



2201 SHANNON PLACE, SE 2ND FLOOR WASHINGTON, DC20002

March 27, 2024

3:00 -4:50 pm

DC Board of Pharmacy Legislative & Regulatory Subcommittee Meeting Minutes

(WEBEX MEETING)

Board of Pharmacy Mission Statement:

"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 Pharmacists, Pharmaceutical Detailers, Pharmacy Interns, and Pharmacy Technicians."

CALL TO ORDER:

PRESIDING:

BOARD MEMBERSHIP/ATTENDANCE:

COMMITEE MEMBERS:		
	Mr. Alan Friedman, R.PH, Vice Chairperson	Present
	DR. BENJAMIN MILES, PHARM.D. R.PH	Present
	DR. ASHLEE BOW, PHARM.D. R.PH	Present
STAFF:	DR. JUSTIN ORTIQUE, EXECUTIVE DIRECTOR	Present
LEGAL STAFF:	CARLA WILLIAMS, SENIOR ASSISTANT GENERAL COUNSEL	Present
	Angel Cruz, Assistant General Counsel	Present
VISITORS:	Grace Sesi	
	Anthony Scerbo	

Open Session Agenda

Quorum:

Introduction:		
0327-0-01	Self-administered Hormonal Contraceptive Pamphlet Final Edits Minor edits • Progestin-only pill is now available over the counter, add a space between "a" and "(" • QR Codes instead of websites on page 1 and under fertility awareness	
0327-O-02	 Pharmacy Working Conditions Draft Chapter 19 regs reviewed from pharmaceutical control division Working conditions addressed in these regulations Mr. Friedman noted that MD solicits informal comments before publishing, VA makes stakeholder workgroups prior to publishing Mr. Friedman recommends including a pharmacy serving an urgent care at a group model HMO for being able to file a waiver for meal break requirement Dr. Ortique will review to try to make this a little more general without being too broad 1901.8 (b): Mr. Freidman recommends changing "pharmacy shall offer" to "pharmacy may offer" to allow options Mr. Cruz addressed some concerns around productivity quotas by mentioning adjustments to the definitions to allow pharmacists to be evaluated appropriately without imposing productivity requirements on them Will also add definition for ancillary services 1920.5 (b): Dr. Bow recommends specifically add pharmacy technician trainees to list with interns, residents, and fellowships due to issues with unlicensed practice 1920.6: Dr. Bow and Mr. Friedman recommend against requiring the PIC to sign and date the inventory, especially if he/she did not perform. Ms. Williams to review other states' regulations and adjust language Full list of expanded scope of practice activities added to HORA by the Council will be presented at the open session of the April Board meeting 	
0327-0-03	Remote Prescription Processing Was not Discussed	
0327-0-04	Action Steps/Next Meeting	

<u>Comments from</u> <u>the Public</u>	

This concludes the Public Open Session of the DC Board of Pharmacy Legislative & Regulatory Subcommittee meeting.

Open Session Meeting Adjourned at 4:50 pm._

This meeting is governed by the Open Meetings Act. Please address any questions or complaints arising under this meeting to the Office of Open Government at opengovoffice@dc.gov.

CONTRACEPTIVE METHODS

Reversible Methods

Intrauterine Contraception (IUD): IUDs are placed in a woman's uterus in a doctor's office and are effective and long-lasting.

Levonorgestrel

Medication is slowly released over the lifetime of the device to prevent pregnancy. Failure Rate: 0.1-0.4% How Long it Lasts: Lasts 3-8 years

Copper T IUD

This IUD is a small T-shaped device that your doctor places inside the uterus to prevent pregnancy. It can also be used as an emergency contraceptive if implanted within 5 days of having sex. Failure Rate: 0.80% How Long it Lasts: Up to 10 years

Hormonal Methods:

These methods use the hormones estrogen and/or progestin to regulate a women's reproductive hormones and prevent pregnancy.

