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Minutes Of The Meeting

Ohio State Board of Pharmacy
Columbus, Ohio
November 8, 9, 10, 1999

MONDAY, NOVEMBER 8, 1999

12:18 p.m. ROLL CALL

The State Board of Pharmacy convened in Room 1952, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

Robert B. Cavendish, R.Ph. (President); Diane C. Adelman, R.Ph. (Vice-President); Ann D. Abele, R.Ph.; Suzanne R. Eastman, R.Ph.; Lawrence J. Kost, R.Ph.; Suzanne L. Neuber, R.Ph.; and Nicholas R. Repke, Public Member.

Also present were William T. Winsley, Executive Director; Timothy Benedict, Assistant Executive Director; David Rowland, Legal Affairs Administrator; Sally Ann Steuk, Assistant Attorney General; and William McMillen, Licensing Administrator.

12:20 p.m.

RES. 2000-068 Mr. Winsley announced that the following Settlement Agreements had been signed by all parties and were now in effect:

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY
(Docket No. D-990513-048)

In The Matter Of:

CVS/Pharmacy #3331
c/o James J. Florian, R.Ph.
1031 West Pleasant Valley Road
Parma, Ohio 44134
(Terminal Distributor No. 02-0338000)

This Settlement Agreement is entered into by and between CVS/Pharmacy #3331 and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

CVS/Pharmacy #3331 voluntarily enters into this Agreement being fully informed of its rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel, the right to a formal adjudication hearing on the issues contained herein, and the right to appeal. CVS/Pharmacy #3331 acknowledges that by entering into this agreement it has waived its rights under Chapter 119. of the Revised Code.

Whereas, the Board is empowered by Section 4729.57 of the Ohio Revised Code to suspend, revoke, or refuse to renew any license issued to a terminal distributor of dangerous drugs pursuant to Section 4729.54 of the Revised Code, or may impose a monetary penalty on the license holder for a violation of any of the enumerated grounds.

Whereas, CVS/Pharmacy #3331 is a licensed terminal distributor of dangerous drugs in the state of Ohio.

Whereas, on or about May 13, 1999, pursuant to Chapter 119. of the Ohio Revised Code, CVS/Pharmacy #3331 was notified of the allegations or charges against it, its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. Further, a hearing was scheduled and continued by the Board. The May 13, 1999, Notice of Opportunity for Hearing contains the following allegations or charges:

- (A) Records of the Board of Pharmacy indicate that James J. Florian is the Responsible Pharmacist at CVS/Pharmacy #3331, 1031 West Pleasant Valley Road, Parma, Ohio pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-5-11 of the Ohio Administrative Code.
- (B) CVS/Pharmacy #3331 did, on or about May 26, 1998, allow persons other than a pharmacist to practice pharmacy, to wit: CVS/Pharmacy #3331 allowed the store's manager and a graduate intern to open the pharmacy and dispense prescriptions from 9:00 a.m. to 1:00 p.m. without a pharmacist in full and actual charge. Such conduct is in violation of Section 4729.27 of the Ohio Revised Code.
- (C) CVS/Pharmacy #3331 did, on or about May 26, 1998, allow a person, who was not a pharmacist or pharmacy intern under personal supervision of a pharmacist to compound, dispense, or sell dangerous drugs or otherwise engage in the practice of pharmacy, to wit: CVS/Pharmacy #3331 allowed the following prescriptions to be compounded and/or dispensed by persons not licensed to do so:

<u>Rx No.</u>	<u>Drug</u>	<u>Quantity</u>
236820	Indapamide 2.5mg	30
236822	Zoloft 100mg	30
236823	Imitrex 50mg	9
236824	Sulfasalazine 500mg	60
236825	Relafen 500mg	60
236826	Pravachol 20mg	34
236827	Dipyridamole 25mg	60
236828	Lanoxin .125mg	100
236829	Potassium CL 10 meq	100
236830	Amoxicillin 500mg	28
236831	Xalatan 0.005 % Eye Drops	3
236834	Procardia XL 30mg	30
236835	Vasotec 20mg	60
236836	Premarin 0.62mg	30
236845	Amoxicillin 250mg	30
236896	Levothroid 50mcs	90
236898	Klor-Con 10meq	30

Such conduct is in violation of Rule 4729-5-25 of the Ohio Administrative Code and Section 4729.28 of the Ohio Revised Code.

- (D) CVS/Pharmacy #3331 did, on May 26, 1998, cease to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, to wit: CVS/Pharmacy #3331 failed to employ a pharmacist to maintain supervision and control over the possession and custody of dangerous drugs, thus, 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. Such conduct is in violation of Rule 4729-9-11 of the Ohio Administrative Code.
- (E) CVS/Pharmacy #3331 did, on or about May 26, 1998, fail to ensure compliance with prospective drug utilization review and patient counseling regulations, to wit: prescription dispensings, original prescription and/or refill information was not checked by a pharmacist for over-utilization, incorrect drug, drug dosage and duration of drug treatment, and/or misuse. Further, the CVS/Pharmacy #3331 failed to offer patient counseling. Such conduct is in violation of Rule 4729-5-22 of the Ohio Administrative Code.

Wherefore, the parties, in consideration of the mutual covenants and promises contained herein, and in lieu of any further formal proceedings at this time, and intending to be bound by said covenants, agree as follows:

- (1) CVS/Pharmacy #3331 agrees to the imposition of a monetary penalty of two thousand dollars (\$2,000.00) due and owing within thirty days from the effective date of this agreement. The monetary penalty should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 S. High St., 17th Floor, Columbus, Ohio 43266-0320.
- (2) CVS/Pharmacy #3331 denies some or all of the allegations or charges. Notwithstanding CVS/Pharmacy #3331's denial of the allegations, the Board hereby adjudicates the same.
- (3) CVS/Pharmacy #3331 admits and acknowledges that it is not a "prevailing eligible party" for purposes of Revised Code Sections 119.092 and 2335.39. Further CVS/Pharmacy #3331 waives any rights it may have under Revised Code Sections 119.09 and 2335.39.
- (4) CVS/Pharmacy #3331, with intention of binding itself and its successors in interest and assigns, hereby releases, and holds harmless from liability and forever discharges the State of Ohio, the Board, the Ohio Attorney General, and any and all of their present and former members, officers, attorneys, agents and employees, personally and in their official capacities, from any and all claims, demands, causes of actions, judgments, or executions that CVS/Pharmacy #3331 ever had, or now has or may have, known or unknown, or that anyone claiming through or under it may have or claims to have, created by or arising out of the allegations or charges filed by the Board against CVS/Pharmacy #3331, set forth in the Notice of Opportunity for Hearing.
- (5) CVS/Pharmacy #3331 acknowledges that it has had an opportunity to ask questions concerning the terms of this Agreement and that all questions asked have been answered in a satisfactory manner.
- (6) This Agreement embodies the entire agreement between and of the parties. There are no express or implied promises, guarantees, terms, covenants, conditions, or obligations other than those contained herein; and this Agreement supersedes all previous communications, representations or agreements, either verbal or written, between the parties.
- (7) The parties hereto acknowledge that this Agreement shall be considered a public record as that term is used in Section 149.43 of the Ohio Revised Code and shall become effective upon the date of the Board President's signature below.

<u>/s/ <i>Barry A. Jasilli</i></u> CVS/Pharmacy #3331, Respondent	<u>/d/ 10/14/99</u> Date of Signature
<u>/s/ <i>James F. Flynn</i></u> Counsel, Attorney for Respondent	<u>/d/ 10/19/99</u> Date of Signature
<u>/s/ <i>Robert B Cavendish</i></u> Robert B. Cavendish, President, Ohio State Board of Pharmacy	<u>/d/ 11/8/99</u> Date of Signature
<u>/s/ <i>Sally Ann Steuk</i></u> Sally Ann Steuk, Ohio Assistant Attorney General	<u>/d/ 11-8-99</u> Date of Signature

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY
(Docket No. D-990721-005)

In The Matter Of:

CVS/Pharmacy #3484
c/o Alan R. Wolford, Sr., R.Ph.
564 Livingston Avenue

Columbus, Ohio 43215
(Terminal Distributor No. 02-0137150)

This Settlement Agreement is entered into by and between CVS/Pharmacy #3484 and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

CVS/Pharmacy #3484 voluntarily enters into this Agreement being fully informed of its rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel, the right to a formal adjudication hearing on the issues contained herein, and the right to appeal. CVS/Pharmacy #3484 acknowledges that by entering into this agreement it has waived its rights under Chapter 119. of the Revised Code.

Whereas, the Board is empowered by Section 4729.57 of the Ohio Revised Code to suspend, revoke, or refuse to renew any license issued to a terminal distributor of dangerous drugs pursuant to Section 4729.54 of the Revised Code, or may impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or one thousand dollars if the acts committed have not been classified as an offense by the Revised Code for a violation of any of the enumerated grounds of the Revised Code Section 4729.57.

Whereas, CVS/Pharmacy #3484 is a licensed terminal distributor of dangerous drugs in the state of Ohio.

Whereas, on or about July 21, 1999, pursuant to Chapter 119. of the Ohio Revised Code, CVS/Pharmacy #3484 was notified of the allegations or charges against it, its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. Further, a hearing was scheduled and continued by the Board. The July 21, 1999, Notice of Opportunity for Hearing contains the following allegations or charges:

- (A) Records of the Ohio State Board of Pharmacy indicate that Alan R. Wolford, Sr. is the Responsible Pharmacist at CVS/Pharmacy #3484 pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-5-11 of the Ohio Administrative Code.
- (B) CVS/Pharmacy #3484 did, on or about September 3, 1998, fail to perform prospective drug utilization review (DUR) and patient counseling, to wit: when dispensing medications to a patient pursuant to prescription number 525926, Alan R. Wolford, Sr. and/or pharmacists under his control at CVS/Pharmacy #3484 failed to review the original prescription and/or refill information for over-utilization, incorrect drug dosage and duration of drug treatment, and misuse; and failed to offer patient counseling. Such conduct is in violation of Rules 4729-5-20 and 4729-5-22 of the Ohio Administrative Code.
- (C) CVS/Pharmacy #3484 did, on or about September 17, 1998, fail to perform prospective drug utilization review (DUR) and patient counseling, to wit: when dispensing medications to a patient pursuant to prescription number 527207, Alan R. Wolford, Sr. and/or pharmacists under his control at CVS/Pharmacy #3484 failed to review the original prescription and/or refill information for over-utilization, incorrect drug dosage and duration of drug treatment, and misuse; and failed to offer patient counseling. Such conduct is in violation of Rules 4729-5-20 and 4729-5-22 of the Ohio Administrative Code.

Wherefore, the parties, in consideration of the mutual covenants and promises contained herein, and in lieu of any further formal proceedings at this time, and intending to be bound by said covenants, agree as follows:

- (1) The CVS/Pharmacy #3484 agrees to the imposition of a monetary penalty one thousand dollars (\$1,000.00) due and owing within 30 days of the effective date of this Agreement. The monetary penalty should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 S. High Street, 17th Floor, Columbus, Ohio 43266-0320.

