

ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-010312-045)

In The Matter Of:

CVS/PHARMACY #3131
c/o Pamela A. McIntyre, R.Ph.
1495 Columbia Road
Westlake, Ohio 44145
(T.D. No. 02-0748850)

INTRODUCTION

THE MATTER OF CVS/PHARMACY #3131 CAME FOR HEARING ON JANUARY 7, 2002, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ANN D. ABELE, R.Ph., (presiding); DIANE C. ADELMAN, R.Ph.; GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ROBERT P. GIACALONE, R.Ph.; LAWRENCE J. KOST, R.Ph.; NATHAN S. LIPSYC, R.Ph.; AND JAMES E. TURNER, R.Ph.

CVS/PHARMACY #3131 WAS REPRESENTED BY JAMES FLYNN AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) James Reye, Ohio State Board of Pharmacy

Respondent's Witnesses:

- (1) Richard Kolezynski
- (2) Scott Komatz
- (3) Steven Heidenthal

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Copy of four-page Notice of Opportunity for Hearing letter dated March 12, 2001.
- (2) Exhibit 1A--Copy of three-page letter from Richard Kolezynski, R.Ph. dated March 20, 2000; Copy of three-page CVS/pharmacy "Explanation of Corrective Action Taken Regarding Pink Slip Issued March 8, 2000"; Copy of CVS/pharmacy "Explanation of Corrective Action Taken Regarding Pink Slip Issued March 9, 2000"; Copies of two CVS/pharmacy Memos Re Pharmacy Alarms dated March 20, 2000.
- (3) Exhibit 1B--Copy of two-page letter from Richard Kolezynski, R.Ph. dated April 2, 2001.

- (4) Exhibit 1C--Copy of Hearing Request letter from Susan M. DelMonico, R.Ph., J.D. dated April 3, 2001.
- (5) Exhibit 1D--Copy of Hearing Schedule letter dated April 5, 2001.
- (6) Exhibit 1E--Two-page letter from Susan DelMonico, R.Ph., J.D. dated April 3, 2001.
- (7) Exhibit 1F--Copy of letter from David L. Rowland to Susan DelMonico, R.Ph., J.D. dated May 15, 2001.
- (8) Exhibit 1G--Copy of Hearing Schedule letter dated May 17, 2001.
- (9) Exhibit 1H--Copy of Ohio Dangerous Drug Distributor Computer Record of CVS/pharmacy #3131.
- (10) Exhibit 1I--Notice of Appearance as Counsel letter from James Flynn dated September 17, 2001.
- (11) Exhibit 1J-- Copy of Ohio Pharmacist Computer Record of Pamela A. McIntyre.
- (12) Exhibit 1K--Letter from James F. Flynn dated October 2, 2001.
- (13) Exhibit 1L--Letter from David Rowland to James F. Flynn, Esq. dated October 19, 2001.
- (14) Exhibit 1M--Copy of Hearing Schedule letter dated November 8, 2001.
- (15) Exhibit 2--Statement of Deborah Evilsizer notarized March 8, 2000.
- (16) Exhibit 3--Two-page Statement of Deborah Evilsizer notarized March 21, 2000.
- (17) Exhibit 4--Two-page Statement of Michael J. Kolpien notarized March 8, 2000.
- (18) Exhibit 5--Two-sided Third Party/Consultation Log Sheet of CVS/pharmacy #3131 with Rx stickers dated March 7, 2000.
- (19) Exhibit 6--Two-sided Third Party/Consultation Log Sheet of CVS/pharmacy #3131 with Rx stickers dated from March 3, 2000 to March 7, 2000.
- (20) Exhibit 7--Copy of three-page Dangerous Drug Distributor Inspection Report for CVS/pharmacy #3131 dated March 8, 2000.
- (21) Exhibit 8--Copy of three-page letter from Richard Kolezynski, R.Ph. dated March 20, 2000; Copy of three-page CVS/pharmacy "Explanation of Corrective Action Taken Regarding Pink Slip Issued March 8, 2000"; Copy of CVS/pharmacy "Explanation of Corrective Action Taken Regarding Pink Slip Issued March 9, 2000".
- (22) Exhibit 9--Copy of Electronic Journal Report for RX Item 000018653603 dated March 9, 2000, with handwritten note and stickers for Prescription 186536 dated March 7, 2000.
- (23) Exhibit 10--Copy of CVS/REVCO #3131 Pharmacist's Statement covering October 13, 1999 through March 13, 2000 dated March 13, 2000.
- (24) Exhibit 11--Copy of Electronic Journal Report for RX Item 000019223101 dated March 9, 2000, with handwritten note and stickers for Prescription 192231 dated March 7, 2000.
- (25) Exhibit 12-- Copy of CVS/REVCO #3131 Pharmacist's Statement covering October 13, 1999 through March 13, 2000 dated March 13, 2000.
- (26) Exhibit 13--Copy of Electronic Journal Report for RX Items 000019114101, 000019002502, and 000019002702 dated March 9, 2000, with handwritten note and stickers for Prescriptions 191141, 190025, and 190027 dated March 7, 2000.
- (27) Exhibit 14--Copy of two-page CVS/REVCO #3131 Pharmacist's Statement covering October 13, 1999 through March 13, 2000 dated March 13, 2000.
- (28) Exhibit 15--Copy of Electronic Journal Report for RX Items 000019408500 and 0000-19408400 dated March 9, 2000, with handwritten note and stickers for Prescriptions 194085 and 194084 dated March 7, 2000.