Implant

The implant is a single, thin rod that is inserted under the skin of a women's upper arm. The rod contains a progestin that is released into the body over 3 years. Failure Rate: 0.1% How Long it Lasts: Lasts 3-8 years

Permanent Methods

Female sterilization (tubal ligation)

Fallopian tubes are blocked or sealed to prevent the eggs reaching the sperm and becoming fertilized. The procedure can be done in a hospital or in an outpatient surgical center. You can go home the same day of the surgery and resume normal activities within a few days. Failure Rate: 0.5%

How Long it Lasts: Permanent

Male sterilization (vasectomy)

This outpatient surgical procedure results in a man's ejaculate no longer containing sperm and is typically done at an outpatient surgical center in just a few hours. Recovery time is often less than one week. Failure Rate: 0.15% How Long it Lasts: Permanent



For more information about these birth control methods including possible side effects, visit:

bit.ly/46ZkXBY

Understand Your Birth Control Options



Pregnancy should be a choice, and you have the power to decide when, or if, it's the right time.

DC HEALTH

COLUMBIA

Hormonal Methods (cont'd):

These methods use the hormones estrogen and/or progestin to regulate a women's reproductive hormones and prevent pregnancy.

Injection

A healthcare provider administers a shot of progestin in the buttocks or arm every three months. Failure Rate: 4% How Long it Lasts: Lasts 3 months

Combined oral contraceptive ("The Pill")

Also called "the pill," it combines estrogen and progestin and must be taken at the same time each day. If you are older than 35 years and smoke, have a history of blood clots or breast cancer, your doctor may advise you not to take the pill.

Failure Rate: 7% How Long it Lasts: Take daily

Progestin-only pill

Sometimes called the mini-pill, it is must be taken at the same time each day and it may be a good option for women who can't take estrogen(a progestin only pill will soon be available over the counter). Failure Rate: 7% How Long it Lasts: Take daily

Patch

The patch attaches to the skin on the lower stomach, buttocks, or upper body (except for the breasts) and releases progestin and estrogen into the bloodstream. You must apply a new patch once a week for three weeks and no patch for the fourth week to facilitate a menstrual period.

Failure Rate: 7% How Long it Lasts: Worn 3 of 4 weeks

Vaginal ring

Leave in for 3 weeks, and remove for 1 week to facilitate a menstrual period. The ring uses progestin and estrogen to prevent pregnancy. Failure Rate: 7% How Long it Lasts: Worn 3 of 4 weeks



These methods use medical devices or spermicide to prevent pregnancy.

Diaphragm or cervical cap

A diaphragm or cervical cap is placed inside the vagina along with spermicide before sexual intercourse to cover the cervix to block sperm. Visit your doctor to determine which size of each is right for you. Failure Rate: 17%

How Long it Lasts: One sexual encounter

Sponge

A contraceptive sponge contains spermicide and is placed in the vagina where it fits over the cervix. The sponge works for up to 24 hours and must be left in the vagina for at least 6 hours after the last act of intercourse. Failure Rate: 14-27% How Long it Lasts: One sexual encounter

Male condom

Male condoms are worn on the penis and keep sperm from entering a woman's body. Condoms can only be used once and are available at most drug stores or pharmacies. Failure Rate: 13%

How Long it Lasts: One sexual encounter

Female condom

Female condoms help keep sperm from getting into the body and can be inserted up to eight hours before sexual intercourse. Female condoms are available at most drug stores and pharmacies. Failure Rate: 21%

How Long it Lasts: One sexual encounter

Spermicides

These products come in several forms including foam, gel, cream, film, suppository, or tablet and are placed in the vagina. Spermicide products can be used along with a diaphragm, cervical cap, or male condom. They are available at most drug stores and pharmacies. **Failure Rate: 7%**

How Long it Lasts: Varies depending on brand and type. See package insert.



Fertility Awareness-Based Methods:

These methods employ knowledge of a woman's regular cycle to determine when she is fertile to avoid unprotected sex during this 9+ day period.