- (2) CVS/Pharmacy #3484 denies some or all of the allegations or charges. Notwithstanding CVS/Pharmacy #3484's denial of the allegations, the Board hereby adjudicates the same.
- (3) CVS/Pharmacy #3484 admits and acknowledges that it is not a "prevailing eligible party" for purposes of Revised Code Sections 119.092 and 2335.39. Further CVS/Pharmacy #3484 waives any rights it may have under Revised Code Sections 119.09 and 2335.39.
- (4) CVS/Pharmacy #3484, with intention of binding itself and its successors in interest and assigns, hereby releases, and holds harmless from liability and forever discharges the State of Ohio, the Board, the Ohio Attorney General, and any and all of their present and former members, officers, attorneys, agents and employees, personally and in their official capacities, from any and all claims, demands, causes of actions, judgments, or executions that CVS/Pharmacy #3484 ever had, or now has or may have, known or unknown, or that anyone claiming through or under CVS/Pharmacy #3484 may have or claims to have, created by or arising out of the allegations or charges filed by the Board against CVS/Pharmacy #3484, set forth in the Notice of Opportunity for Hearing.
- (5) CVS/Pharmacy #3484 acknowledges that it has had an opportunity to ask questions concerning the terms of this Agreement and that all questions asked have been answered in a satisfactory manner.
- (6) This Agreement embodies the entire agreement between and of the parties. There are no express or implied promises, guarantees, terms, covenants, conditions, or obligations other than those contained herein; and this Agreement supersedes all previous communications, representations or agreements, either verbal or written, between the parties.
- (7) The parties hereto acknowledge that this Agreement shall be considered a public record as that term is used in Section 149.43 of the Ohio Revised Code and shall become effective upon the date of the Board President's signature below.

<u>/s/ <i>Barry A. Jasilli</i></u> _____, on behalf of CVS/Pharmacy #3484	<u>/d/ <i>10/20/99</i></u> Date of Signature
<u>/s/ <i>Barry A. Jasilli</i></u> _____, Counsel, CVS/Pharmacy #3484	<u>/d/ <i>10/20/99</i></u> Date of Signature
<u>/s/ <i>Robert B Cavendish</i></u> Robert B. Cavendish, President, Ohio State Board of Pharmacy	<u>/d/ <i>11/8/99</i></u> Date of Signature
<u>/s/ <i>Sally Ann Steuk</i></u> Sally Ann Steuk, Ohio Assistant Attorney General	<u>/d/ <i>11-8-99</i></u> Date of Signature

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY
 (Docket No. D-990721-006)

In The Matter Of:

CVS/Pharmacy #6149
 c/o Edward H. Wilford, R.Ph.
 1945 West Henderson Road
 Columbus, Ohio 43221
 (Terminal Distributor No. 02-0485300)

This Settlement Agreement is entered into by and between CVS/Pharmacy #6149 and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

CVS/Pharmacy #6149 voluntarily enters into this Agreement being fully informed of its rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel, the right to a formal adjudication hearing on the issues contained

herein, and the right to appeal. CVS/Pharmacy #6149 acknowledges that by entering into this agreement it has waived its rights under Chapter 119. of the Revised Code.

Whereas, the Board is empowered by Section 4729.57 of the Ohio Revised Code to suspend, revoke, or refuse to renew any license issued to a terminal distributor of dangerous drugs pursuant to Section 4729.54 of the Revised Code, or may impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or one thousand dollars if the acts committed have not been classified as an offense by the Revised Code for a violation of any of the enumerated grounds of the Revised Code Section 4729.57.

Whereas, CVS/Pharmacy #6149 is a licensed terminal distributor of dangerous drugs in the state of Ohio.

Whereas, on or about July 21, 1999, pursuant to Chapter 119. of the Ohio Revised Code, CVS/Pharmacy #6149 was notified of the allegations or charges against it, its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. Further, a hearing was scheduled and continued by the Board. The July 21, 1999, Notice of Opportunity for Hearing contains the following allegations or charges:

- (A) Records of the Ohio State Board of Pharmacy indicate that Edward H. Wilford is the Responsible Pharmacist at CVS/Pharmacy #6149 pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-5-11 of the Ohio Administrative Code.
- (B) CVS/Pharmacy #6149 did, on or about September 3, 1998, fail to perform prospective drug utilization review (DUR) and patient counseling, to wit: when dispensing medications to a patient pursuant to prescription number 115269, Edward H. Wilford and/or pharmacists under his control at CVS/Pharmacy #6149 failed to review the original prescription and/or refill information for over-utilization, incorrect drug dosage and duration of drug treatment, and misuse and failed to offer patient counseling. Such conduct is in violation of Rules 4729-5-20 and 4729-5-22 of the Ohio Administrative Code.
- (C) CVS/Pharmacy #6149 did, on or about September 17, 1998, fail to perform prospective drug utilization review (DUR) and patient counseling, to wit: when dispensing medications to a patient pursuant to prescription number 115997, Edward H. Wilford and/or pharmacists under his control at CVS/Pharmacy #6149 failed to review the original prescription and/or refill information for over-utilization, incorrect drug dosage and duration of drug treatment, and misuse; and failed to offer patient counseling. Such conduct is in violation of Rules 4729-5-20 and 4729-5-22 of the Ohio Administrative Code.

Wherefore, the parties, in consideration of the mutual covenants and promises contained herein, and in lieu of any further formal proceedings at this time, and intending to be bound by said covenants, agree as follows:

- (1) The CVS/Pharmacy #6149 agrees to the imposition of a monetary penalty one thousand dollars (\$1,000.00) due and owing within 30 days of the effective date of this Agreement. The monetary penalty should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 S. High Street, 17th Floor, Columbus, Ohio 43266-0320.
- (2) CVS/Pharmacy #6149 denies some or all of the allegations or charges. Notwithstanding CVS/Pharmacy #6149's denial of the allegations, the Board hereby adjudicates the same.
- (3) CVS/Pharmacy #6149 admits and acknowledges that it is not a "prevailing eligible party" for purposes of Revised Code Sections 119.092 and 2335.39. Further CVS/Pharmacy #6149 waives any rights it may have under Revised Code Sections 119.09 and 2335.39.
- (4) CVS/Pharmacy #6149, with intention of binding itself and its successors in interest and assigns, hereby releases, and holds harmless from liability and forever discharges the State of Ohio, the Board, the Ohio Attorney General, and

any and all of their present and former members, officers, attorneys, agents and employees, personally and in their official capacities, from any and all claims, demands, causes of actions, judgments, or executions that CVS/Pharmacy #6149 ever had, or now has or may have, known or unknown, or that anyone claiming through or under CVS/Pharmacy #6149 may have or claims to have, created by or arising out of the allegations or charges filed by the Board against CVS/Pharmacy #6149, set forth in the Notice of Opportunity for Hearing.

- (5) CVS/Pharmacy #6149 acknowledges that it has had an opportunity to ask questions concerning the terms of this Agreement and that all questions asked have been answered in a satisfactory manner.
- (6) This Agreement embodies the entire agreement between and of the parties. There are no express or implied promises, guarantees, terms, covenants, conditions, or obligations other than those contained herein; and this Agreement supersedes all previous communications, representations or agreements, either verbal or written, between the parties.
- (7) The parties hereto acknowledge that this Agreement shall be considered a public record as that term is used in Section 149.43 of the Ohio Revised Code and shall become effective upon the date of the Board President's signature below.

/s/ Barry A. Jasilli
_____, on behalf of CVS/Pharmacy #6149

/d/ 10/20/99
Date of Signature

/s/ Barry A. Jasilli
_____, Counsel, CVS/Pharmacy #6149

/d/ 10/20/99
Date of Signature

/s/ Robert B. Cavendish
Robert B. Cavendish, President, Ohio State Board of Pharmacy

/d/ 11/8/99
Date of Signature

/s/ Sally Ann Steuk
Sally Ann Steuk, Ohio Assistant Attorney General

/d/ 11-8-99
Date of Signature

12:22 p.m.

Ms. Abele moved that the Board go into Executive Session for the purpose of conferring with the Assistant Attorney General regarding pending and imminent court matters pursuant to Section 121.22(G)(3) of the Revised Code, and for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Revised Code. The motion was seconded by Mr. Repke and a roll call vote was conducted by President Cavendish as follows: Abele-Yes, Adelman-Yes, Eastman-Yes, Kost-Yes, Neuber-Yes, and Repke-Yes.

12:40 a.m.

Board member Amonte Littlejohn, R.Ph. arrived and joined the Executive Session in progress.

1:05 p.m.

The Executive Session ended and the Board meeting resumed in Public Session.

RES. 2000-069 Mrs. Neuber moved that the Board accept the proposed settlement offered by Clinton Medical Transport in response to their Notice of Opportunity for a Hearing letter. The settlement is to become official and is to be published in the Board minutes after it is signed by all parties. The motion was seconded by Ms. Abele and approved by the Board (Aye-6/Nay-0/Abstain-1[Littlejohn]).

RES. 2000-070 Mr. Repke then moved that the Board deny the proposed settlement agreement offered in the matter of Thomas William Foti. The motion was seconded by Ms. Abele and approved by the Board (Aye-6/Nay-0/Abstain-1[Littlejohn]).

1:20 p.m.

The Board took a brief recess.

1:47 p.m.

The Board was joined by Assistant Attorney General Sally Ann Steuk for the purpose of conducting an adjudication hearing in accordance with Ohio Revised Code Chapters 119. and 4729. in the matter of David Angelo Pishotti, R.Ph., Warren, Ohio.

5:12 p.m.

The hearing concluded and the record was closed.

5:15 p.m.

The Board meeting recessed until Tuesday, November 9, 1999 at 8:00 a.m.

TUESDAY, NOVEMBER 9, 1999

8:01 a.m. ROLL CALL

The State Board of Pharmacy convened in Room 1952, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

Robert B. Cavendish, R.Ph. (President); Diane C. Adelman, R.Ph. (Vice-President); Ann D. Abele, R.Ph.; Lawrence J. Kost, R.Ph.; Suzanne L. Neuber, R.Ph.; and Nicholas R. Repke, Public Member.

Ms. Abele moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Revised Code. The motion was seconded by Mrs. Adelman and a roll call vote was conducted by President Cavendish as follows: Abele-Yes, Adelman-Yes, Kost-Yes, Neuber-Yes, and Repke-Yes.

8:07 a.m.

RES. 2000-071 The Executive Session ended and the Board meeting resumed in Public Session. Mr. Kost moved that the Board issue the following Cease and Desist Letter to Drug Emporium. The motion was seconded by Mrs. Neuber and approved by the Board (5-0).

CEASE AND DESIST

David L. Kriegel, Chairman, C.E.O., President
Drug Emporium, Inc.
3410 London Drive
Lima, Ohio 45805

Dear Mr. Kriegel:

It has come to the Board's attention that Drug Emporium has implemented a program wherein confidential patient information is transmitted to an outside database management company without having a release from the patient to do so. A copy of such letter to a patient is enclosed herewith.

You are hereby advised that Section 3719.13 of the Ohio Revised Code states as follows:

Prescriptions, orders, and records, required by Chapter 3719. of the Revised Code, and stocks of dangerous drugs and controlled substances, shall be open for inspection only to federal, state, county, and municipal officers, and employees of the state board of pharmacy whose duty it is to enforce the laws of this state or of the United States relating to controlled substances. Such prescriptions, orders, records, and stocks shall be open for inspection by employees of the state medical board for purposes of enforcing Chapter 4731. of the Revised Code. No person having knowledge of any such prescription, order, or record shall divulge such knowledge, except in connection with a prosecution or proceeding in court or before a licensing or registration board or officer, to which prosecution or proceeding the person to whom such prescriptions, orders, or records relate is a party.

