



Government of the
District of Columbia
Department of Health

Health Regulations and Licensing
Administration
Pharmaceutical Control Division
Inspection Report

899 North Capitol St, NE, 2nd Floor
Washington, DC 20002
202-724-8800
202-727-8677 (fax)
www.hpla.doh.dc.gov

PHARMACY INSPECTION REPORT

Annual Follow-Up New Licensure Complaint Other: _____

Date: _____ Inspector: _____

Pharmacy: _____

Address: _____

Hours of operation:

| | | | |
|---------------|----------|--------|---------|
| Monday-Friday | Saturday | Sunday | Holiday |
|---------------|----------|--------|---------|

Telephone: _____ Fax: _____ E-mail: _____

| | <u>Number</u> | <u>Expiration date</u> |
|------------------|---------------|------------------------|
| Pharmacy License | _____ | _____ |
| DCCS | _____ | _____ |
| DEA | _____ | _____ |
| C of O | _____ | _____ |

| | <u>Name</u> | <u>Number</u> | <u>Expiration date</u> |
|----------------------|-------------|---------------|------------------------|
| Pharmacist in Charge | _____ | _____ | _____ |
| Pharmacist(s) | _____ | _____ | _____ |
| | _____ | _____ | _____ |
| Other Staff | _____ | _____ | _____ |
| | _____ | _____ | _____ |

NOTICE OF ATTEMPT TO CONDUCT INSPECTION/SURVEY

No one was available at the time that we attempted to conduct our inspection/survey.

Please contact our office immediately.

Inspector/Surveyor: _____

Date: _____

Time: _____



VIOLATIONS OF LICENSURE AND/OR DISPLAY REQUIREMENTS

| DCOC/ DCMR/ CFR Citation | Conduct | Compliant | | | Fine Amount |
|--|--|-----------|----|----|-------------|
| | | Yes | No | NA | |
| DCOC 47-2885.03(d)/ 22-B DCMR 1900.1 | Operating a pharmacy without a valid license | | | | 2,000.00 |
| D.C. Official Code § 47- 2885.08(b) | Failure to renew a pharmacy license | | | | 2,000.00 |
| DCOC 48-903.02(a)/ 22-B DCMR 1002.1 | Expired DCCS registration or failure register. | | | | 2,000.00 |
| 22-B DCMR 1502.1/ 22-B DCMR 1000.2/ 21 CFR 1301.11(a) | Expired DEA registration or failure register | | | | 2,000.00 |
| DCOC 47-2885.09(a)/ 22-B DCMR 1901.1 | Unlicensed pharmacist on duty | | | | 2,000.00 |
| DCOC 47-2885.09(a)/ 22-B DCMR 1901.2 | Pharmacy open without Pharmacist being on duty | | | | 2,000.00 |
| DCOC 47-2885.06, DCOC 3- 1210.06(b)(4), and 17 DCMR 6509.3 | Unregistered Pharmacy Intern on duty | | | | 2,000.00 |
| DCOC 47-2885.09(a)/ 22-B DCMR 1901.3 | Failure of pharmacist on duty to conspicuously post his or her pharmacist license. | | | | 500.00 |
| 22-B DCMR 1901.3 | Failure to conspicuously post pharmacy license, occupancy permit, DEA or DCCS registrations, pharmacist licenses, or intern registrations. | | | | 500.00 |
| DCOC 47-2885.09(a)/ 22-B DCMR 1901.3 | Failure to properly display hours of operation | | | | 500.00 |
| DCOC 48-801.03 | Failure to post top 100 drugs pricing poster | | | | 500.00 |
| DCOC 48-803.03a | Failure to prominently display sign regarding drug substitution. | | | | 500.00 |

Comments:



