



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Donald W. Taylor, Board President - LaVerne G. Naesea, Executive Director

CERTIFIED MAIL RETURN RECEIPT REQUESTED
ARTICLE #7008 1830 0001 1597 9209

October 7, 2009

Mr. Steven Rigglin
CVS Pharmacy
11729 Beltsville Drive
Beltsville, MD 20705

Re: CVS #1489
Permit No. P00546
Finding of Deficiencies and Imposition of Civil Monetary Penalty
By Consent

Dear Mr. Rigglin:

On March 29, 2007, an annual inspection was conducted by the Division of Drug Control ("DDC") to determine if CVS Pharmacy #1489 (the "Pharmacy") was in compliance with federal and state laws regarding the operation of a pharmacy. The Inspection Report indicated that the Pharmacy was not in substantial compliance with regulatory requirements. Among other things, the Pharmacy did not post an original CDS permit, nor maintain proper records of its controlled dangerous substances inventory, and had several outdated and misbranded medications on its shelves. The Board then ordered a follow-up inspection, which was conducted by DDC on October 18, 2007. The re-inspection noted that the prior deficiencies had still not been addressed.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Reports dated March 29, 2007, and October 18, 2007, and attached as Exhibits A and B.

Based upon deficiencies cited at your Pharmacy, the Board finds that the Pharmacy was in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Pharmacy in violation of Health Occ. Art. § 12-403(b)(1) and (12), Health Gen. Art. §§ 21-216, 21-217, COMAR 10.19.03.03, 10.34.24.03 and 21 CFR § 1304.4 and § 1304.21.

II. CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-410 and COMAR 10.34.11, the Board of Pharmacy has the authority to impose a civil monetary penalty based upon violations of the Maryland Pharmacy Act.

Based upon the deficiencies cited at the Pharmacy, and the subsequent remediation by the Pharmacy, the Board hereby imposes a **civil monetary penalty of \$2,000.00**. The deficiencies upon which the civil monetary penalty is based are enclosed with this letter on Pharmacy Inspection Reports dated March 29, 2007 and October 18, 2007. **Of particular concern was the Pharmacy's failure, even upon re-inspection, to properly document the receipt of Schedule III-V drugs on invoices and the continued existence of outdated and misbranded drugs.**

In determining whether to impose a civil monetary penalty, the Board took into consideration the following factors:

1. The extent to which the permit holder derived any financial benefit from the unprofessional or improper conduct;
2. The willfulness of the unprofessional or improper conduct;
3. The extent of actual or potential public harm caused by the unprofessional or improper conduct;
4. The permit holder's history or previous violations;
5. The existence of mitigating factors.

The civil monetary penalty is **due within thirty (30) days** of the date of this letter, in the form of a check made payable to the Maryland Board of Pharmacy.

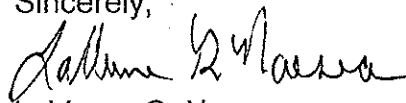
III. FOLLOW-UP INSPECTION

Please be advised that the Board, or its agents, may perform a follow-up inspection of the Pharmacy to insure that it continues to comply with Maryland laws and regulations. Should a follow-up inspection indicate that the Pharmacy is not in substantial compliance, the Board may pursue further disciplinary action against the Pharmacy that may result in the imposition of sanctions such as suspension, revocation or additional monetary penalties.

Upon the Pharmacy's payment of the civil monetary penalty, this Finding will constitute the Board's final action with respect to the Inspection Reports dated March 29, 2007, and October 18, 2007, and shall be a public document in accordance with the Maryland Public Information Act.

If you have any questions concerning the instructions contained in this letter, please contact Vanessa Thomas-Gray, Compliance Specialist, at 410-764-5928.

Sincerely,



LaVerne G. Naesea
Executive Director

cc: Linda Bethman, Assistant Attorney General
Board Counsel

Attachments

EXHIBIT

A

STATE OF MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE Division of Drug Control Pharmacy Inspection Report

RECEIVED
APR 03 2007
Board of Pharmacy

9/17/07

NOTICE: Failure to comply with any of the applicable provisions set forth in Article 27, Sections 276-302, Annotated Code of Maryland; and/or Health General Title 21, Food, Drug, and Cosmetics, Subtitle 1, 2, 11, and 12, Annotated Code of Maryland; and/or Health Occupations Title 12, Pharmacists and Pharmacies, Subtitles 1, 2, 3, 4, 5, 6, 7, and 8, Annotated Code of Maryland; and/or Health General Title 22, Poisons and Child Resistant Packaging, Subtitles 2 and 3, Annotated Code of Maryland and/or Regulations thereof — may subject you to civil proceedings by the Department of Health and Mental Hygiene and/or possible prosecution by the State's Attorney's Office; may lead to suspension or revocation of your Controlled Dangerous Substances Registration and/or appropriate action by the Maryland Board of Pharmacy. Consent of the owner, operator, or agent in charge to inspect the premises is granted to the drug inspector unless stated to the contrary.