Fertility Awareness Methods

If you have a regular menstrual cycle, you have about nine or more fertile days each month. Understanding your monthly fertility pattern can help you to get or avoid getting pregnant. For more information on understanding your fertility pattern go to bit.ly/3KblORp Failure Rate: 2-23% How Long it Lasts: Requires daily tracking

Emergency Contraception

Emergency contraception is NOT a long-term method of birth control. Emergency contraception can be used after no birth control was used during sex, or if the birth control method failed, such as if a condom broke.

Copper IUD

Women can utilize the Copper T IUD long-term birth control device as an emergency contraceptive if it is inserted within five days of unprotected sex. Must be inserted within 5 days after sexual intercourse

Emergency contraceptive pills - take as soon as possible (Levonorgestrel/Plan B)

Most effective for women when taken within 72 hours after intercourse and not effective after 5 days. There are no age restrictions on emergency contraceptive pills, and they can be purchased without a prescription. **Must be taken within 5 days after sexual intercourse**

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West's District of Columbia Municipal Regulations Title 22. Health Subtitle B. Public Health and Medicine Chapter B19. Pharmacies

22-B DCMR § 1901 D.C. Mun. Regs. Subt. 22-B, § 1901 1901. GENERAL OPERATING STANDARDS Currentness

1901.1 A pharmacy shall be <u>managedoperated</u> only by <u>the</u> pharmacist<u>-in-charge or the director of</u> <u>pharmacy in an institutional pharmacy</u>, holding a valid license in the District of Columbia to practice pharmacy or, if a non-resident pharmacy, a valid license in the state in which the pharmacy is physically located.

1901.2 A licensed pharmacist shall be on duty at all times that a pharmacy is open for business. In a pharmacy staffed by (2) or more pharmacists, the pharmacists shall stagger breaks so that at least one pharmacist shall remain on duty during all business hours. Where only one pharmacist is on duty, the pharmacy shall be closed for business during the pharmacist's meal period and breaks. An inpatient institutional pharmacy may seek a waiver from the Director to not close the pharmacy if one pharmacist is on duty and needs a break.

- 1901.3A pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee
shall not be required to work longer than twelve (12) continuous hours and shall be
allowed at least eight (8) hours of off-time between consecutive shifts, inclusive of the
breaks required in § 1901.4. A pharmacist may volunteer to work longer than twelve
(12) continuous hours.
- 1901.4A pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician traineeworking longer than six (6) continuous hours shall take an uninterrupted thirty (30)minute break.
- 1901.5Where only one pharmacist is on duty and the pharmacy must close for business during
the pharmacist's meal period and breaks pursuant to § 1901.2, the pharmacist shall:
 - (a) <u>Close and secure the pharmacy;</u>
 - (b) Remove all pharmacy interns, pharmacy technicians, and pharmacy technician trainees from the pharmacy during the pharmacist's absence; and
 - (c) Post a sign that is visible to the public stating the pharmacist is on a break and the time the pharmacist shall return from the break.
- 1901.6Where a pharmacy closes for a meal period and breaks pursuant to § 1901.2, apharmacist-in-charge or the director of pharmacy in an institutional pharmacy shall createpolicies and procedures for how pharmacy staff shall handle the closing and reopening of

the pharmacy. The meal period and breaks shall occur at the same time each day, and the pharmacy shall provide a fourteen (14) day notice to the public if the daily meal period and break time for the pharmacy changes.

- 1901.7 To provide a safe working environment in a pharmacy a pharmacist-in-charge shall:
 - (a) <u>Provide adequate time for a pharmacist to complete professional duties and</u> responsibilities, including:
 - 1. Drug utilization review;
 - 2. Immunization;
 - 3. Patient counseling;
 - 4. Dispensing of prescriptions;
 - 5. Patient testing; and
- <u>6.</u>

All other duties of pharmacists as authorized in this Chapter; and

(b) Ensure sufficient personnel are scheduled to work at all times in order to prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable competence and safety. Staffing levels shall not be solely based on prescription volume but shall consider any other requirements of pharmacy personnel.