VIOLATIONS OF OPERATIONS REQUIREMENTS

| DCOC/ DCMR/ CFR Citation | Conduct | Compliant | | | Fine Amount |
|---------------------------------|---|-----------|----|----|----------------|
| | | Yes | No | NA | |
| DCOC 47-2885.08(c) | Using a pharmacy license for a location other than the one specified on the license, or under a different name, or transferring a pharmacy license. | | | | 2,000.00 |
| 22-B DCMR 1902.1 and 1902.12 | Operating a pharmacy outside of the classification for which the license was issued; or failing to adhere to restrictions placed on the license. | | | | 2,000.00 |
| 22-B DCMR 1907.3 | Operating a pharmacy in either a temporary or trailer-type facility without approval. | | | | 2,000.00 |
| 22-B DCMR 1900.3 | Having drugs in a pharmacy before a pharmacy license has been obtained from the Director | | | | 1,000.00 |
| 22-B DCMR 1920 | Failure of pharmacist-in-charge to comply with requirements and duties, to be physically present in the pharmacy to provide supervision and control; or serving as PIC for more than one pharmacy without approval. | | | | 2,000.00 |
| DCOC 47-2885.09(b) | Failure of pharmacist on duty to control all professional aspects of the practice of pharmacy; or allowing any usurpation of his or her professional judgment by a non-pharmacist proprietor or personnel. | | | | 1,000.00 |
| 22-B DCMR 1902.8 | Failure to notify the Director within thirty (30) days after a change in the pharmacist-in-charge, Director of Pharmacy, or Responsible Nuclear Pharmacist. | | | | 1,000.00 |
| 22-B DCMR 1905.4 | Failure to notify the Director at least sixty (60) days prior to the change of proprietorship of a pharmacy; or to apply for a new license. | | | | 1,000.00 |
| 22-B DCMR 1906.1 through 1906.4 | Failure to comply with the requirements for closing a pharmacy. | | | | 1,000.00 |

Comments:



VIOLATIONS OF PHYSICAL STANDARDS AND EQUIPMENT

| DCOC/ DCMR/ CFR Citation | Conduct | Compliant | | | Fine Amount |
|--|--|-----------|----|----|-------------|
| | | Yes | No | NA | |
| 22-B DCMR 1907.4(a) | Failure of pharmacy compounding and dispensing area to be a minimum of one-hundred and fifty (150) square feet | | | | 1,000.00 |
| 22-B DCMR 1907.4(c) | Failure to have a confidential patient counseling area | | | | 1,000.00 |
| 22-B DCMR 1907.4(g) | Failure of pharmacy to have a goose-neck faucet; hot and cold water; soap or detergent; air driers or single-use towels | | | | 1,000.00 |
| 2-B DCMR 1907.4(i) | Failure to have refrigeration facilities exclusively for cold storage drugs storage | | | | 1,000.00 |
| DCOC 47-2885.13(a)/22-B DCMR 1907.4(i)/ 22-B DCMR 1907.5 | Failure to maintain pharmacy storage area temperature compatible with the proper storage of drugs with a thermometer to maintain drug storage temperature between 36 and 46 degrees Fahrenheit | | | | 1,000.00 |
| 22-B DCMR 1909.2- 1909.5 | Failure to maintain required equipment and references consistent with the pharmacy's scope of practice, the public's safety; and as required by law | | | | 500.00 |

Comments:

VIOLATIONS OF SECURITY REQUIREMENTS

| DCOC/ DCMR/ CFR Citation | Conduct | Compliant | | | Fine Amount |
|---|---|-----------|----|----|-------------|
| | | Yes | No | NA | |
| DCOC 47-2885.09(d)/ 22-B DCMR 1901.8 | Failure to report thefts, suspected diversions, significant losses of drug inventory or the inability to account for such inventory, to the Director within forty-eight (48) hours after discovery. | | | | 2,000.00 |
| 22-B DCMR 1907.4(d)/ D.C. Code 47-2885.09(c)(1) | Failure to have a barrier that renders pharmacy inaccessible to unauthorized persons | | | | 1,000.00 |
| DCOC 47-2885.09(c)(1)/ 22-B DCMR 1910.4 | Failure to keep controlled substances stored outside compounding and dispensing area in a locked storage area | | | | 1,000.00 |
| 22-B DCMR 1910.2/ 22-B DCMR 1910.7 | Failure to have an operating security alarm system | | | | 1,000.00 |
| DCOC 47-2885.09(c)(1)/ 22-B DCMR 1910.5/ 22-B DCMR 1910.7 | Failure to securely enclose pharmacy area to prevent unauthorized access or diversion of drugs when the pharmacy is closed but other areas of an establishment are open. | | | | 1,000.00 |
| 22-B DCMR 1910.5/ 22-B DCMR 1910.7/ 47-2885.09(c)(3) | Failure to have doors capable of being locked; to securely lock the pharmacy; or to restrict pharmacy access to authorized persons | | | | 1,000.00 |
| DCOC 47-2885.09(c)(4)/ 22-B DCMR 1910.8 | Failure to keep the key or keys to the pharmacy areas under the control or in the possession of the pharmacy on duty or the pharmacy proprietor | | | | 1,000.00 |
| 22-B DCMR 1910.9 | Displaying or storing prohibited drugs in an area accessible to the public | | | | 500.00 |