Further, Rule 4729-5-29 of the Ohio Administrative Code states in pertinent part as follows:

(A) Records of dispensing or administering of drugs are not a public record. A person having custody of, or access to, such records shall not divulge the contents thereof, or provide a copy thereof, to anyone except:

(1) The patient for whom the prescription or medication order was issued.

- (2) The practitioner who issued the prescription or medication order.
 - (3) Certified/licensed health care personnel who are responsible for the care of the patient.
 - (4) A member, inspector, agent, or investigator of the board of pharmacy or any federal, state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug.
 - (5) An agent of the state medical board when enforcing Chapter 4731. of the Revised Code.
 - (6) An agency of government charged with the responsibility of providing medical care for the patient upon a written request by an authorized representative of the agency requesting such information.
 - (7) An agent of a medical insurance company who provides prescription insurance coverage to the patient upon authorization and proof of insurance by the patient or proof of payment by the insurance company for those medications whose information is requested.
 - (8) Any person, other than those listed in paragraphs (A)(1) to (A)(6) of this rule, only when the patient has given consent for such disclosure in writing, except where a patient requiring medication is unable to deliver a written consent to the necessary disclosure. Any consent must be signed by the patient and dated. Any pharmacist may disclose the prescription information when, in the professional judgment of the pharmacist, it is deemed to be in the best interest of the patient. A pharmacist making an oral disclosure in an emergency situation must prepare a written memorandum showing the patient's name, the date and time the disclosure was made, the nature of the emergency, and the names of the individuals by whom and to whom the information was disclosed.
- (B) . . .

You are further advised that a violation of Section 3719.13 of the Ohio Revised Code is a misdemeanor of the third degree in the state of Ohio, punishable by a fine up to \$3,000 and incarceration up to 90 days. Entering into contracts with pharmacies to receive confidential information could be regarded as complicity to the dissemination of the information from those pharmacies. The State Board of Pharmacy regards the improper dissemination of confidential patient records as a serious offense and will not hesitate to pursue violators.

Please note that the goals of the program, as can be gleaned from a reading of the literature, appear to be admirable. If the patients' consents were to be obtained prior to dissemination of the information to the database management company, the program may very well comply with Ohio law.

WHEREFORE, Drug Emporium is hereby notified to CEASE engaging in conduct which aids and abets the violation of Ohio's patient confidentiality statutes, and DESIST from any violations of Ohio law.

BY ORDER OF THE STATE BOARD OF PHARMACY

8:10 a.m.

The Board was joined by Ernest Boyd, R.Ph., Executive Director of the Ohio Pharmacists Association, and by Robert Parsons, R.Ph., Executive Vice-President of the Ohio Society of Health-system Pharmacists, for a discussion of issues regarding current legislation. Bills discussed specifically included H.B. 241, S.B. 172, and S.B. 130.

9:00 a.m.

The Board took a brief recess. Mr. Littlejohn arrived and joined the Board meeting.

9:20 a.m.

The Board was joined by Assistant Attorney General Sally Ann Steuk for the purpose of conducting an adjudication hearing in accordance with Ohio Revised Code Chapters 119. and 4729. in the matter of Robert Paul Blasko, R.Ph., Canfield.

10:42 a.m.

The hearing concluded and the record was closed. The Board took a brief recess.

11:04 a.m.

RES. 2000-072

The Board was joined by Timothy Benedict, R.Ph., Assistant Executive Director of the Board, and Brian Rosen of Knoll Pharmaceutical Co. to discuss a request that the Board issue a letter to Knoll Pharmaceutical Co. regarding the lack of problems with Knoll's

product Meridia®, a Schedule IV controlled substance. After discussion, the consensus of the Board was that Mr. Benedict could issue such a letter in the Board's name.

11:10 a.m.

Mr. Winsley then presented a request for an exemption from Rule 4729-5-10 (Prescription pick up station) from Visiting Nurse Hospice and Health Care (VNS).

11:15 a.m.

Ms. Eastman arrived and joined the Board meeting in progress.

11:28 a.m.

RES. 2000-073 After discussion of the VNS request, Ms. Abele moved that the Board approve the request with the following stipulations:

- (1) Delivery to the patient must occur within 36 hours of the time the VNS system receives the prescription.
- (2) There must be an approved method to deal with the destruction of medications.
- (3) There must be an approved mechanism in place to deal with those items that are not delivered to the patient in a timely fashion.

The motion was seconded by Mrs. Adelman and approved by the Board (Aye-6/Nay-0/-Abstain-1[Neuber]).

11:33 a.m.

RES. 2000-074 The Board then considered the request of Mariane R. Letargo that, pursuant to Rule 4729-3-04(B), she be permitted to renew her Pharmacy Internship license one additional year so that she can complete her internship requirements. Noting that she has already had an extension previously, Mr. Littlejohn moved that the Board approve Ms. Letargo's request for one more year, but that the Board staff notify Ms. Letargo that this will be the last renewal of this license. The motion was seconded by Ms. Eastman and approved by the Board (Aye-5/Nay-2).

11:35 a.m.

The Board recessed for lunch.

1:00 p.m.

RES. 2000-075 All of the Board members except Mr. Giacalone convened in Room 1919 for the purpose of meeting with the candidates for licensure by reciprocity. Following presentations by Board members and self-introductions by the candidates for licensure by reciprocity, Mr. Repke moved that the Board approve the following candidates for licensure. The motion was seconded by Mrs. Neuber and approved by the Board (Aye-7/Nay-0).

ALLEGRO, JOHN FRANCIS	PENNSYLVANIA
BRANNEN, ELIZABETH ANNE	SOUTH CAROLINA
CAPITANO, BLAIR	PENNSYLVANIA
DAVIS, ARNOLD NORMAN	NEW YORK
KARNANEY, JYOTI	ARIZONA
LE, NGOCLUAN THI	ILLINOIS
McSWIGGIN, MICHAEL VICTOR	MARYLAND
PRYER, JASON SCOTT	MICHIGAN
PULICE, MARIA CARMELA	WEST VIRGINIA
REDDY, VIJAYASEKHAR T.	NEW JERSEY
SHEARER, WILLIAM ROBERT	INDIANA
SHEPLER, KARYN LEIGH	INDIANA
TOBIAS, RODNEY DEAN	MINNESOTA

1:32 p.m.

The Board reconvened in Room 1952 to continue the business of the Board. The Board was joined by the following members of the Board of Directors for the Ohio Pharmacists Rehabilitation Organization (PRO) for a discussion of concerns that exist for the two groups:

Nick Kallis – Chairman
David Baker – President
Wayne Miller – Vice President/Treasurer
Charlie Broussard – Secretary
Keith Wire – Screen Monitor

Robert Garrity – Legal Liaison
Rick Kryc – Speaker

2:47 p.m.

The discussion with the representatives of PRO ended and the Board took a brief recess.

3:00 p.m.

The Board began a discussion of the new and amended rules that are to be considered for implementation by the Board early in calendar year 2000.

3:40 p.m.

Ms. Abele moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Revised Code. The motion was seconded by Mr. Repke and a roll call vote was conducted by President Cavendish as follows: Abele-Yes, Adelman-Yes, Eastman-Yes, Kost-Yes, Littlejohn-Yes, Neuber-Yes, and Repke-Yes.

4:10 p.m.

RES. 2000-076

The Executive Session ended and the Board meeting resumed in Public Session. Mrs. Neuber moved that the Board adopt the following Order in the matter of Robert Paul Blasko, R.Ph., Canfield:

ORDER OF THE STATE BOARD OF PHARMACY
(Docket No. D-990803-011)

In The Matter Of:

ROBERT PAUL BLASKO, R.Ph.
8031 Camden Way
Canfield Township, Ohio 44406
(R.Ph. No. 03-1-17307)

INTRODUCTION

THE MATTER OF ROBERT PAUL BLASKO CAME TO HEARING ON NOVEMBER 9, 1999, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ROBERT B. CAVENDISH, R.Ph. (presiding); ANN D. ABELE, R.Ph.; DIANE C. ADELMAN, R.Ph.; LAWRENCE J. KOST, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; SUZANNE L. NEUBER, R.Ph.; AND NICHOLAS R. REPKE, PUBLIC MEMBER.

ROBERT PAUL BLASKO WAS REPRESENTED BY DAVID W. GRAUER, AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) George Pavlich, Ohio State Board of Pharmacy

Respondent's Witnesses:

- (1) Robert Paul Blasko, R.Ph., Respondent
- (2) Joe Salmen, R.Ph., Pharmacists Rehabilitation Organization

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1—Copy of four-page Summary Suspension Order/Notice of Opportunity for Hearing dated August 3, 1999.
- (2) Exhibit 1A—Notice of Appearance in the matter of Robert Paul Blasko, R.Ph. and Certificate of Service dated August 10, 1999.
- (3) Exhibit 1B—Hearing Request letter and Certificate of Service dated August 25, 1999.
- (4) Exhibit 1C—Copy of Hearing Schedule letter dated September 10, 1999.

- (5) Exhibit 1D—Copy of Pharmacist File Front Sheet of Robert Paul Blasko showing original date of registration as July 29, 1988, and two-page copy of Renewal Application for Pharmacist License No. 03-1-17307, for a license to practice pharmacy in Ohio from September 15, 1999, to September 15, 2000, of Robert P. Blasko dated July 10, 1999.
- (6) Exhibit 2—Statement of Sherry Pieton dated July 6, 1999.
- (7) Exhibit 2A—Copy of Affidavit of Robert Paul Blasko, R.Ph. dated August 23, 1999.
- (8) Exhibit 3—Statement of Dominic Dundee dated June 30, 1999.
- (9) Exhibit 4—Statement of David M. Noday dated June 30, 1999.
- (10) Exhibit 5—Copy of Toxicology Medical Legal-Specimen Chain of Custody Form with attached copy of TB syringe, sealed July 2, 1999.
- (11) Exhibit 6—Toxicology-Forensic Report dated June 30, 1999.
- (12) Exhibit 7—Copy of prescription bottle of Jacquelyn Fisher labeled Prescription No. 9823208561-03 dated August 20, 1998.
- (13) Exhibit 8—Statement of Allyn J. Booher dated August 4, 1999.
- (14) Exhibit 9—Copy of four-page Video Recorder Request Report for the main pharmacy dated July 7, 1999, and copy of four-page Video Recorder Request Report for the oncology clinic dated July 7, 1999.
- (15) Exhibit 10—Eight-page copy of forty-six video-freeze-frame photographs dated from July 12, 1999, 2:47:57 p.m. through July 13, 1999, 4:35:07 p.m.
- (16) Exhibit 11—Copy of Perpetual Controlled Drug Inventory Record of Owen Health Inc. dated June 30, 1999 through July 13, 1999.
- (17) Exhibit 12—Dangerous Drug Distributor Inspection Report of Forum Health NS Hospital dated July 13, 1999, with attached copies of: an envelope marked "Evidence"; six Morphine PCA 250mg/per 50ml units; and an envelope marked "Reference Unit Prepared for Quantitative Analysis of Morphine PCA 250mg/per 50 ml (5mg/per ml)".
- (18) Exhibit 13—Chain of Custody Form with the following attachments: six pages of Toxicology/Therapeutic Drug Monitoring Test Results of tests ordered on August 24, 1999, with Order ID numbers 20240553, 20240556, 20240558, 20240561, 20240563, and 20240565.