1901.8A pharmacy license holder shall not establish any productivity or production quotas
relating to ancillary services, and shall develop and implement organizational policies that
do not override the judgment or control of the pharmacist-in-charge, director of pharmacy
in an institutional pharmacy, or pharmacist on duty regarding the following:

(a) <u>A pharmacist-in-charge or director of pharmacy's scheduling and staffing decisions;</u>

- (b) A pharmacist on duty's decision not to administer or supervise immunizations or provide other ancillary services if, in the pharmacist's professional judgment, providing the ancillary services cannot be provided safely or may negatively impact patient access to medications. The pharmacy shall offer to make an appointment for the patient or may refer the patient to another location offering the ancillary services; and
- (c) A pharmacist's decision to limit pharmacy access points if, in the pharmacist's professional judgment, limiting access points shall prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable competence and safety. Limiting access points shall not interfere with a patient's ability to drop off or receive dispensed prescriptions during the pharmacy's posted hours of operation.

1901.<u>9</u>³ The following items shall be posted conspicuously in the vicinity of the pharmacy practice area:

- (a) Certificate of Occupancy Permit (where applicable);
- (b) Pharmacy license;
- (c) Federal and District of Columbia Controlled Substances Registrations;
- (d) Professional licenses of pharmacists on duty;
- (e) Certificates of registration of pharmacy interns; and
- (f) The hours that the pharmacy is open for business.

1901.<u>10</u>4 A pharmacy shall stock, maintain, sell, compound, dispense, and distribute only FDA registered drugs, medical devices, and chemicals for compounding.

1901.<u>11</u>⁵ A pharmacy shall sell, dispense, or otherwise distribute only drugs and medical devices that are safe for their intended purposes, and that are neither misbranded nor adulterated.

1901.<u>126</u> Drugs and medical devices with expired dating, or that are otherwise misbranded or adulterated, shall not be stored with currently dated products or those that are safe for their intended purposes, but shall be separated from active stock and so identified.

1901.<u>137</u> A pharmacy shall only obtain a drug or medical device from a pharmacy, manufacturer, distributor, or wholesaler that is registered or exempted from registration in the District of Columbia pursuant to § 302 (c) of the Uniform Controlled Substances Act or, if a non-resident pharmacy, be registered or exempted from registration by the federal government or the state in which the pharmacy, manufacturer, distributor, or wholesaler is located.

1901.<u>148</u> 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.

1901.<u>159</u> Neither drugs nor other merchandise shall be dispensed, sold, held for sale, or given away in any pharmacy damaged by fire, flood, or other causes until the Director or designee has determined that the merchandise is not adulterated or otherwise unfit for sale, use, or consumption. Damaged premises shall be inspected by the Director or designee to determine their continued suitability for pharmacy operations.

1901.16As part of a pharmacy's record keeping requirements under § 1913, a pharmacy shall
maintain documentation demonstrating their compliance with this Section. -

1901.<u>17</u>¹⁰ Chapter 65 (Pharmacists) of Title 17 DCMR and Chapter 13 of Title 22 DCMR supplement this chapter.

Credits

SOURCE: Adopted at 38 DCR 6734 Nov. 8, 1991; Amended at 55 DCR 270 Jan. 11, 2008. Amended Nov. 12, 2010.

Current through District of Columbia Register, Volume 71, Number 4, dated January 26, 2024. 22-B DCMR § 1901, 22-B DC ADC § 1901

End of Document

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West's District of Columbia Municipal Regulations Title 22. Health Subtitle B. Public Health and Medicine Chapter B19. Pharmacies

22-B DCMR § 1920 D.C. Mun. Regs. Subt. 22-B, § 1920 1920. PHARMACIST-IN-CHARGE Currentness

1920.1 A retail/community pharmacy, special or limited use pharmacy, or non-resident pharmacy shall be managed by a pharmacist (hereafter referred to as "pharmacist-in-charge"). The pharmacist-in-charge shall be licensed to practice pharmacy in the District of Columbia, except that the pharmacist-in-charge of a non-resident pharmacy shall be licensed in the state in which the pharmacy is located.