Comments:



VIOLATIONS OF SANITATION REQUIREMENTS

| DCOC/ DCMR/ CFR Citation | Conduct | Compliant | | | Fine Amount |
|--|--|-----------|----|----|-------------|
| | | Yes | No | NA | |
| 22-B DCMR 1900.4 | Failure to maintain written policies and procedures regarding sanitation standards | | | | 2,000.00 |
| 22-B DCMR 1908.2 | Failure to keep pharmacy clean and in a sanitary condition; (i.e. dusty shelves, trash on the floor, food lying around on counters) | | | | 2,000.00 |
| 22-B DCMR 1908.2 | Failure to maintain clean and sanitary restroom facilities. | | | | 2,000.00 |
| 22-B DCMR 1908.2 | Failure to keep pharmacy free of infestation by infested by rodents, birds, insects, or other vermin | | | | 2,000.00 |
| 22-B DCMR 1908.3 | Failure to keep pharmacy and storage areas dry and well ventilated. | | | | 2,000.00 |
| 22-B DCMR 1908.4 | Failure to keep equipment clean and in good operating condition. | | | | 2,000.00 |
| 22-B DCMR 1908.5 | Failure to cover trash containers or use opaque trash bags | | | | 2,000.00 |
| 22-B DCMR 1908.6 | Failure to remove trash in a timely and sanitary manner | | | | 2,000.00 |
| 22-B DCMR 1908.7 | Failure of pharmacy to have restroom facilities in an area reasonably accessible to pharmacy personnel and supplied with a hand washing sink, soap or detergent, toilet paper, and air driers or single-service towels | | | | 2,000.00 |
| 22-B DCMR 1908.8 | Failure to keep pharmacy plumbing facilities in good repair | | | | 2,000.00 |
| 22-B DCMR 1908.9 | Permitting animals in the pharmacy or areas immediately adjacent to and under the control of the pharmacy except for guide dogs accompanying disabled persons. | | | | 2,000.00 |
| DCOC 47-2885.11(b)(2)-(4)/ 22-B DCMR 1908.10 | Failure of persons working in the pharmacy to follow hygienic practices | | | | 2,000.00 |

Comments:



| VIOLATIONS OF PACKAGING/ HANDLING AND DRUG LABELING REQUIREMENTS | | | | | |
|---|--|------------------|-----------|-----------|--------------------|
| DCOC/ DCMR/ CFR Citation | Conduct | Compliant | | | Fine Amount |
| | | Yes | No | NA | |
| 22-B DCMR 1911.2 | Failure to dispense drugs in new and clean containers or original manufacturer packaging | | | | 2,000.00 |
| 22-B DCMR 1911.3 | Failure to dispense drugs in child-resistant containers without documentation of patient request. | | | | 2,000.00 |
| 22-B DCMR 1911.4 | Reuse of manufacturer bottle or container | | | | 2,000.00 |
| 22-B DCMR 1911.5 | Reuse of bottle or container that previously held toxic, adulterated, or misbranded substances | | | | 2,000.00 |
| 22-B DCMR 1911.6 | Failure to obtain drugs from approved suppliers | | | | 2,000.00 |
| 22-B DCMR 1911.7 | Failure to obtain drugs in original manufacturer or distributor container | | | | 2,000.00 |
| 22-B DCMR 1911.8 | Failure of pharmacist to direct and supervise compounding, repackaging, or prepackaging of drugs | | | | 2,000.00 |
| DCOC 47-2885.13(a)/ 22-B DCMR 1911.11 | Failure to store all drugs and devices in a proper and safe manner, in an appropriate container, in a manner to insure accurate identification and in accordance with applicable federal and D.C. laws | | | | 2,000.00 |
| DCOC 47-2885.10(a)(3)/ 22-B DCMR 1901.6 | Storing misbranded drugs with currently dated products | | | | 2,000.00 |
| DCOC 47-2885.14/ 22-B DCMR 1912 | Failure to dispense a drug, except to hospital inpatients, in a suitable container appropriately labeled | | | | \$1,000.00 |
| DCOC 48-903.08(e)/ 22-B DCMR 1308.1/22-B DCMR 1912.2 | Failure to label written or emergency CS II substances as required by law | | | | 1,000.00 |
| DCOC 48-903.08(e)/ 22-B DCMR 1312.1/ 22-B DCMR 1912.2 | Failure to label CS III-V as required by law | | | | 1,000.00 |
| 22-B DCMR 1912.4 | Failure to label prepackaged or repackaged container with label containing required information. | | | | 1,000.00 |
| 22-B DCMR 1912.6 | Failure to place appropriate expiration date on multi-dose container after opening it | | | | 1,000.00 |
| 22-B DCMR 1325.6 | Failure to affix a label to non-controlled substance prescription package | | | | \$2,000.00 |