Respondent's Exhibits:

- (1) Exhibit A—Copy of two-page Pharmacist's Recovery Contract for Robert P. Blasko dated August 12, 1999.
- (2) Exhibit B—Copy of letter from Carol Fambro dated November 3, 1999.
- (3) Exhibit C—Copy of letter from Kenneth Coulson dated November 3, 1999.
- (4) Exhibit D—Three-page copy of Record of Meeting Attendance of Robert Blasko dated August 6, 1999, through November 4, 1999.
- (5) Exhibit E—Copies of two Drug Urine Screen Reports of Robert Blasko for samples collected on September 22, 1999, and October 21, 1999.
- (6) Exhibit F—Copy of two-page affidavit of Dominic Dundee dated August 23, 1999.
- (7) Exhibit G—Copy of letter from Robert P. Blasko dated September 12, 1999.

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 Ohio State Board of Pharmacy indicate that Robert Paul Blasko was originally licensed in the state of Ohio on July 29, 1988, pursuant to examination, and on August 3, 1999, Robert Paul Blasko's pharmacist identification card was summarily suspended pursuant to Divisions (A) and (B) of Section 3719.121 of the Ohio Revised Code.
- (2) Robert Paul Blasko is addicted to liquor or drugs or impaired physically or mentally to such a degree as to render him unfit to practice pharmacy, to wit: A pharmacy technician observed Robert Paul Blasko acting in an irregular manner during his shift, placing a syringe with Morphine residue and having blood inside the cap into a Sharps container in the IV room. Robert Paul Blasko had been observed displaying obsessive behavior; he reported to work with bloodshot eyes, with blurred vision, lethargic in action, and was sometimes forgetful. It was also

observed that he exhibited overall different appearances as well as actions. Such conduct indicates that Robert Paul Blasko falls within the ambit of Divisions (A) and (B) of Section 3719.121 of the Ohio Revised Code.

- (3) Robert Paul Blasko is addicted to liquor or drugs or impaired physically or mentally to such a degree as to render him unfit to practice pharmacy, to wit: Robert Paul Blasko admitted that he would inject himself five or six times a shift, while practicing pharmacy during the 3:00 p.m. to 11:00 p.m. shift, with up to 2cc of Morphine, "not to get high, just to take the edge off." Such conduct indicates that Robert Paul Blasko falls within the ambit of Divisions (A) and (B) of Section 3719.121 of the Ohio Revised Code.
- (4) Robert Paul Blasko did, on or about July 13, 1999, with purpose to deprive, knowingly obtain or exert control over dangerous drugs, the property of Forum Health-Northside Hospital, beyond the express or implied consent of the owner, to wit: Videotapes show Robert Paul Blasko diverting Morphine from PCA units on three separate occasions; shortly thereafter, he admitted to State Board of Pharmacy agents that he had been diverting Morphine since March of 1999. Such conduct is in violation of Section 2913.02 of the Ohio Revised Code.
- (5) Robert Paul Blasko did, on or about unknown and various dates during 1999, adulterate a drug, to wit: Robert Paul Blasko admitted to State Board of Pharmacy agents that he had replaced diverted Morphine with sterile saline so as to avoid detection of diversion. Such conduct is in violation of Section 3715.52 of the Ohio Revised Code.
- (6) Robert Paul Blasko did, on or about March 1999, through July 13, 1999, with purpose to deprive, knowingly obtain or exert control over dangerous drugs, the property of Forum Health-Northside Hospital, beyond the express or implied consent of the owner, to wit: Robert Paul Blasko admitted to State Board of Pharmacy agents that he stole an undetermined quantity of Hydrocodone Bitartrate w/APAP 5/500, a schedule III controlled substance. Such conduct is in violation of Section 2913.02 of the Ohio Revised Code.

CONCLUSIONS OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (6) of the Findings of Fact constitute being guilty of gross immorality as provided in Division (A)(1) of Section 4729.16 of the Ohio Revised Code.
- (2) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (6) of the Findings of Fact constitute being guilty of dishonesty and unprofessional conduct in the practice of pharmacy as provided in Division (A)(2) of Section 4729.16 of the Ohio Revised Code.
- (3) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) and (3) of the Findings of Fact constitute being addicted to or abusing liquor or drugs or impaired physically or mentally to such a degree as to render him unfit to practice pharmacy as provided in Division (A)(3) of Section 4729.16 of the Ohio Revised Code.
- (4) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2), (3), and (5) of the Findings of Fact constitute willfully violating, attempting to violate, or aiding and abetting the violation of provisions of Section 3715.52 or Chapter 3719. of the Revised Code as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.

ACTION OF THE BOARD

Pursuant to Section 3719.121 of the Ohio Revised Code, the State Board of Pharmacy hereby removes the Summary Suspension Order issued August 3, 1999.

Pursuant to Section 4729.16 of the Ohio Revised Code, the State Board of Pharmacy takes the following actions in the matter of Robert Paul Blasko:

- (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 pharmacist identification card, No. 03-1-17307, held by Robert Paul Blasko 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 pharmacist identification card, No. 03-1-17307, held by Robert Paul Blasko effective as of the date of the mailing of this Order.
- (C) On the basis of the Findings of Fact and paragraph (3) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes the pharmacist identification card, No. 03-1-17307, held by Robert Paul Blasko effective as of the date of the mailing of this Order.
- (D) On the basis of the Findings of Fact and paragraph (4) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes the pharmacist identification card, No. 03-1-17307, held by Robert Paul Blasko effective as of the date of the mailing of this Order.

Division (B) of Section 4729.16 of the Ohio Revised Code provides: "Any individual whose identification card is revoked, suspended, or refused, shall return his identification card and license to the offices of the state board of pharmacy within ten days after receipt of notice of such action." The wall certificate and identification card should be forwarded by certified mail, return receipt requested.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mr. Repke and approved by the Board (Aye-5/Nay-1). Ms. Eastman did not participate in the discussion, nor did she vote since she did not participate in the hearing.

4:17 p.m.

RES. 2000-077 Ms. Abele then moved that the Board adopt the following Order in the matter of David Angelo Pishotti, R.Ph., Warren:

ORDER OF THE STATE BOARD OF PHARMACY
(Docket No. D-991103-029)

In The Matter Of:

DAVID ANGELO PISHOTTI, R.Ph.
7866 Casherock Drive, N.E.
Warren, Ohio 44484
(R.Ph. No. 03-3-18491)

INTRODUCTION

THE MATTER OF DAVID ANGELO PISHOTTI CAME TO HEARING ON NOVEMBER 8, 1999, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ROBERT B. CAVENDISH, R.Ph. (presiding); ANN D. ABELE, R.Ph.; DIANE C. ADELMAN, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; LAWRENCE J. KOST, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; SUZANNE L. NEUBER, R.Ph.; AND NICHOLAS R. REPKE, PUBLIC MEMBER.

DAVID ANGELO PISHOTTI WAS REPRESENTED BY MICHAEL D. ROSSI, AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) George Pavlich, Ohio State Board of Pharmacy

Respondent's Witnesses:

- (1) Kent Douglas Potts, R.Ph., Pharmacists Rehabilitation Organization, Inc.
- (2) Anita Pirone, M.S. Ed., L.P.C.C., C.C.D.C. III, 2 North Park, Inc.
- (3) David Angelo Pishotti, R.Ph., Respondent

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Copy of six-page Order of the State Board of Pharmacy, Docket No. D-980210-039, in the matter of David Angelo Pishotti dated September 9, 1998.
- (2) Exhibit 1A--Hearing Request letter dated June 28, 1999, Petition for Hearing dated June 28, 1999, and copy of 2 North Park, Inc. treatment contract of David A. Pishotti dated April 20, 1999.
- (3) Exhibit 1B--Copy of two-page Hearing Schedule letter dated July 6, 1999.
- (4) Exhibit 2--Copy of three-page Youngstown Police Department Ohio Uniform Incident Report, No. 98-8347, of David Pishotti for incident occurring on February 2, 1998.
- (5) Exhibit 3--Copy of two-page Tri-State Laboratories, Inc. urine drug screen report, No. 980164, of David Pishotti dated February 4, 1998.
- (6) Exhibit 4--Copy of six-page Mahoning County Drug Task Force Investigative Report of Officer T. Malone regarding David Pishotti, date of occurrence: February 3, 1998.
- (7) Exhibit 5--Copy of two-page CVS Voluntary Statement of David Pishotti signed and witnessed on February 9, 1998.
- (8) Exhibit 6--Copy of two-page Mahoning County Drug Task Force Written Statement of Marsha Vlosich signed and witnessed on July 23, 1998.
- (9) Exhibit 7--Copy of CVS/Revco #4154 Pharmacist's Statement of David Pishotti dated from December 1, 1997, through February 3, 1998; and two-page copy of Troutman Drug Co. record of prescriptions for Dave Pishotti dated from January 1, 1997, to February 25, 1998.
- (10) Exhibit 8--Copy of Youngstown Police Department Waiver of Rights Form of David Pishotti signed and witnessed on February 3, 1998; and attached copy of eight-page transcribed interview of David Angelo Pishotti, R.Ph. conducted at CVS/Revco #4154 on February 3, 1998.
- (11) Exhibit 9--Copy of two-page Tri-State Laboratories, Inc. report, No. 980196, regarding the David Pishotti case dated February 17, 1998.
- (12) Exhibit 10--Copy of Trumbull County Common Pleas Court Bill of Information, Case No. 98-CR-377-A, of David Angelo Pishotti; copy of five-page Trumbull County Common Pleas Court Finding on Guilty Plea to Bill of Information, State of Ohio vs. David Angelo Pishotti, Case No. 98-CR-377-A; and copy of two-page Trumbull County Common Pleas Court Journal Entry, State of Ohio vs. David Pishotti, Case No. 98-CR-377, dated September 8, 1998.

Respondent's Exhibits:

- (1) Exhibit A-1--Copy of letter from Murphy Lewis dated November 16, 1998, with attached copy of St. Joseph Health Center treatment contract of David A. Pishotti dated September 9, 1998.
- (2) Exhibit A-2--Copy of St. Joseph Health Center Authorization to Release Information to Agency dated April 23, 1999.
- (3) Exhibit A-3--Copy of 2 North Park, Inc. treatment contract of David A. Pishotti dated April 20, 1999.
- (4) Exhibit B--Eleven-page copy of Support Group Attendance Verification Sheets of David Pishotti dated from July 9, 1998, through October 24, 1999.