1920.2 A pharmacist may not serve as a pharmacist-in-charge unless he is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as a pharmacist-in-charge for more than one (1) pharmacy at a time except upon obtaining written permission from the Director.

<u>1920.2</u> A retail/community pharmacy, special or limited use pharmacy, or non-resident pharmacy shall not operate without an eligible pharmacist-in-charge. Operation of the pharmacy without an eligible pharmacist-in-charge is a violation of the law and each day so operated shall be a separate offense.

1920.3 To be eligible to serve as a pharmacist-in-charge, a pharmacist shall:

- (a) <u>Be licensed, in good standing, to practice pharmacy in the District of Columbia, except that</u> <u>the pharmacist-in-charge of a non-resident pharmacy shall be licensed, in good standing, in</u> <u>the state in which the pharmacy is located;</u>
- (b) Have not less than two years of active pharmacist practice experience in the United States, except that the Board of Pharmacy may grant an exception to the minimum number of years of experience required for good cause shown;
- (c) Be physically present in the pharmacy a minimum of thirty-two (32) hours per week;
- (d) Not serve as the pharmacist-in-charge for more than one (1) pharmacy at a time except upon obtaining written permission from the Director; and
- (e) Complete the affidavit of responsibilities and duties attesting to understanding and accepting the duties and responsibilities of a pharmacist-in-charge as set forth in this Chapter.
- <u>1920.4</u> If the pharmacist-in-charge shall be absent from the pharmacy or on leave for more than thirty (30) days, a new pharmacist-in-charge shall be designated and the Director shall be notified.

1920.<u>5</u>³ In addition to any other responsibilities set forth under this Title, the pharmacist-in-charge or proprietor of a pharmacy shall have the following <u>duties and</u> responsibilities:

(a) <u>To supervise all of the professional employees of the pharmacy;</u>

(b) <u>To ensureEnsuring</u> that <u>all persons working in the pharmacy, including those participating in an internship, residency, or fellowship program at the pharmacy are appropriately licensed or registered with the Board of Pharmacy;</u>

(c) To supervise all employees of the pharmacy regarding any duties related to the procurement, sale, or storage of drugs;

(d) To establish and supervise the method and manner for the storing and safekeeping of drugs;

(e) <u>To establish and supervise the record keeping system for the purchase, sale, possession, storage, safekeeping and return of drugs;</u>

(f) <u>Establishing or ensuring that</u> quality assurance programs are in place for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. Quality assurance programs shall be designed to prevent and detect drug diversion<u>and to decrease and monitor</u> <u>prescription errors</u>;

(gb) Developing or adopting, implementing, and maintaining a training manual and program for the training of all individuals employed in the pharmacy who are legally authorized to assist in the practice of pharmacy. The pharmacist-in-charge shall be responsible for supervising the training program;

(<u>he</u>) <u>Establishing or Developing or ensuring the establishment of policies</u> <u>developing policies</u> and procedures for the procurement, storage, <u>compounding</u>, <u>dispensing</u>, security, and disposition of drugs and devices, and for ensuring the provision of the required information to the public in relation to drug therapies beyond the offer to counsel such as package inserts;

(id) Developing or ensuring the establishment of policies and procedures for the provision of pharmacy services;

(je) Ensuring that the automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards;

(<u>k</u>f) Implementing an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures;

(g) Ensuring that all pharmacists employed at the pharmacy are currently licensed in the District of Columbia, or if it is a non-resident pharmacy, in the state in which the pharmacy is located;

(h) Ensuring that all pharmacy interns employed at the pharmacy are currently registered in the District of Columbia;

(<u>l</u>i) Ensuring the making or filing any reports required by federal or District of Columbia laws or regulations, which shall include but not be limited to, notifying the Director of the occurrence of any of the following:

- (1) Permanent closing;
- (2) Change of proprietorship, management, location, or pharmacist-in-charge;
- (3) Any theft or loss of prescription drugs or medical devices;
- (4) Conviction of any employee of any federal, state, or District of Columbia drug laws;