- (29) Exhibit 16--Copy of four-page CVS/REVCO #3131 Pharmacist's Statement covering October 13, 1999 through March 13, 2000 dated March 13, 2000.
- (30) Exhibit 17--Copy of Electronic Journal Report for RX Item 000019412200 dated March 9, 2000, with handwritten note and stickers for Prescription 194122 dated March 7, 2000.
- (31) Exhibit 18--Copy of two-page CVS/REVCO #3131 Pharmacist's Statement covering October 13, 1999 through March 13, 2000 dated March 13, 2000.
- (32) Exhibit 19--Copy of Electronic Journal Report for RX Item 000019412000 dated March 9, 2000, with handwritten note and stickers for Prescription 194120 dated March 7, 2000.
- (33) Exhibit 20--Copy of CVS/REVCO #3131 Pharmacist's Statement covering October 13, 1999 through March 13, 2000 dated March 13, 2000.
- (34) Exhibit 21--Copy of Electronic Journal Report for RX Items 000019408300 and 0000-19408200 dated March 9, 2000, with handwritten note and stickers for Prescriptions 194083 and 194082 dated March 7, 2000.
- (35) Exhibit 22--Copy of two-page CVS/REVCO #3131 Pharmacist's Statement covering October 13, 1999 through March 13, 2000 dated March 13, 2000.
- (36) Exhibit 23--Copy of Electronic Journal Report for RX Item 000018950702 dated March 9, 2000, with handwritten note and stickers for Prescription 189507 dated March 7, 2000.
- (37) Exhibit 24--Copy of CVS/REVCO #3131 Pharmacist's Statement covering October 13, 1999 through March 13, 2000 dated March 13, 2000.
- (38) Exhibit 25--Copy of Electronic Journal Report for RX Item 000019413800 dated March 9, 2000, with handwritten note and stickers for Prescription 194138 dated March 7, 2000.
- (39) Exhibit 26--Copy of CVS/REVCO #3131 Pharmacist's Statement covering October 13, 1999 through March 13, 2000 dated March 13, 2000.
- (40) Exhibit 27--Copy of Electronic Journal Report for RX Items 000018535504, 000018535304, and 000018535404 dated March 9, 2000, with handwritten note and stickers for Prescriptions 185355, 185353, 185354 dated March 7, 2000.
- (41) Exhibit 28--Copy of two-page CVS/REVCO #3131 Pharmacist's Statement covering October 13, 1999 through March 13, 2000 dated March 13, 2000.
- (42) Exhibit 29--Envelope dated March 4, 2000 containing Front and Pharmacy codes.
- (43) Exhibit 30--Copy of Terminal Distributor Notification of Change of Responsible Person form of Brian G. Rose dated November 21, 1999.
- (44) Exhibit 31--Copy of Change of Employment form of Brian G. Rose dated February 22, 2000.
- (45) Exhibit 32--Copy of Notification of Change of Responsible Person form of Pamela A. McIntyre effective March 9, 2000.