- (5) Exhibit C--Copy of ten urine drug screen reports of David A. Pishotti dated as follows: September 15, 1998; October 13, 1998; October 20, 1998; December 8, 1998; December 25, 1998; January 27, 1999; February 9, 1999; February 8, 1999; page one of two-page report dated March 9, 1999; and two-page report dated April 7, 1999.
- (6) Exhibit C Supplement--Copy of six two-page urine drug screen reports of David A. Pishotti dated as follows: April 7, 1999; May 31, 1999; July 2, 1999; August 12, 1999; September 17, 1999, and October 21, 1999; and copy of one three-page urine drug screen report dated July 22, 1999.
- (7) Exhibit D-1--Copy of letter from Murphy Lewis dated March 18, 1999.
- (8) Exhibit D-2--Copy of page one of two-page urine drug screen report of David A. Pishotti showing a collection date of April 1, 1999 with handwritten notation of David Pishotti; copy of letter from Michael D. Rossi dated April 19, 1999; and copy of letter from Michael D. Rossi dated May 13, 1999.
- (9) Exhibit D-3--Copy of letter from Murphy Lewis dated April 6, 1999, with handwritten notation of David Pishotti.
- (10) Exhibit D-4--Copy of letter from Murphy Lewis dated April 19, 1999, with handwritten notation of David Pishotti.
- (11) Exhibit E--Copy of Trumbull County Common Pleas Court Journal Entry, State of Ohio vs. David Pishotti, Case No. 98-CR-377, dated October 13, 1999.
- (12) Exhibit F--Copy of page 1 and 2 of four-page Power-Pak Communications Online Test History for David Pishotti dated from February 24, 1998, through September 29, 1999.
- (13) Exhibit G-1--Letter from Jose L. Alappatt dated October 28, 1999.
- (14) Exhibit G-2--Letter from Candida G. Franklin dated October 26, 1999.
- (15) Exhibit G-3--Letter from Robert J. Garrity, not dated.
- (16) Exhibit G-4--Letter from Emil Dontenville dated October 30, 1999.
- (17) Exhibit G-5--Letter from Nick Su dated November 1, 1999.
- (18) Exhibit G-6--Letter from Tom Savage, not dated.
- (19) Exhibit G-7--Letter from David F. Merk dated October 25, 1999.
- (20) Exhibit H-1--Copy of three pages of a five-page fax as follows: cover-page dated August 18, 1997; copy of letter from S. C. Bombeck dated August 18, 1997; and copy of letter from David Pishotti, not dated.
- (21) Exhibit H-2--Copy of two-page fax as follows: cover-page dated September 24, 1997; and letter from S. C. Bombeck dated September 24, 1997.
- (22) Exhibit H-3--Copy of letter from Daniel Ahlstrom dated September 24, 1997; and copy of Clark County District Attorney's Office Bad Check Collection Unit agreement of David Pishotti, not signed nor dated.
- (23) Exhibit H-4--Copy of two-page fax as follows: cover-page dated February 26, 1998; and copy of letter from David Pishotti, not dated.
- (24) Exhibit H-5--Copy of two-page Voluntary Petition in the United States Bankruptcy Court, Northern District of Ohio, of David A Pishotti and Monica A. Pishotti, Case No. 98-42478 dated August 25, 1998 with attachments as follows: "Summary of Schedules" sheet; six-page Schedule F-"Creditors Holding Unsecured Nonpriority Claims"; Schedule I-"Current Income of Individual Debtor(s)"; Schedule J-"Current Expenditures of Individual Debtor(s)"; "Declaration Concerning Debtor's Schedules" signed and dated August 5, 1998; six-page "Statement of Financial Affairs" signed and dated August 5, 1998; and seven-page fax from Joanne Jacobson dated October 18, 1999, consisting of the Cover Sheet, copy of Arrest Warrant in the Justice Court, Las Vegas Township, Clark County Nevada, The State of Nevada vs. David Pishotti, Case No. 98F10388X dated August 6, 1998, with attached business card of Agent George Pavlich, Ohio State Board of Pharmacy, and copy of five-page Criminal Complaint in the Justice Court, Las Vegas Township, Clark County Nevada, The State of Nevada vs. David Pishotti, Case No. 98F10388X, not signed, dated July 30, 1998.
- (25) Exhibit I--Copy of Pharmacists Rehabilitation Organization, Inc. Pharmacist's Recovery Contract of David Pishotti signed and dated July 7, 1998.

FINDING 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) David Angelo Pishotti has not complied with the terms as set forth in the Order of the State Board of Pharmacy, Docket No. D-980210-039, dated September 9, 1998.

ACTION OF THE BOARD

On the basis of the Finding of Fact set forth above, the State Board of Pharmacy takes the following actions in the matter of David Angelo Pishotti:

- (A) The State Board of Pharmacy hereby denies the reinstatement petition of David Angelo Pishotti. Pursuant to Rule 4729-9-01(F) of the Ohio Administrative Code, David Angelo Pishotti may not be employed by or work in a facility licensed by the Board of Pharmacy to possess or distribute dangerous drugs during suspension.
- (B) January 1, 2002, or thereafter, the Board will consider any petition filed by David Angelo Pishotti for a hearing, pursuant to Ohio Revised Code Chapter 119., upon the question of reinstatement. The Board will only consider reinstatement of the license to practice pharmacy in Ohio if the following conditions have been met:
 - (1) David Angelo Pishotti must enter into a new contract, after the effective date of this Order, with an Ohio Department of Alcohol and Drug Addiction Services (ODADAS) treatment provider acceptable to the Board for a period of not less than five years and, upon signing, submit a copy of the contract to the Board office. The contract must provide:
 - (a) **Random, observed** urine drug screens shall be conducted at least every three months.
 - (i) The urine sample must be given within twelve hours of notification. The urine screen must include testing for creatinine or specific gravity of the sample as the dilutional standard.
 - (ii) Carisoprodol, meprobamate, phentermine, and alcohol must be added to the standard urine drug screen. A Breathalyzer may be used to test for alcohol, but the test must be conducted by an appropriately certified individual within twelve hours of notification.
 - (iii) Results of all urine screens must be negative. Any positive results, including those which may have resulted from ingestion of food, but excluding false positives which resulted from medication legitimately prescribed, indicates a violation of the contract and probation.
 - (b) Regular attendance, a minimum of three times per week, at an Alcoholics Anonymous, Narcotics Anonymous, and/or similar support group meeting is required.
 - (c) The program shall immediately report to the Ohio Board of Pharmacy any violations of the contract and/or lack of cooperation.
 - (2) David Angelo Pishotti must provide, at the reinstatement petition hearing, documentation of the following:
 - (a) Compliance with the contract required in paragraph (B)(1) above (e.g.-copies of all urine screen reports, proof of giving the urine sample within twelve hours of notification, copies of meeting attendance records, copies of treatment program reports, etc.);

- (b) Compliance with the continuing pharmacy education requirements as set forth in Chapter 4729-7 of the Ohio Administrative Code (if applicable);
 - (c) Compliance with the terms of this Order.
- (3) If reinstatement is not accomplished within three years of the effective date of this Order, David Angelo Pishotti must show successful completion of the NAPLEX examination or an equivalent examination approved by the Board.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Ms. Eastman and approved by the Board (Aye-7/Nay-0).

4:20 p.m.

RES. 2000-078 Ms. Eastman then moved that the Board deny the settlement offers presented on behalf of John Lafferty, R.Ph. and Imogene Maynard, R.Ph. and that the hearings for these individuals proceed as scheduled. The motion was seconded by Mr. Littlejohn and approved by the Board (Aye-7/Nay-0).

4:30 p.m.

The Board meeting recessed until Wednesday, November 10, 1999 at 8:00 a.m.

WEDNESDAY, NOVEMBER 10, 1999

8:06 a.m. ROLL CALL

The State Board of Pharmacy convened in Room 1952, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

Robert B. Cavendish, R.Ph. (President); Diane C. Adelman, R.Ph. (Vice-President); Ann D. Abele, R.Ph.; Suzanne R. Eastman, R.Ph.; Lawrence J. Kost, R.Ph.; Amonte B. Littlejohn, R.Ph.; Suzanne L. Neuber, R.Ph.; and Nicholas R. Repke, Public Member.

RES. 2000-079 The Board was joined by Mr. Benedict and Mr. McMillen to continue the discussion of the rules to be filed for implementation in calendar year 2000. After discussion, Ms. Eastman moved that the following rules dealing with central filling operations be approved for filing with the appropriate agencies in anticipation of their implementation by the Board:

4729-5-10 Prescription pick-up station.

- (A) No pharmacist shall accept prescriptions obtained from a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled UNLESS SUCH PLACE IS A PHARMACY AS DEFINED IN SECTION 4729.01 OF THE REVISED CODE, HAS RECEIVED BOARD APPROVAL TO FUNCTION IN SUCH A MANNER, AND ALL OF THE FOLLOWING APPLY:
- (1) THE SITE IS LICENSED WITH THE STATE BOARD OF PHARMACY AS A TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS;
 - (2) THE RECEIPT, STORAGE, CONTROL, AND DISTRIBUTION OF PRESCRIPTIONS ARE IN THE FULL AND ACTUAL CHARGE OF A PHARMACIST LICENSED PURSUANT TO CHAPTER 4729. OF THE REVISED CODE;
 - (3) AN APPROPRIATE RECORDKEEPING SYSTEM IS IN PLACE THAT WILL PROVIDE ACCOUNTABILITY FOR PROPER RECEIPT, DELIVERY, AND RETURN OF ALL PRESCRIPTIONS;

(4) THERE IS A DOCUMENTED METHOD IN PLACE TO ENSURE COMPLIANCE WITH RULE 4729-5-22 OF THE ADMINISTRATIVE CODE.

(B) No pharmacist shall dispense dangerous drugs to a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered unless SUCH PLACE IS A PHARMACY AS DEFINED IN SECTION 4729.01 OF THE REVISED CODE, HAS RECEIVED BOARD APPROVAL TO FUNCTION IN SUCH A MANNER, AND PARAGRAPHS (B)(1) THROUGH (B)(4) OF THIS RULE APPLY OR, IF NOT A PHARMACY, UNLESS all of the following apply:

- (1) The site is licensed with the state board of pharmacy as a terminal distributor of dangerous drugs.
- (2) The receipt, storage, control, and distribution of prescriptions or drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4723., 4729., or 4731. of the Revised Code.
- (3) An appropriate recordkeeping system is in place that will provide accountability for proper receipt, ~~and delivery,~~ AND RETURN of all prescription medications.
- (4) There is a documented method in place to ensure compliance with rule 4729-5-22 of the Administrative Code.
- (5) The state board of pharmacy has approved the site for such activity due to clear and convincing evidence that delivery of prescription medication directly to the patient would result in:
 - (a) Danger to public health or safety, or
 - (b) Danger to the patient without increased involvement by a health care professional in the patient's drug therapy.

4729-5-16 Labeling of drugs dispensed on prescription.

(A) No drug may be dispensed on prescription unless a label is affixed to the container in which such drug is dispensed and such label includes:

- (1) The name and address of the pharmacy as it appears on the terminal distributor of dangerous drugs license UNLESS IT IS FILLED PURSUANT TO A BOARD-APPROVED CENTRAL FILLING OPERATION, IN WHICH CASE THE LABEL SHALL BEAR THE NAME AND ADDRESS OF THE ORIGINATING PHARMACY AS IT APPEARS ON THE TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE;
- (2) The name of the patient for whom the drug is prescribed; or, if the patient is an animal, the name of the owner and ~~the species~~ IDENTIFICATION of the animal;
- (3) The name of the prescriber;
- (4) Directions for use of the drug;
- (5) The date of dispensing;
- (6) Any cautions which may be required by federal or state law;
- (7) The serial number of the prescription;
- (8) The proprietary name, if any, or the generic name and the name of the distributor of the drug dispensed; and the strength, if more than one strength of the drug is marketed. The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission in writing in the case of a written prescription, or verbally in the case of an orally transmitted prescription;

- (9) The quantity of drug dispensed;
 - (10) IF FILLED AS PART OF A BOARD-APPROVED CENTRAL FILLING OPERATION, AN IDENTIFICATION OF THE PHARMACY PROVIDING THE DRUGS FOR THE DISPENSING OPERATION.
- (B) The term "affix" means the prescription label must be attached or fastened to the container.
 - (C) At least the prescription number and the name of the patient must be placed on all prescription containers too small to bear a complete prescription label and dispensed in a container bearing a complete prescription label. The label bearing only the prescription number and the name of the patient does not need to be applied to any product whose function would be impaired by such a label. In all cases, a complete prescription label meeting the requirements of paragraph (A) of this rule must be applied to the container in which such product is dispensed.
 - (D) This rule does not apply to drugs which are dispensed for use by inpatients of an institutional facility whereby the drug is not in the possession of the ultimate user prior to administration. Such drugs shall be labeled in accordance with rule 4729-17-10 of the Administrative Code.

