Section 1300 - Drugs

Pharmacy Law and Regulations

- DCMR Title 22 Public Health & Medicine

- Chapter 4 – Distribution, Manufacturer, or Wholesaler of Drugs

- Chapter 10 – Controlled Substance Registration for Manufacturers, Distributors, and Dispensers

- Chapter 12 – Controlled Substances

- Chapter 13 – Prescription and Distribution

- Chapter 15 – Inspections

- Chapter 19 – Pharmacies

- Chapter 20 - Hospital and Clinics, Pharmacy Services

- Chapter 32 – Nursing Facilities, Pharmaceutical Services

Laws/Regulations

- DCMR Title 17 Business, Industry Professions
 - Chapter 40 – Health Occupations, General Rules
 - Chapter 41 – Health Occupations, Administrative Procedures
 - Chapter 65 – Pharmacists, Pharmacy Interns
 - Chapter 83 – Pharmaceutical Detailers
 - Chapter 85 – Criminal Background Check

Where can I find this?

- DC Municipal Regulations and DC Register www.dcregs.dc.gov
 - Subscribe
 - My favorites
- DC Board of Pharmacy webpage
 - <http://hpla.doh.dc.gov/bop>
- DC Pharmaceutical Control webpage
 - <http://hrla.doh.dc.gov/pcd>

What's New in Regulations?

Final

- Criminal Background Check
- Schedule II multiple prescriptions
- Student Pharmacist Hours
- Civil Infractions

Proposed

- Safe Disposal of Unused Pharmaceuticals

Criminal Background Check

- As of January 3, 2011
- Initial, renewal or reinstatement license
- All health care professionals
- MPD and FBI
- 7 year look back
- Repeat every 4 years
- In District/Out of District Process
- <http://hpla.doh.dc.gov/cbc>

22 DCMR 1306.2

CII Multiple Prescriptions

- Conform with CSA
- More than 30 days after the date written
 - Clear on the prescription that individual practitioner issued multiple prescriptions for up to 90 day supply
 - Legitimate medical purpose
 - Earliest date on which pharmacy may fill each prescription
 - RX presented not more than 90 days after written

22 DCMR Chapter 19

Clarify theft reporting

- 1901.8 General Operating Standards

Burglaries, thefts, suspected diversions, significant losses of drug inventory or the inability to account for such inventory, and damage to a pharmacy or its inventory by fire, flood, or other causes shall be reported by the licensee or agent of the licensee to the Director within forty-eight (48) hours after discovery

22 DCMR Chapter 19

Clarify theft reporting

- 1921.4 Institutional Pharmacies
 - Addition of paragraph (w) and (x)
- 1922.9 Nuclear Pharmacies
 - Addition of paragraph (j) and (k)
- Tie reporting functions back to the general operating standards for consistency

17 DCMR Chapter 65

Student Pharmacist Hours

- 6502 Educational and Training Requirements
 - Start with graduating class of 2014
 - Additional 400 hours of independent pre-licensure practice
 - Emphasis on distribution of medicines and prescriptions

17 DCMR Chapter 65

Student Pharmacist Hours

- 6509 Registration of Pharmacy Interns
 - Starting with graduating class of 2014
 - All individuals engaging in pre-licensure professional practice or working as a pharmacy intern in the District shall register with the Board after entering the first professional year of a college of pharmacy whether or not the hours will be counted toward the total requirement for licensure as a pharmacist.

16 DCMR Chapter 36

Civil Infractions

- Section 3615, 3616, 3617, 3618
- Fine amounts imposed by rulemaking
- Civil fines for violations of the law with respect to:
 - Law governing the licensing and operating standards of pharmacies
 - The dispensing, storing, or handling of controlled substances

22 DCMR Chapter 5

Safe Disposal of Unused Pharmaceuticals

- Health care facility
- Shall not disposed of unused pharmaceuticals by flushing the product down a drain or any method that uses the public sewer system
- Comment period ended Monday, September 19, 2011

Findings on Inspection

- Failure to document administration and/or wasting of CSII substances
- Failure to obtain drugs from an approved supplier
- Failure to conduct CSII audit as indicated
- Medication Administration Records (MARs) not consistently reflecting current date and time
- Physician signature log missing DC Controlled Substance and DEA numbers and respective expiration dates

AccessRx

Prescription Drug Marketing Costs

- requires manufacturers and labelers of prescription drugs dispensed in the District who engage in marketing to report to the Department of Health their costs for pharmaceutical drug marketing in the District
- 2009 report \$96M (119 companies)
- Reports on PCD website

Future

- Regulations
 - Prescription Drug Monitoring Program
 - Manufacturer/Distributor
 - Safe Disposal
- Processes (improve communication)
 - Board of Pharmacy Policy Statements
 - Missing prescription pads
 - Missing controlled substance reporting
 - Rogue Internet Drug Sites
 - Impaired pharmacist program

Board of Pharmacy Meeting

First Thursday of every month

9:30am

899 North Capitol Street, NE

2nd Floor Conference Room

Open to the Public



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