Pharmacy Name: CVA Pharmacy #1489 Address: 6516 Landover Road
City: Landover MD Zip: 20785 County: Prince Georges
Shopping Ctr.: None noted Fax No.: 301 583-9846 Phone No.: 301 773-3355
Pharmacy Hours: Mon.-Fri. 8-10 Sat.: 8-6 Sun.: 10-6 Hol.: Vacill
Inspection Date: 3/29/07 Arrival Time: 9:39 AM Departure Time: 6:40 PM

DIVISION OF DRUG CONTROL

- | | |
|---|-----|
| 1. MD CDS Registration expires: <u>6/30/08</u> | X |
| 2. Fed. DEA Registration No.: <u>AP2320733</u> Exp: <u>12/31/07</u> | ✓ |
| 3. CDS Rx filing as req.: <u>Calypsoic garb</u> File system <u>3</u> | ✓ |
| 4. Red "C" used properly on Rx when req. | N/A |
| 5. Federal "No Transfer" label for CDS Rx with no <u>(less than 6-point type)</u> | X |
| 6. CDS biennial inventory properly completed | X |
| 7. Sch. III-V invoices dated & initialed when received | X |
| 8. Who is authorized to sign Form 222 <u>Simon U.</u> | ✓ |
| 9. 3rd copy Form 222 properly completed and filed <u>Ornitho voga</u> | X |
| 10. Patient's address on CDS Rx | ✓ |
| 11. Practitioner's address on CDS Rx | ✓ |
| 12. Practitioner's DEA No. on CDS Rx | ✓ |
| 13. Sch. II drugs dispersed <u>(lock & key)</u> | ✓ |
| 14. CDS orders for office use (Form 222) <u>None noted</u> | ✓ |
| 15. Sch. II emergency procedure <u>None noted</u> | ✓ |
| 16. Outdated products (holding, possession) | X |
| 17. Misbranded products (holding, possession) | X |
| 18. Pertinent label data not obstructed | X |
| 19. Amphet/Methamphet dispensing procedure | N/A |
| 20. Nitroglycerin dispensing | N/A |
| 21. Refrig./protection of drugs from light, exposure, etc. | ✓ |
| 22. Safety closure utilized Yes <u>✓</u> No <u>_____</u> | ✓ |
| a. Documentation if not desired by patient | ✓ |
| 23. Computer utilized Yes <u>✓</u> No <u>_____</u> | ✓ |
| If yes, does system provide: | |
| a. Immed. retrieval of orig. Rx info. | ✓ |
| b. Documentation of pharmacist's verification that refill info is correct | X |
| c. Printout of info. necessary for audit | ✓ |
| d. "Down-time" procedure for proper documentation of refills properly handled | ✓ |