4729-5-19 Serial numbering of prescriptions.

All outpatient prescriptions must be serially numbered when entered into the computer system or when dispensed under a manual system.

- (A) This number must appear on the original prescription. If an alternate recordkeeping system is being used pursuant to rules 4729-5-27 and 4729-5-28 of the Administrative Code, the serial number must also appear on the records in this alternate system.
- (B) There must be a complete accounting of all numbers used in the serial numbering system.
- (C) All prescriptions which are not refillable, either because of the dispensing of all refills or the length of time since issuance, shall be assigned a new serial number upon authorization by the prescriber to continue the medication, except:
 - (1) The prescriber may authorize additional refills of a schedule III or IV controlled substance through an oral refill authorization transmitted to a pharmacist, provided the additional refills do not exceed five refills of the original prescription nor does any refill occur beyond six months from the date of issuance of the original prescription; or
 - (2) The prescriber may authorize additional refills of a schedule V controlled substance or a non-controlled drug through an oral refill authorization transmitted to a pharmacist provided that no refill may occur beyond one year from the date of issuance of the original prescription.
 - (3) All additional refills authorized by the prescriber shall be marked on the original prescription listing authorizing agent, date, number of refills authorized, and pharmacist receiving the authorization. If an alternative recordkeeping system is used, this information must also be maintained in that system.
- (D) IN THE CASE OF A BOARD-APPROVED CENTRAL FILLING OPERATION IN WHICH THE PHARMACIES ARE ACCESSING THE SAME REAL-TIME, ON-LINE DATABASE, THE SERIAL NUMBER USED MAY BE THE ORIGINAL SERIAL NUMBER ISSUED AT THE ORIGINATING PHARMACY IF ALL OF THE FOLLOWING REQUIREMENTS ARE MET:
 - (1) THE COMPUTER SYSTEM MAINTAINS THE APPROPRIATE RECORDS FOR THE PRESCRIPTION SO THAT IT IS POSSIBLE TO DETERMINE THE IDENTITY OF EVERY PERSON INVOLVED IN THE DISPENSING OF THE PRESCRIPTION WHO PERFORMS AN ACT THAT WOULD CONSTITUTE THE PRACTICE OF PHARMACY.

- (2) THE COMPUTER SYSTEM ASSIGNS A UNIQUE INTERNAL CODE TO THE PRESCRIPTION SO THAT IT IS POSSIBLE TO DETERMINE THE LOCATION OF THE PERSONNEL INVOLVED IN THE DISPENSING AS WELL AS THE LOCATION OF THE DRUG STOCK USED IN THE DISPENSING FUNCTION.

4729-5-24 Prescription copy.

- (A) A pharmacist may transfer a copy of a prescription; a pharmacist may refill a copy of a prescription; such actions must be in accordance with the following:
- (1) Copies of prescriptions shall be transferred only between pharmacists; copies of prescriptions for controlled substances pursuant to sections 3719.41, 3719.43, and 3719.44 of the Revised Code shall be communicated directly between two pharmacists and shall be transferred only one time. However, pharmacies electronically sharing a real-time, on-line database may transfer a controlled substance prescription up to the maximum number of refills permitted by law and the prescriber's authorization pursuant to paragraph (A)(4) of this rule.
 - (2) The copy transferred shall be an exact duplicate of the original prescription except that it shall also include:
 - (a) Serial prescription number assigned to the prescription;
 - (b) Name and address (and "D.E.A." number for controlled substance prescriptions) of the pharmacy transferring the copy;
 - (c) Date of issuance of the prescription;
 - (d) Date of original dispensing of the prescription;
 - (e) Original number of refills;
 - (f) Date of last refill;
 - (g) Number of valid refills remaining; and
 - (h) The name of the transferring pharmacist.
 - (3) Copies transferred for non-refillable prescriptions shall be marked on the face of the prescription or orally noted by the transferring pharmacist "For Information Purposes Only" and are not valid prescriptions for the dispensing of drugs.
 - (4) The pharmacist transferring a copy of a prescription must:
 - (a) Cancel the original prescription by writing the word "void" on the face of the prescription in such a way as to avoid destroying any of the original information contained on the prescription;
 - (b) Record on the reverse side of the original written prescription:
 - (i) Date of transfer;
 - (ii) His/her signature; and
 - (iii) When transferring an oral prescription, the name and address (and "D.E.A." number for controlled substance prescriptions) OF₁ and name of the pharmacist at₁ the receiving pharmacy.
 - (c) Except, if an automated data processing system is being used as an alternate system of recordkeeping for prescriptions pursuant to rules 4729-5-27 and 4729-5-28 of the Administrative Code, copies of prescriptions may be transferred by a pharmacist if the prescription

record in the system is invalidated to prevent further dispensing at the original site. The prescription record in the system must contain the date of transfer, name of pharmacist making transfer, and the name and address of the pharmacy receiving the copy. Also, original written prescriptions for controlled substances must be canceled as required in paragraphs (A)(4)(a) and (A)(4)(b) of this rule.

- (5) The pharmacist receiving a copy of a prescription must:
 - (a) Exercise reasonable diligence to determine validity of the copy;
 - (b) Reduce an oral prescription to writing by recording all of the information transferred (must include all information required in paragraph (A)(2) of this rule) and write the word "transfer" on the face of the prescription;
 - (c) Record date of transfer on the face of the prescription.
- (B) A prescription copy may be transferred between two pharmacies if the two pharmacies are accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner. The computerized systems must satisfy all information requirements of paragraphs (A)(2) and (A)(4)(c) of this rule. This shall include invalidation of the prescription record in the system to prevent further dispensing at the original site and, if a controlled substance prescription, the canceling of the original written prescription as required in paragraphs (A)(4)(a) and (A)(4)(b) of this rule. A system must be in place that will allow only authorized access to these computerized prescription records by a pharmacist and indicate on the prescription record when and by whom such access was made.
- (C) A prescription copy may be transferred between two pharmacists by the use of a facsimile machine. This facsimile may be considered to be a copy of a prescription if all information requirements of paragraph (A) of this rule, including invalidation of the original prescription or computer records, are met. A system must be in place that will show on the facsimile positive identification of the transferring and receiving pharmacists which must become a part of the prescription record. Facsimile copies must be recorded in writing pursuant to section 4729.37 of the Revised Code, or stored in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.
- (D) Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient. Original copies of prescriptions shall be maintained by pharmacies for the purpose of documenting the dispensing of drugs to a particular patient.
 - (1) In the event that the pharmacy is not able to provide the medication when needed by the patient pursuant to an authorized refill, the pharmacist shall, upon the request of the patient, transfer the prescription information to the pharmacy designated by the patient.
 - (2) No pharmacy shall refuse to transfer information about a previously dispensed prescription to another pharmacy when requested by the patient. Prescription information shall be transferred in accordance with this rule as soon as possible in order to assure that the patient's drug therapy is not interrupted.
- (E) Prescriptions entered into a computer system but not dispensed may be transferred to another pharmacy if all of the following conditions are met:
 - (1) The complete prescription information has been entered into the computer system;
 - (2) the information is displayed on the patient's profile;
 - (3) There is positive identification, either in the computer system or on the hard-copy prescription, of the pharmacist who is responsible for entering the prescription information into the system;

(4) The original prescription is filed in accordance with rule 4729-5-09 of the Administrative Code;

(5) All requirements of this rule are met for the transfer of the prescription.

(F) TRANSFER OF PRESCRIPTION INFORMATION BETWEEN TWO PHARMACIES WHICH ARE ACCESSING THE SAME REAL-TIME, ON-LINE DATABASE PURSUANT TO THE OPERATION OF A BOARD-APPROVED CENTRAL FILLING OPERATION SHALL NOT BE CONSIDERED A PRESCRIPTION COPY AND, THEREFORE, IS NOT SUBJECT TO THE REQUIREMENTS OF THIS RULE.

The motion was seconded by Mrs. Neuber and approved by the Board (Aye-7/Nay-0).

RES. 2000-080 Mr. Winsley then requested the Board's evaluation of an agreement between Merck-Medco and CVS, Inc. regarding transfer of new prescription information for prescription compounding between pharmacists for the two companies. The consensus of the Board was that the current rules regarding the transfer of prescription information would adequately deal with the situation and that Board staff should communicate this information to the parties involved.

RES. 2000-081 Mr. Benedict presented a request from Patty Baxter, R.Ph. regarding a potential employment situation with a company licensed by the Board. She requested the Board's approval in order to avoid any potential conflict with her Board order. Since there would be no drugs available at the employment site, Mrs. Adelman moved that the Board approve the employment situation. The motion was seconded by Mr. Kost and approved by the Board (Aye-7/Nay-0).

9:46 a.m.

The Board was joined by Assistant Attorney General Sally Ann Steuk for the purpose of conducting an adjudication hearing in accordance with Ohio Revised Code Chapters 119. and 4729. in the matters of Gerald R. Poorbaugh, R.Ph., Sebring, and Gromoll Drug Store, T.D., Sebring.

11:50 a.m.

The hearing concluded and the record was closed. The Board took a brief recess.

12:01 p.m.

Mr. Repke moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Revised Code. The motion was seconded by Mr. Littlejohn and a roll call vote was conducted by President Cavendish as follows: Abele-Yes, Adelman-Yes, Eastman-Yes, Kost-Yes, Littlejohn-Yes, Neuber-Yes, and Repke-Yes.

1:00 p.m.

Mr. Cavendish left the meeting for personal reasons. Mrs. Adelman assumed the chair.

1:36 p.m.

RES. 2000-082 The Executive Session ended and the Board meeting resumed in Public Session. Ms. Abele moved that the Board adopt the following Order in the matter of Gerald R. Poorbaugh, R.Ph.:

ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-990914-020)

In The Matter Of:

GERALD R. POORBAUGH, R.Ph.

445 Royal Oak Circle

Sebring, Ohio 44672

(R.Ph. No. 03-1-08325)

INTRODUCTION

THE MATTER OF GERALD R. POORBAUGH CAME TO HEARING ON NOVEMBER 10, 1999, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ROBERT B. CAVENDISH, R.Ph. (presiding); ANN D. ABELE, R.Ph.; DIANE C. ADELMAN, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; LAWRENCE J.

KOST, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; SUZANNE L. NEUBER, R.Ph.; AND NICHOLAS R. REPKE, PUBLIC MEMBER.