Respondent's Exhibits:

- (1) Exhibit A--Copy of "Facts Regarding Store #3131 - Board of Pharmacy Violation", not dated.
- (2) Exhibit B--Copy of three-page CVS/pharmacy "Explanation of Corrective Action Taken Regarding Pink Slip Issued March 8, 2000.
- (3) Exhibit C--Copy of CVS/pharmacy "Explanation of Corrective Action Taken Regarding Pink Slip Issued March 9, 2000".

- (4) Exhibit D--Copy of two-page "Procedures for Closing a CVS Pharmacy", not dated.
- (5) Exhibit E--Copy of CVS/REVCO #3131 Dispensing Time Report for March 8, 2000.
- (6) Exhibit F--Copy of Coaching & Counseling Form dated March 16, 2000.
- (7) Exhibit G--Copy of Coaching & Counseling Statement of Mike Kolpien dated March 17, 2000.
- (8) Exhibit H--Copy of CVS/pharmacy Memo re Pharmacy Alarms-Pharmacy Security Baseline Practices (State of Ohio) dated March 20, 2000.
- (9) Exhibit I--Copy of CVS/pharmacy Memo re Pharmacy Alarms-Pharmacy Security Baseline Practice dated March 20, 2000.
- (10) Exhibit J--Copy of "Urgent Message" to pharmacists from Rick Kolezynski, not dated.
- (11) Exhibit K--Copy of eight-page CVS procedures titled, "Topic: Pharmacy Access/Alarm", dated August 1998.
- (12) Exhibit L--Copy of Personnel Change Of Status form of Brian Rose dated February 20, 2000.
- (13) Exhibit M--Copy of two-page HRSA News Release titled "HHS Report Finds Emerging Shortage of Licensed Pharmacists" dated December 12, 2000.
- (14) Exhibit N--Copy of five-page Introduction and ninety-one-page Report To Congress re "The Pharmacist Workforce: A Study of the Supply and Demand for Pharmacists" made by the Department of Health and Human Services/Health Resources and Services Administration/Bureau of Health Professions dated December 2000.
- (15) Exhibit O--Affidavit of Michael J. Kolpien notarized November 2, 2001 with attached copy of five-page handwritten statement of Michael J. Kolpien dated March 10, 2000.
- (16) Exhibit P--Copy of CVS/pharmacy Memo re Pharmacy Alarm/Access Baseline Practices dated April 10, 2000.

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witnesses, considered the evidence, and weighed the credibility of each, the State Board of Pharmacy finds the following to be fact:

- (1) Records of the State Board of Pharmacy indicate that Pamela A. McIntyre was the Responsible Pharmacist at CVS/pharmacy #3131 pursuant to Rule 4729-5-11 of the Ohio Administrative Code and Sections 4729.27 and 4729.55 of the Ohio Revised Code at the time of the occurrences documented in the Notice of Opportunity For Hearing dated March 12, 2001.
- (2) CVS/pharmacy #3131 did, on or about March 8, 2000, cease to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in Section 4729.55 of the Ohio Revised Code, to wit: a pharmacist did not maintain supervision and control over the possession and custody of the dangerous drugs; and adequate safeguards were not assured to prevent the sale or other distribution of dangerous drugs by persons other than a pharmacist or licensed health professional authorized to prescribe drugs. On said date, a Board agent observed activities, defined as the practice of pharmacy, occurring when a pharmacist was not present in the store. Such conduct constitutes ceasing to satisfy the qualifications of a terminal distributor within the meaning of Section 4729.57 of the Ohio Revised Code.