Comments:

VIOLATIONS OF RECORDKEEPING REQUIREMENTS

| DCOC/ DCMR/ CFR Citation | Conduct | Compliant | | | Fine Amount |
|--|--|-----------|----|----|----------------|
| | | Yes | No | NA | |
| 22-B DCMR 1503.1 and 22-B DCMR 1913 | Failure to maintain prescription files in conformity with the requirements of 22 DCMR 1913.1 et. seq. | | | | 2,000.00 |
| 22-B DCMR 1502.1 | Failure of registrant to keep records, maintain inventories and file reports as required by fed. law | | | | 2000.00 |
| 22-B DCMR 1913.8 | Failure to file CSII prescriptions separately from other pharmacy records | | | | 2,000.00 |
| 22-B DCMR 1306.3 | Failure to cancel out CS II prescription by drawing a line through the entire prescription order, with date dispensed and initials of person who dispensed the drug | | | | 2,000.00 |
| 22-B DCMR 1310.3/ 22-B DCMR 1310.4/ 22-B DCMR 1310.8 | Failure to record CSIII, IV, and V prescription refills in a readily retrievable record with the required information | | | | 2,000.00 |
| 22-B DCMR 1913.9 | Failure to maintain separate file for CSIII, IV, and V prescriptions, or to mark in red letter "C"; unless an electronic recordkeeping system is used to identify by prescription number | | | | 2,000.00 |
| 22-B DCMR 1302.2 | Failure to immediately reduce an oral prescription order to writing | | | | 2,000.00 |
| 22-B DCMR 1302.3 to 22-B DCMR 1302.9 | Failure to include all required information on an oral prescription drug order | | | | 2,000.00 |
| 22-B DCMR 1303.6 to 22-B DCMR 1303.12 | Failure of telephone facsimile orders to contain all required information | | | | 2,000.00 |
| DCOC 47-2885.15(a)/ 22-B DCMR 1911.9 | Failure to keep required log of compounded or repackaged or prepackaged drugs | | | | 2,000.00 |
| DCOC 47-2885.15(b)(1) | Failure to maintain a record of over-the-counter CS V drugs sales | | | | 500.00 |
| DCOC 47-2885.15(b)(2)(a) | Failure to maintain a record of hypodermic syringes, needles, or other medical devices which may be used in the administration of controlled substances | | | | 500.00 |
| 22-B DCMR 1913.11 | Failure to maintain a patient record system with immediate retrieval of required patient information during pharmacy operating hours. | | | | 2000.00 |
| 22-B DCMR 1301.6 | Failure to document the pharmacist's name, initials or any changes on a prescription order | | | | 2,000.00 |
| 22-B DCMR 1301.7 | Failure to document authorization for a substitution on the prescription order | | | | 2,000.00 |
| 22-B DCMR 1913.6 | Failure to put in place systems to assign a secure identification for each pharmacist for use on verification of records, or to require manual signatures of pharmacists performing final verifications. | | | | 500.00 |



**VIOLATIONS OF RECORDKEEPING REQUIREMENTS
(CONTINUED)**

| DCOC/ DCMR/ CFR Citation | Conduct | Compliant | | | Fine Amount |
|--|---|-----------|----|----|----------------|
| | | Yes | No | NA | |
| 22 DCMR 1502.1/ 21 CFR 1305.12/ 21 CFR 1305.13(e) | Failure to execute DEA 222 Forms as required by law | | | | 2000.00 |
| 22-B DCMR 1325.10 | Failure to document and uniformly maintain in a readily retrievable record each refilling of a non- controlled substance. | | | | 1,000.00 |
| 22-B DCMR 1325.12 | Failure to properly document the required refill authorization information on each refill of a non- controlled substance. | | | | 1,000.00 |
| 22-B DCMR 1325.15 | Failure to properly document the partial filling of a prescription for a non-controlled substance | | | | 1,000.00 |