GERALD R. POORBAUGH WAS NOT REPRESENTED BY COUNSEL, AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) George Pavlich, Ohio State Board of Pharmacy

Respondent's Witnesses:

- (1) Gerald Poorbaugh, R.Ph., Respondent
- (2) Karen Ellen Poorbaugh, Wife of Respondent
- (3) Raymond J. Poorbaugh, Pharmacy Intern, Son of Respondent

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Copy of four-page Notice of Opportunity for Hearing letter of Gerald R. Poorbaugh dated September 14, 1999.
- (2) Exhibit 1A--Four-page Notice of Opportunity for Hearing letter of Gromoll Drug Store dated September 14, 1999.
- (3) Exhibit 1B--Hearing Request letter dated September 30, 1999.
- (4) Exhibit 1C--Hearing Schedule letter of Gerald R. Poorbaugh dated October 6, 1999.
- (5) Exhibit 1D--Hearing Schedule letter of Gromoll Drug Store dated October 6, 1999.
- (6) Exhibit 1E--Copy of Pharmacist File Front Sheet of Gerald R. Poorbaugh showing original date of registration as March 2, 1965.
- (7) Exhibit 1F--Two-page copy of Renewal Application for Pharmacist License No. 03-1-08325 for a license to practice pharmacy in Ohio from September 15, 1999, to September 15, 2000, of Gerald R. Poorbaugh dated July 19, 1999; and attached copy of four-page "Judgment Entry of Conviction" in the Mahoning County Court, District No. 3, State of Ohio vs. Gerald Poorbaugh, Case No. 99CRB149, dated June 1, 1999.
- (8) Exhibit 1G--Copy of Renewal Application for DDD License No. 02-0079650 for a Terminal Distributor of Dangerous Drugs License from January 1, 1999, to December 31, 1999, of Gromoll Drug Store, Inc. dated October 17, 1998.
- (9) Exhibit 2--Twenty-five prescriptions numbered as follows: 4048941, 6260757, 4047163 with transaction number 000000, 2005722, 4047163 with transaction number 067877, 4047164, 4049014, 2005721, 6261127, 4049009, 6261097, 2005718, 2005720, 2005719, 4048996, 4048994, 6260944, 2005717, 4048978, 6260789, 4048949, 2005703, 2005704, 4048924, and 2005707.
- (10) Exhibit 3--Two-page copy of Renewal Application for Pharmacist License No. 03-1-08325 for a license to practice pharmacy in Ohio from September 15, 1998, to September 15, 1999, of Gerald R. Poorbaugh dated August 5, 1998.
- (11) Exhibit 3A--Copy of Notice of Unacceptable C.P.E. Report Form of Gerald R. Poorbaugh dated September 9, 1998; and copy of Continuing Pharmacy Education Report Form of Gerald R. Poorbaugh dated August 28, 1998, and received September 9, 1998.
- (12) Exhibit 3B--Copy of letter from William F. McMillen dated September 28, 1998, and Notice of Unacceptable C.P.E. Report Form of Gerald R. Poorbaugh dated September 28, 1998.
- (13) Exhibit 3C--Copy of Continuing Pharmacy Education Report Form of Gerald R. Poorbaugh dated August 28, 1998, showing that Mr. Poorbaugh cleared the audit on October 13, 1998.
- (14) Exhibit 3D--Copy of payment stub portion of Gerald R. Poorbaugh's Annual Pharmacist License Renewal, No. 03-1-08325, for licensure period September 15, 1998, to September 15, 1999; and copy of Pharmacist's Computer Record Print-out of Gerald R. Poorbaugh, License No. 03-1-08325, dated December 29, 1998.

- (15) Exhibit 4A--Copy of five-page Dangerous Drug Distributor Inspection Report of Gromoll Drug Store, Terminal Distributor No. 02-079650, dated February 18, 1992; copy of letter from Gerald R. Poorbaugh dated March 2, 1992; copy of Work Order Invoice for Gromoll Drug dated February 18, 1992; copy of DEA Form 106-Report of Theft or Loss of Controlled Substances (received in the Board office on or about March 9, 1992); and copy of four-page DEA Controlled Substance Inventory of Gromoll Drug dated February 25, 1992.
- (16) Exhibit 4B--Inspector copy of seven-page Dangerous Drug Distributor Inspection Report of Gromoll Drug Store, Terminal Distributor No. 02-0079650, dated September 30, 1998.
- (17) Exhibit 4C--Inspector copy of three-page Dangerous Drug Distributor Inspection Report of Gromoll Drug Store, Terminal Distributor No. 02-0079650, dated November 27, 1998.
- (18) Exhibit 4D--Inspector copy of Dangerous Drug Distributor Inspection Report of Gromoll Drug Store, Terminal Distributor No. 02-0079650, dated January 21, 1999.
- (19) Exhibit 5--Twenty-eight Accountability Statements of Gromoll Drug, Terminal Distributor No. 02-0079650, dated December 28, 1998, for the following drugs: Daypro 600mg, Hytrin Cap 1mg, Hytrin 2mg, Hytrin 5mg, Hytrin 10mg, Lotensin HCT 20/12.5, Lotensin HCT 20/25, Lotensin 5mg, Lotensin 10mg, Lotensin 40mg, Lotrel cap 2.5/10, Lotrel cap 5/10, Lotrel cap 5/20, Norvasc 2.5mg, Norvasc 5mg, Norvasc 10mg, Serzone 50mg, Serzone 100mg, Serzone 150mg, Serzone 200mg, Serzone 250mg, Covera HS tab 180mg, Covera HS tab 240mg, Calan SR caplet 180mg, Calan SR caplet 240mg, Isoptin SR tab 180mg, Verelan cap 180mg, and Verelan 240mg; one Accountability Statement of Gromoll Drug, Terminal Distributor No. 02-0079650, dated December 28, 1998, for the following drugs (combined): Calan SR caplet 180mg, Isoptin SR 180mg, Covera HS 180mg, and Verelan 180mg; and one Accountability Statements of Gromoll Drug, Terminal Distributor No. 02-0079650, dated December 28, 1998, for the following drugs (combined): Calan SR 240mg, Verelan 240mg, and Covera HS 240mg.
- (20) Exhibit 6--Two-page handwritten Statement of Gerald Poorbaugh dated January 21, 1999.
- (21) Exhibit 7--Notarized letter from John J. Lenzi dated January 29, 1999, with attached notarized list of Dr. Dichter's Prescription Reimbursement.
- (22) Exhibit 8--Four-page certified copy of "Judgment Entry of Conviction" in the Mahoning County Court, District No. 3; State of Ohio vs. Gerald Poorbaugh, dated June 1, 1999.

Respondent's Exhibits:

- (1) None

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 Board of Pharmacy indicate that Gerald R. Poorbaugh was originally licensed in the state of Ohio on March 2, 1965, pursuant to examination, and is the Responsible Pharmacist at Gromoll Drug Store pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-9-11 of the Ohio Administrative Code.
- (2) Gerald R. Poorbaugh did, on or about September 15, 1998, through September 29, 1998, compound, dispense, or sell dangerous drugs or otherwise engage in the practice of pharmacy, while not licensed to do so, to wit: Gerald R. Poorbaugh continued to practice pharmacy after his license had lapsed. Such conduct is in violation of Section 4729.28 of the Ohio Revised Code.
- (3) Gerald R. Poorbaugh did, on or about September 30, 1998, despite receiving a pink inspection sheet on February 18, 1992, permit persons other than a registered pharmacist to possess keys to a pharmacy which was not secured by a physical barricade when personal supervision of the dangerous drug stock was not provided, to wit: Gerald R. Poorbaugh allowed two store employees, not

registered pharmacists, to possess keys to the pharmacy. Such conduct is in violation of Section 4729.27 of the Ohio Revised Code and Rule 4729-9-11 of the Ohio Administrative Code.

- (4) Gerald R. Poorbaugh did, on or about September 30, 1998, and dates immediately preceding, fail to maintain the minimum standards for a pharmacy, to wit: Gerald R. Poorbaugh, as responsible pharmacist at Gromoll Drug Store, did not possess a copy of the current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio. Such conduct is in violation of Rule 4729-9-02 of the Ohio Administrative Code.
- (5) Gerald R. Poorbaugh did, on or about the period of September 1, 1997, through September 30, 1998, fail to record the name of the person from whom dangerous drugs were received and the date of receipt; and the name and residence of each person to whom dangerous drugs were sold, the description of the dangerous drugs sold to each person, and the date the dangerous drugs were sold, to wit: the drug audit conducted at Gromoll Drug Store on December 28, 1998, showed overages for the following dangerous drugs:

<u>Drug</u>	<u>Strength</u>	<u>Overage Doses</u>	<u>% of Purchased Stock</u>
Daypro	600mg	8,972	46%
Hytrin Caps	1mg	33	33%
Hytrin Caps	2mg	1,329	222%
Hytrin Caps	5mg	1,287	36%
Hytrin Caps	10mg	290	32%
Lotensin HCT 20	12.5mg	240	17%
Lotensin	5mg	515	21%
Lotensin	10mg	1,536	22%
Lotensin	40mg	218	15%
Lotrel Caps 2.5	10mg	220	37%
Lotrel Caps 5	10mg	225	45%
Lotrel Caps 5	20mg	60	7%
Norvasc	2.5mg	288	36%
Norvasc	5mg	4,010	23%
Norvasc	10mg	994	32%
Serzone	50mg	20	33%
Serzone	100mg	470	87%
Serzone	150mg	694	39%
Serzone	200mg	480	36%
Serzone	250mg	90	150%
Covera HS	180mg	837	60%
Covera HS	240mg	1,190	63%
Calan SR Caplets	180mg	61	61%
Calan SR Caplets	240mg	1,441	51%
Isoptin SR	180mg	90	15%
Verelan	180mg	210	21%
Verelan	240mg	580	18%

Such conduct is in violation of Sections 3719.07(C)(3) and 4729.37 of the Ohio Revised Code and Rule 4729-9-14 of the Ohio Administrative Code.

- (6) Gerald R. Poorbaugh did, on or prior to September 30, 1998, and dates immediately preceding, knowingly furnish another a sample drug, to wit: Gerald R. Poorbaugh admitted accepting drug samples from Dr. Dichter, valued at approximately \$20,000.00, and selling the samples at retail using the retail stock NDC numbers for the sales. Gerald R. Poorbaugh was subsequently convicted of One Count of Illegal Dispensing of Drug Samples, a Second Degree Misdemeanor. State of Ohio vs. Gerald Poorbaugh, R.Ph., Case No. 99CRB149, Mahoning County Court District No. 3, dated June 1, 1999. Such conduct is in violation of Section 2925.36(A) of the Ohio Revised Code and Rule 4729-9-13 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 (2) through (5) of the Findings of Fact constitute being guilty of dishonesty and unprofessional conduct in the practice of pharmacy as provided in Division (A)(2) of Section 4729.16 of the Ohio Revised Code.
- (2) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (6) of the Findings of Fact constitutes having been convicted of a misdemeanor related to, or committed in, the practice of pharmacy as provided in Division (A)(4) of Section 4729.16 of the Ohio Revised Code.
- (3) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (5) of the Findings of Fact constitute being guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of provisions of Chapter 3719. or 4729. of the Revised Code as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.

ACTION OF THE BOARD

Pursuant to Section 4729.16 of the Ohio Revised Code, the State Board of Pharmacy takes the following actions in the matter of Gerald R. Poorbaugh:

- (A) On the basis of the Findings of Fact and paragraphs (1) and (2) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby suspends the pharmacist identification card, No. 03-1-08325, held by Gerald R. Poorbaugh for thirty days.
- (B) Further, the Board stays the suspension and places Gerald R. Poorbaugh's identification card on probation for two years, effective as of the date of the mailing of this Order. The terms of probation are as follows:
 - (1) The State Board of pharmacy hereby declares that Gerald R. Poorbaugh's pharmacist identification card is not in good standing and thereby denies the privilege of being a preceptor and training pharmacy interns pursuant to paragraph (D)(1) of Rule 4729-3-01 of the Ohio Administrative Code.
 - (2) Gerald R. Poorbaugh must not violate the drug laws of the state of Ohio, any other state, or the federal government.
 - (3) Gerald R. Poorbaugh must abide by the rules of the State Board of Pharmacy.
 - (4) Gerald R. Poorbaugh must comply with the terms of this Order.
- (C) On the basis of the Findings of Fact and paragraph (3) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby imposes a monetary penalty of two thousand five hundred dollars (\$2,500.00) due and owing within thirty days of the issuance of this Order. The monetary penalty should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, Ohio 43266-0320.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mr. Littlejohn and approved by the Board (Aye-7/Nay-0).