MARYLAND BOARD OF PHARMACY

- | | |
|---|-----|
| 24. Current pharmacy permit posted conspicuously <u>Yes</u> Permit No. <u>P00546</u> | ✓ |
| 25. Pharmacist's certificate of renewal available. List other pharms: Name: <u>Anthony U. Enchalay - validity</u> No.: <u>16610</u> Exp.: <u>10/31/08</u> | ✓ |
| 26. Required pharmacy equip. on hand | X |
| 27. Running water available (hot & cold) | ✓ |
| 28. Pharmacy area clean, neat, well organized <u>from</u> | X |
| 29. Rx files maintained for 5 years <u>Neutony, Fictal</u> | ✓ |
| 30. Required data on patient label <u>very org clean</u> | ✓ |
| 31. Service nursing homes, other facilities | N/A |
| 32. Paraphernalia register correctly maintained | N/A |
| 33. Rx presented more than 120 days after issue <u>None</u> | ✓ |
| 34. Adequate Rx Dept. security <u>Not at</u> | ✓ |
| 35. Rx pick-up after hours <u>0</u> Hours posted <u>at the front of pharmacy</u> (Pharmacies inside other businesses) | ✓ |
| 36. Name of mfg. of generic substitute recorded on Rx | ✓ |
| 37. Name of mfg./distributor of generic substitute on label | ✓ |
| 38. Refrigerator/drugs only <u>2 drugs, 1 food</u> | ✓ |
| 39. Refrigerator temperature (36F-46F) <u>? 23.9 °F</u> | X |
| 40. Current generic substitution info. available. | ✓ |
| 41. Rx Dept. enclosed & locked if pharmacist absent | ✓ |
| 42. Number of pharmacist on duty <u>1</u> | ✓ |
| Number of support personnel on duty <u>3</u> | ✓ |
| 43. Reference library <u>Text + Online</u> | ✓ |
| 44. Owner Pharmacist | N/A |
| Non-pharmacist | N/A |
| 45. Rx storage areas locked | N/A |
| 46. Rx shelf items properly stored (59F-86F) | ✓ |
| 47. Dispensing date & pharmacist's initials on Rx's. | ✓ |
| 48. OBRA compliance: (a) screening, (b) counseling, (c) documentation | ✓ |
| 49. Prescriber's name printed, stamped or typed | ✓ |
| 50. Facsimile transmission <u>+ Electronic</u> | ✓ |
| 51. Pharmacist only receive telephone order for new Rx or refill authorization | ✓ |

Received by: A. Smey Bakh
Anthony U. Enchalay 03/29/07

Inspected by: Peter Smith

Schedule 2 Inventory after Rx#: N159892

Percocet 5/325 mg tablet: 15 (60)

Adderall XR 15mg cap: 35 (65)

Ritalin LA 20mg cap: 70 (150)

Oxycontin 40mg tab: 16

Perpetual inventory counts, if different from physical counts, are noted in ().

Noted: Multiple discrepancies among the perpetual inventory record which need to be resolved. If discrepancies cannot be resolved report to DEA & MD Division of Drug Control.

* Schedule 2 Survey: From: N154579 2/26/07

To: N156206 3/7/07

Schedule 3-5 Survey: From: C158014 3/19/07

To: C158703 3/22/07

Non-controlled Rx#: 158: 056, 057, 296, 466

- 1 Posted CDS registration expired 6/30/06. As necessary, contact the MD Division of Drug Control regarding a copy. Ph: 410 7642890, Fax: 410 358-1793
- 6 Last Biennial inventory in Not properly documented. Done by S. Schnapp, Closing of business. However, date of inventory is indicated simply as 4/30 Mon. There is no indication of year.
- 7 Sampled documentation is Not being dated to indicate date of receipt of the Schedule 3-5 invoices. Date of receipt must be indicated upon invoice whether invoice is from wholesaler or warehouse.
- 9 Date of receipt Not indicated or Not Indicated on EACH line. Form#/dated: 056752049 3/27/07, 056752048 2/14/07, 056752047 1/11/07, 0556986832 12/20/06, 056752056 11/8/06, 057101512 10/5/06, 057101514 8/25/06, 057101531 5/15/06, 057101535 4/28/06, 057101530 4/14/06, 057101504 2/23/06 + Schedule 2 ordering is infrequent, 1 or 2 times a month usually.

16 OTC (Inappropriate) Nutritionals: 2 x 11/1/06, 2 x 12/1/06, short dated 4/1/07, 5/1/07 noted.

~~Eye-products: 2 x 5/05, 7/05, 4/06, 8/06, 10/06, 11/1/06, 12/06, 2/07, 4 x 1/07.~~

Baby formula: short dated 4/1/07 noted.

Brought to the attention of Delanto Cook, assistant store manager. Please check stock for other outdated, short dated products.

Rx (Inappropriate): Drug refrigerator: 4/06 (exp date covered by a sticker), 3 x 6/06, 8/29/06 (a return-to-stock), 4 x 8/06, 2 x 10/06, 3 x 12/06, 4 x 1/1/07, 1/07, 2/07, 3/3/07 (reconstituted antibiotic exp date covered by label/sticker),

Return-to-stock: 3/27/06, 5/25/06, 7/1/06, 7/19/06, 11/11/06, 11/16/06, 11/16/06, 12/1/06, 12/11/06, 1/2/07, 1/27/07, 2 x 2/2/07, 2/21/07, 3/1/07, 3/14/07, 3/15/07,

Drug shelves: 1/07 mfg container present on shelf even though written upon the container is: 'Expired - Don't Use'. Short dated: 3/07, 4/1/07, 4/07 noted.