- (3) CVS/pharmacy did, on or about March 8, 2000, permit persons not a pharmacist or a pharmacy intern under the personal supervision of a pharmacist to dispense or sell dangerous drugs or otherwise engage in the practice of pharmacy, to wit: the following prescriptions were dispensed by non-pharmacists:

<u>Prescription #</u>	<u>Drug</u>	<u>Quantity</u>
185355	Prozac 20mg	30
185354	Norvasc 5mg	30
185353	Prinivil 40mg	30
194138	Methotrexate 2.5mg	12
189507	Wellbutrin SR	60
194083	Imdur 30mg	34
194082	Coumadin 2.5mg	50
194120	Diprolene AF 0.05%	15
194122	Prevacid 30mg	30
194084	Warfarin Sodium 2.5mg	60
194085	Furosemide 40mg	15
191141	Urex 1gm	30
190025	Lorazepam 2mg	90
190027	Nortriptyline HCL	60
192231	Clomiphene Citrate 50mg	5
186536	Hydrochlorothiazide 25mg	30

Such conduct is in violation of Section 4729.28 of the Ohio Revised Code.

- (4) CVS/pharmacy did, on or about March 8, 2000, fail to offer or otherwise perform patient counseling, to wit: when dispensing medications to patients pursuant to the prescriptions listed in paragraph (3) above, pharmacists were not available to offer patient counseling, to counsel patients, or to document refusal. Such conduct is in violation of Rule 4729-5-22 of the Ohio Administrative Code.
- (5) CVS/pharmacy did, from January 31, 2000, through March 8, 2000, fail to employ a pharmacist in full and actual charge of the pharmacy, to wit: the pharmacy did not have a responsible pharmacist during this time period. Such conduct is in violation of Section 4729.27 of the Ohio Revised Code and Rule 4729-5-11 of the Ohio Administrative Code.
- (6) CVS/pharmacy did, from January 31, 2000, through March 8, 2000, upon the change of the responsible pharmacist, fail to take a complete inventory of all controlled substances on hand. Such conduct is in violation of Rule 4729-5-11(C)(2) of the Ohio Administrative Code.

CONCLUSIONS OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (4) through (6) of the Findings of Fact constitute violating any rule of the Board as provided in Division (A)(2) of Section 4729.57 of the Ohio Revised Code.

- (2) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (3) and (5) of the Findings of Fact constitute violating the provisions of Chapter 4729. of the Revised Code as provided in Division (A)(3) of Section 4729.57 of the Ohio Revised Code.
- (3) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (2) of the Findings of Fact constitutes ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs as provided in Division (A)(7) of Section 4729.57 of the Ohio Revised Code.

ACTION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code, the State Board of Pharmacy takes the following actions in the matter of CVS/pharmacy #3131:

- (A) On the basis of the Findings of Fact and paragraph (1) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes the terminal distributor license, No. 02-0748850, held by CVS/pharmacy #3131 effective as of the date of the mailing of this Order.
- (B) On the basis of the Findings of Fact and paragraph (2) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes the terminal distributor license, No. 02-0748850, held by CVS/pharmacy #3131 effective as of the date of the mailing of this Order.
- (C) On the basis of the Findings of Fact and paragraph (2) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes the terminal distributor license, No. 02-0748850, held by CVS/pharmacy #3131 effective as of the date of the mailing of this Order.

Pursuant to Section 4729.57 of the Ohio Revised Code, CVS/pharmacy #3131 must return the terminal distributor license to the office of the State Board of Pharmacy within ten days after receipt of this Order. The license should be sent by certified mail, return receipt requested.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY (Aye-5/Nay-2).

MOTION CARRIED.

SO ORDERED.

ORDER EFFECTIVE JANUARY 11, 2002

DUE TO AN APPEAL, THE ACTION OF THE BOARD TOOK EFFECT SEPTEMBER 2, 2003