Comments:



| VIOLATIONS OF DISPENSING AND DISTRIBUTION REQUIREMENTS | | | | | |
|--|---|-----------|----|----|-------------|
| DCOC/ DCMR/ CFR Citation | Conduct | Compliant | | | Fine Amount |
| | | Yes | No | NA | |
| 22-B DCMR 1300.7 | Dispensing a medication or device pursuant to a prescription that the pharmacist knows is not based on a valid patient–practitioner relationship | | | | 2,000.00 |
| 22-B DCMR 1305.6 | Dispensing a medication or device pursuant to a prescription that the pharmacist knows was not issued in the usual course of professional treatment or in legitimate and authorized research. | | | | 2,000.00 |
| 22-B DCMR 1306.2 | CS II prescription filled more than thirty (30) days after the prescription was issued | | | | 2,000.00 |
| 22-B DCMR 1306.3 | Refilled a CS II prescription. | | | | 2,000.00 |
| 22-B DCMR 1306.4 | Failure to obtain the original written prescription before dispensing a CSII prescription that was transmitted via telephone facsimile | | | | 2,000.00 |
| 22-B DCMR 1306.5 | Failure to comply with requirements for dispensing a CSII in an emergency situation | | | | 2,000.00 |
| 22-B DCMR 1306.7 to 22-B DCMR 1306.9 | Failure to comply with requirements for dispensing a CSII via telephone facsimile | | | | 2,000.00 |
| 22-B DCMR 1310.1 | Refilled a CS III through V prescription more than six months after issuance | | | | 2,000.00 |
| 22-B DCMR 1310.2 | Refilled a CS III through V prescription more than five (5) times | | | | 2,000.00 |
| DCOC 47-2885.10(a)(3)/ 22-B DCMR 1901.5 | Selling, or offering for sale, adulterated or misbranded drugs or devices | | | | 2,000.00 |
| DCOC 47-2885.13(a)/ 22-B DCMR 1901.6 | Selling or dispensing expired drugs; or storing expired drugs with currently dated products | | | | 2,000.00 |
| DCOC 47-2885.13(c)/ 22-B DCMR 1329.1 | Placing in stock for reuse or resale, or accepting back to the pharmacy, a drug which has been returned after leaving the pharmacy. | | | | 2,000.00 |
| 22-B DCMR 1901.4 | Stocking, selling, dispensing, or distributing non-FDA registered drugs, medical devices, or chemicals for compounding | | | | 2,000.00 |
| 22-B DCMR 1901.7 | Obtaining drugs or medical devices from a non-registered entity. | | | | 2,000.00 |
| DCOC 47-2885.13(b) | Selling drugs designated as “sample.” | | | | 1,000.00 |
| 22-B DCMR 1919 | Failure to offer to counsel (all patients) | | | | 500.00 |

Comments:



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Controlled Substances II Computation Chart

Facility Name: _____ Date: _____ Biennial Date: _____
 Signer: _____ DEA #: _____ WDC CS#: _____

| 1 | 2 | 3 | 4 | 5 | | 6 | 7 | 8 | | 9 | 10 |
|----|--|--|--|---|--|---|--|--|--|--|----|
| | Name & Strength of Medication | Initial Inventory Date <small>(Amts. recorded on Biennial)</small> | Total Purchases <small>(Total from all invoices/ DEA222's)</small> | Total available for sale <small>(Add columns 3+4)</small> | | Current Inventory Date <small>(Take physical count)</small> | Total Sales <small>(Totals from computer printout)</small> | Total Accounted for <small>(Add columns 6+7)</small> | | Difference <small>(Subtract column 5 from 8)</small> | |
| 1 | | | | | | | | | | | |
| 2 | | | | | | | | | | | |
| 3 | | | | | | | | | | | |
| 4 | | | | | | | | | | | |
| 5 | | | | | | | | | | | |
| 6 | | | | | | | | | | | |
| 7 | | | | | | | | | | | |
| 8 | | | | | | | | | | | |
| 9 | | | | | | | | | | | |
| 10 | | | | | | | | | | | |