Please check stock for other outdated/short dated items.

When checking stock don't forget the Return-to-stock & refrigerator items.

17 Multiple pt type vials containing identified drug product. However, neither a lot# nor an expiration date is present.

Several pt type bottle contents unidentified as labels have been partially removed & in doing so the product information is obliterated.

Noted 2 items (return-to-stock) acquired from: 'Community Pharmacy 2955 Mercy Lane, Cheverly, MD 20785', no expiration date present.

Rx#:	'Date filled'	'Discard after'	Product exp
131899	9/28/06	9/28/07	10/06
150317	1/29/07	1/29/08	4/07 & 1/08
157770	3/16/07	3/15/08	12/07
146061	3/19/07	3/18/08	2/08

Insulin products, no other exp date indicator present. Be aware of date relationships.

Inspection Flag:

CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT FOR WHOM IT WAS PRESCRIBED.

Division of Drug Control
Pharmacy Inspection Report

EXHIBIT B

Notice: Failure to comply with any of the applicable provisions set forth in Article 27, sections 276 - 302, Annotated Code of Maryland; and/or Health General Title 21, Food, Drug, and Cosmetics, Subtitle 1, 2, 11, and 12, Annotated Code of Maryland; and/or Health Occupations Title 12, Pharmacists and Pharmacies, Subtitles 1, 2, 3, 4, 5, 6, 7, and 8, Annotated Code of Maryland; and/or Health General Title 22, Poisons and Child Resistant Packaging, Subtitles 2 and 3, Annotated Code of Maryland and/or Regulations thereof - may subject you to Civil proceedings by the Department of Health and Mental Hygiene and/or possible prosecution by the State's Attorney's Office; may lead to suspension or revocation of your Controlled Dangerous Substances Registration and/or appropriate action by the Maryland Board of Pharmacy. Consent of the owner, operator, or agent in charge to inspect the premises is granted to the drug inspector unless stated to the contrary.

RECEIVED
OCT 30 2007
Board of Pharmacy

Pharmacy Name: **CVS PHARMACY 1489**
Address: **LANDOVER**
City: **Landover Park**
Business Hours: **F: 8 AM - 10 PM, Sat: 8 AM - 6 PM, Sun: 10 AM - 6 PM, HD: 10 AM - 6 PM**

Address: **6516 LANDOVER RD**
Zip Code: **20785** County: **Prince George's Co**
Fax Number: **(301) 583-9848** Telephone Number: **(301) 773-3355**
Email: **None**
Arrival Time: **9:21 AM** Departure Time: **3:30 PM**

DIVISION OF DRUG CONTROL

MARYLAND BOARD OF PHARMACY

1. MD CDS Registration posted conspicuously No
- a. MD CDS Registration expiration date 6/30/2008
2. Fed. DEA Registration in Compliance Yes
Fed. DEA Registration # AP2320733
Fed. DEA Registration Exp. date 12/31/2007
3. CDS Rx filing as required
CDS Rx filing system
5. Fed. "No Transfer" label for CDS Rx's no less than 6-point type No
6. CDS biennial inventory properly completed Yes
a. Date last inventory 4/30/2007
7. Sch III-V invoices dated initialed when received No
8. Who is authorized to sign Form 222
9. 3rd Copy Form 222 properly completed and filed Yes
10. Patient's address on CDS Rx's
11. Practitioner's address on CDS Rx's
12. Practitioner's DEA Number on CDS Rx's
13. Sch II drugs dispense/secured
14. CDS orders for office use (Form 222)
15. Sch II emergency procedure
16. Outdated products (holding, possession) Inappropriate
17. Misbranded products (holding, possession) Inappropriate
18. Pertinent label data not obstructed Appropriate
21. Refrig/protection of drugs from light, exposure .etc Inappropriate
22. Safety Closure utilized
a. Documentation if not desired by patient
23. Computer utilized If yes does the system provide the following:
a. Immediate retrieval of original Rx information
b. Documentation of pharmacist's verification that refill information is correct No
c. Printout of information necessary for audit
d. "Down-time" procedure for proper documentation of refills properly handled