(5) Disasters, accidents, or any theft, destruction, or loss of records required to be maintained by federal or District of Columbia law or regulation;

- (6) Occurrences of significant adverse drug reactions;
- (7) Illegal use or disclosure of protected patient health information;

(<u>m</u>j) Developing or ensuring the establishment of policies and procedures for preventing the illegal use or disclosure of protected health information, or verifying the existences thereof and ensuring that all employees of the pharmacy read, sign, and comply with the established policies and procedures; and

 (\underline{nk}) Developing or ensuring the establishment of a procedure for proper management of drug recalls which may include, where appropriate, contacting patients to whom the recalled drug product(s) have been dispensed.

- 1920.6 The pharmacist-in-charge shall be responsible for the accuracy and completeness of the biennial inventory of all controlled substances, and shall sign and date the biennial inventory upon its completion. This requirement applies whether the inventory is conducted by the pharmacist-in-charge or another licensed pharmacist.
- 1920.7 Whenever there is a change of a pharmacist-in-charge of a pharmacy:
 - (a) <u>The outgoing pharmacist-in-charge shall conduct an inventory of all controlled substances</u> in the pharmacy before leaving the position; and
 - (b) The incoming pharmacist-in-charge shall conduct an inventory of all controlled substances in the pharmacy within seventy-two (72) hours after beginning to function as the pharmacistin-charge.

1920.8 If the outgoing pharmacist-in-charge is unable to perform the inventory required by § 1920.6, the pharmacy license holder shall designate an alternative pharmacist, other than the incoming pharmacist-in-charge, to perform the inventory in the outgoing pharmacist-in-charge's place.

<u>1920.9</u>4 The pharmacist-in-charge shallmay be assisted by a sufficient number of pharmacists, pharmacy interns,<u>and</u> pharmacy technicians, and pharmacy technician trainees, as may be required to competently and safely provide pharmacy services in keeping with the size, scope, and complexity of the pharmaceutical services provided by the pharmacy.

1920.<u>10</u>⁵ The pharmacist-in-charge or proprietor of a pharmacy-shall assure the development and implementation of written policies and procedures to specify the duties to be performed by pharmacy interns, and pharmacy technician trainees. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum:

(a) Specify that pharmacy interns, and pharmacy technicians, and pharmacy technician trainees, are to be personally and directly supervised by a pharmacist stationed within the same work area who has the ability to control and who is responsible for the activities of the pharmacy interns, and pharmacy technicians, and pharmacy technician trainees; and

(b) Specify th<u>e duties that can be performed by</u> at pharmacy interns and pharmacy technicians and pharmacy technician trainees pursuant to Chapter 99 (Pharmacy Technicians) of Title 17 DCMR; and

(c) Specify the duties that shall only be performed by a pharmacist and not be assigned to a pharmacy intern duties that may be performed only by a pharmacist, which shall include but not be limited to:

- (1) Drug utilization review;
- (2) Clinical conflict resolution;
- (3) Prescriber contact concerning prescription drug order clarification;
- (4) Patient counseling on prescription, over-the-counter, and herbal products;
- (35) Dispensing process validation;
- (4) Providing transition-of-care services;
- (5) Administering anticoagulation therapy;

(6) Extending prescriptions as medically necessary, excluding controlled stubstances or specialized medications; and

(7) Initiation of Pre Exposure Prophylaxis (PrEP) and Post Exposure Prophylaxis (PEP) for the prevention of HIV/Aids pursuant to a protocol.

(6) Receiving new oral prescription drug orders, or refill authorizations;

(7) Prescription transfers; and

(8) Independent compounding.

1920.11 The pharmacy license holder shall not subvert or impede the authority and ability of the pharmacist-in-charge, or Director of Pharmacy, to manage the by impeding the pharmacist-in-charge's management of the pharmacy in compliance with federal and District of Columbia pharmacy laws and regulations.