24. Current Pharmacy Permit Posted conspicuously Yes
a. Current Pharmacy Permit Number P00546
25. Pharmacist certificate available Yes
26. Required pharmacy equipment on hand No
27. Running water available (hot and cold)
28. Pharmacy area clean, neat, well organized Fair
29. Rx files maintained for 5 years
30. Required data on patient label
33. Rx not presented more than 120 days after Issue
34. Adequate Rx Department security
35. Rx hours posted (Pharmacies inside other businesses) In compliance
36. Name of manufacturer of generic substitute recorded on prescription
37. Name of Manufactures/distributor of generic substitute on label
38. Refrigerator/drugs only Yes
39. Refrigerator temperature (36F-46F) ~34F, ~45F
40. Procedures for determining appropriate generic substitution
41. Rx Department closed secured if pharmacist absent
42. Number of pharmacist on duty 1
Number of support personnel on duty 3
43. Reference Library
a. Reference Library Current
46. Rx shelf items properly stored (59F - 86F)
47. Dispensing date pharmacist's initials on Rx's
48. OBRA compliance: (a) screening
(b) counseling
(c) documentation
49. Prescriber's name printed, stamped or typed
50. Electronic transmission
51. Pharmacist only receives telephone order for new Rx or refill authorization

Received by: **Simon N. Onuakogu**

Inspected by: **Peter Smith**

18-Oct-07 03:15 PM

[Signature]

[Signature]

Inspection Flag:**Division of Drug Control****Pharmacy Inspection Report**

Notice: Failure to comply with any of the applicable provisions set forth in Article 27, sections 276 - 302, Annotated Code of Maryland; and/or Health General Title 21, Food, Drug, and Cosmetics, Subtitle 1, 2, 11, and 12, Annotated Code of Maryland; and/or Health Occupations Title 12, Pharmacists and Pharmacies, Subtitles 1, 2, 3, 4, 5, 6, 7, and 8, Annotated Code of Maryland; and/or Health General Title 22, Poisons and Child Resistant Packaging, Subtitles 2 and 3, Annotated Code of Maryland and/or Regulations thereof -- may subject you to Civil proceedings by the Department of Health and Mental Hygiene and/or possible prosecution by the State's Attorney's Office; may lead to suspension or revocation of your Controlled Dangerous Substances Registration and/or appropriate action by the Maryland Board of Pharmacy. Consent of the owner, operator, or agent in charge to inspect the premises is granted to the drug inspector unless stated to the contrary.

- 23b Yes EACH pharmacist, who has refilled controlled dangerous substance (CDS) prescriptions, is to sign the daily documentation, for their OWN work.
Too often the documentation is not being signed, or is being signed by the wrong pharmacist.
Sign legibly, as one would sign a check or legal document.
Sign in the designated area.
Please enact procedure.
- 25 Re: Janet Egbe Ayuk. Spoke with Ms. Ayuk via telephone. Ms. Ayuk confirmed pharmacist registration # as 13096, exp. Date 10/08. As this is the principle place of employment, please post CURRENT, ORIGINAL, FULL SIZE, SIGNED pharmacist registration.
- 26 Yes An electronic balance is present, the protective cover lacks the sides. Please obtain same.
Please obtain a selection of graduates, e.g. 10ml, 25ml. Presently have: 5 - 50ml cylindrical, 20 - 100ml conical, 20 - 250ml cylindrical, 100 - 500ml conical.
Please obtain a glass mortar and pestle.
- 28 Yes Neatness: Fair. Please remove extraneous materials from floor, dust the drug shelves, clean bottom shelf of the small drug refrigerator.

Noted: Cardboard box present on the pharmacy floor containing various controlled drug products. Some items are short dated, others are not. Why are these items present in this manner on the pharmacy floor? Please address, as appropriate.
- 38 2 drug, 1 food refrigerator.
- 39 Yes Small drug refrigerator approx. 34 F, too cold. Maintain drug refrigerators in range of 36 - 46 F.
Large drug refrigerator ~45 F.
- A Yes Noted: During the work flow pattern, the manufacturer's package/container is not routinely passed by the technician, to the pharmacist, for review. When on-screen technology does not allow the pharmacist to verify the drug product, the pharmacist must retrieve the manufacturer's package/container, if not passed by the technician. Additionally, failure to routinely pass the manufacturer's package/container does not allow the pharmacist to check the product's expiration date. Always pass the manufacturer's package/container to the pharmacist for the final check.