1:40 p.m.

RES. 2000-083 Mr. Littlejohn then moved that the Board adopt the following Order in the matter of Gromoll Drug Store:

ORDER OF THE STATE BOARD OF PHARMACY
(Docket No. D-990914-021)

In The Matter Of:

GROMOLL DRUG STORE
c/o Gerald R. Poorbaugh, R.Ph.
109 East Ohio Avenue
Sebring, Ohio 44672
(Terminal Distributor No. 02-0079650)

INTRODUCTION

THE MATTER OF GROMOLL DRUG STORE CAME TO HEARING ON NOVEMBER 10, 1999, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: ROBERT B. CAVENDISH, R.Ph. (presiding); ANN D. ABELE, R.Ph.; DIANE C. ADELMAN, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; LAWRENCE J. KOST, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; SUZANNE L. NEUBER, R.Ph.; AND NICHOLAS R. REPKE, PUBLIC MEMBER.

GROMOLL DRUG STORE WAS NOT REPRESENTED BY COUNSEL, AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) George Pavlich, Ohio State Board of Pharmacy

Respondent's Witnesses:

- (1) Gerald Poorbaugh, R.Ph., Respondent
(2) Karen Ellen Poorbaugh, Wife of Respondent
(3) Raymond J. Poorbaugh, Pharmacy Intern, Son of Respondent

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- (13) Exhibit 3C--Copy of Continuing Pharmacy Education Report Form of Gerald R. Poorbaugh dated August 28, 1998, showing that Mr. Poorbaugh cleared the audit on October 13, 1998.
- (14) Exhibit 3D--Copy of payment stub portion of Gerald R. Poorbaugh's Annual Pharmacist License Renewal, No. 03-1-08325, for licensure period September 15, 1998, to September 15, 1999; and copy of Pharmacist's Computer Record Printout of Gerald R. Poorbaugh, License No. 03-1-08325, dated December 29, 1998.
- (15) Exhibit 4A--Copy of five-page Dangerous Drug Distributor Inspection Report of Gromoll Drug Store, Terminal Distributor No. 02-079650, dated February 18, 1992; copy of letter from Gerald R. Poorbaugh dated March 2, 1992; copy of Work Order Invoice for Gromoll Drug dated February 18, 1992; copy of DEA Form 106-Report of Theft or Loss of Controlled Substances (received in the Board office on or about March 9, 1992); and copy of four-page DEA Controlled Substance Inventory of Gromoll Drug dated February 25, 1992.
- (16) Exhibit 4B--Inspector copy of seven-page Dangerous Drug Distributor Inspection Report of Gromoll Drug Store, Terminal Distributor No. 02-0079650, dated September 30, 1998.
- (17) Exhibit 4C--Inspector copy of three-page Dangerous Drug Distributor Inspection Report of Gromoll Drug Store, Terminal Distributor No. 02-0079650, dated November 27, 1998.
- (18) Exhibit 4D--Inspector copy of Dangerous Drug Distributor Inspection Report of Gromoll Drug Store, Terminal Distributor No. 02-0079650, dated January 21, 1999.
- (19) Exhibit 5--Twenty-eight Accountability Statements of Gromoll Drug, Terminal Distributor No. 02-0079650, dated December 28, 1998, for the following drugs: Daypro 600mg, Hytrin Cap 1mg, Hytrin 2mg, Hytrin 5mg, Hytrin 10mg, Lotensin HCT 20/12.5, Lotensin HCT 20/25, Lotensin 5mg, Lotensin 10mg, Lotensin 40mg, Lotrel cap 2.5/10, Lotrel cap 5/10, Lotrel cap 5/20, Norvasc 2.5mg, Norvasc 5mg, Norvasc 10mg, Serzone 50mg, Serzone 100mg, Serzone 150mg, Serzone 200mg, Serzone 250mg, Covera HS tab 180mg, Covera HS tab 240mg, Calan SR caplet 180mg, Calan SR caplet 240mg, Isoptin SR tab 180mg, Verelan cap 180mg, and Verelan 240mg; one Accountability Statement of Gromoll Drug, Terminal Distributor No. 02-0079650, dated December 28, 1998, for the following drugs (combined): Calan SR caplet 180mg, Isoptin SR 180mg, Covera HS 180mg, and Verelan 180mg; and one Accountability Statements of Gromoll Drug, Terminal Distributor No. 02-0079650, dated December 28, 1998, for the following drugs (combined): Calan SR 240mg, Verelan 240mg, and Covera HS 240mg.
- (20) Exhibit 6--Two-page handwritten Statement of Gerald Poorbaugh dated January 21, 1999.
- (21) Exhibit 7--Notarized letter from John J. Lenzi dated January 29, 1999, with attached notarized list of Dr. Dichter's Prescription Reimbursement.
- (22) Exhibit 8--Four-page certified copy of "Judgment Entry of Conviction" in the Mahoning County Court, District No. 3; State of Ohio vs. Gerald Poorbaugh, dated June 1, 1999.

Respondent's Exhibits:

- (1) None

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 Ohio State Board of Pharmacy indicate that Gerald R. Poorbaugh is the Responsible Pharmacist at Gromoll Drug Store pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-9-11 of the Ohio Administrative Code.
- (2) Gromoll Drug Store did, on or about September 15, 1998, through September 29, 1998, allow a person who was not a pharmacist or pharmacy intern under the personal supervision of a pharmacist to compound, dispense, or sell dangerous drugs or otherwise engage in the practice of pharmacy, to wit: Gerald R. Poorbaugh practiced pharmacy at Gromoll Drug Store after his license lapsed on September 15, 1998. Such conduct is in violation of Section 4729.28 of the Ohio Revised Code and Rule 4729-5-25 of the Ohio Administrative Code.
- (3) Gromoll Drug Store did, on or about September 30, 1998, despite receiving a written warning on February 18, 1992, permit persons other than a registered pharmacist to possess keys to a pharmacy which was not secured by a physical barricade when personal supervision of the dangerous drug stock was not provided, to wit: Gromoll Drug Store allowed two store employees, not registered pharmacists, to possess keys to the pharmacy. Such conduct is in violation of Rule 4729-9-11 of the Ohio Administrative Code.
- (4) Gromoll Drug Store did, on or about September 30, 1998, and dates immediately preceding, fail to maintain the minimum standards for a pharmacy, to wit: Gromoll Drug Store did not possess a copy of the current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio. Such conduct is in violation of Rule 4729-9-02 of the Ohio Administrative Code.
- (5) Gromoll Drug Store did, on or about the period of September 1, 1997, through September 30, 1998, fail to record the name of the person from whom dangerous drugs were received and the date of receipt; and the name and residence of each person to whom dangerous drugs were sold, the description of the dangerous drugs sold to each person, and the date the dangerous drugs were sold, to wit: Gromoll Drug Store's audit conducted on December 28, 1998, showed overages for the following dangerous drugs:

<u>Drug</u>	<u>Strength</u>	<u>Overage Doses</u>	<u>% of Purchased Stock</u>
Daypro	600mg	8,972	46%
Hytrin Caps	1mg	33	33%
Hytrin Caps	2mg	1,329	222%
Hytrin Caps	5mg	1,287	36%
Hytrin Caps	10mg	290	32%
Lotensin HCT 20	12.5mg	240	17%
Lotensin	5mg	515	21%
Lotensin	10mg	1,536	22%
Lotensin	40mg	218	15%
Lotrel Caps 2.5	10mg	220	37%
Lotrel Caps 5	10mg	225	45%
Lotrel Caps 5	20mg	60	7%
Norvasc	2.5mg	288	36%
Norvasc	5mg	4,010	23%
Norvasc	10mg	994	32%
Serzone	50mg	20	33%
Serzone	100mg	470	87%
Serzone	150mg	694	39%
Serzone	200mg	480	36%
Serzone	250mg	90	150%
Covera HS	180mg	837	60%
Covera HS	240mg	1,190	63%

Calan SR Caplets	180mg	61	61%
Calan SR Caplets	240mg	1,441	51%
Isoptin SR	180mg	90	15%
Verelan	180mg	210	21%
Verelan	240mg	580	18%

Such conduct is in violation of Sections 3719.07(C)(3) and 4729.37 of the Ohio Revised Code and Rule 4729-9-14 of the Ohio Administrative Code.

- (6) Gromoll Drug Store did, on or prior to September 30, 1998, knowingly furnish another a sample drug, to wit: Gerald R. Poorbaugh or someone under his supervision admitted to accepting drug samples from Dr. Dichter valued at approximately \$20,000.00, and then selling the samples at retail, using the retail stock NDC numbers for the sales. Gerald R. Poorbaugh, Responsible Pharmacist of Gromoll Drug Store, was subsequently convicted of One Count of Illegal Dispensing of Drug Samples, a Second Degree Misdemeanor. State of Ohio vs. Gerald Poorbaugh, R.Ph., Case No. 99CRB149, Mahoning County Court District No. 3, dated June 1, 1999. Such conduct is in violation of Section 2925.36 of the Ohio Revised Code.

CONCLUSIONS OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (5) of the Findings of Fact constitute violating a 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 (2), (4), and (5) of the Findings of Fact constitute violating 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 paragraphs (5) and (6) of the Findings of Fact constitute violating provisions of the federal narcotic law or Chapter 2925. or 3719. of the Revised Code as provided in Division (A)(5) of Section 4729.57 of the Ohio Revised Code.
- (4) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (4) of the Findings of Fact constitutes ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in Section 4729.55 of the Revised Code 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 Gromoll Drug Store:

- (A) On the basis of the Findings of Fact and Conclusions of Law set forth above, the State Board of Pharmacy hereby imposes a monetary penalty of two thousand five hundred dollars (\$2,500.00) due and owing within thirty days of the issuance of this Order. The monetary penalty should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, Ohio 43266-0320.
- (B) Further, an inspection will be conducted at Gromoll Drug Store within one year from the date of this Order to determine that adequate safeguards are assured to prevent the recurrence of such violations, and that the pharmacy is in compliance with all federal and state laws and regulations governing the legal distribution of drugs.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mrs. Neuber and approved by the Board (Aye-7/Nay-0).

1:43 p.m.

Ms. Abele moved that the Minutes of the October 4, 5, and 6, 1999 meeting be approved as amended. The motion was seconded by Mr. Littlejohn and approved by the Board (Aye-7/Nay-0).

Mr. Repke presented the probation report. There were no issues requiring Board action.

Ms. Abele reported that the Nursing Board's Formulary Committee was to meet on November 17, 1999 and that Mrs. Neuber would be attending in her place.

1:55 p.m.

RES. 2000-084

Mrs. Neuber moved that the Board approve the following rules for filing with the appropriate agencies in anticipation of their implementation by the Board:

4729-5-13 Prescription format.

EXCEPT AS PROVIDED IN RULE 4729-5-14 OF THE ADMINISTRATIVE CODE:

- (A) No pharmacist shall dispense dangerous drugs pursuant to a written outpatient prescription unless the following conditions are met:
 - (1) The prescription is issued in compliance with rule 4729-5-30 of the Administrative Code.
 - (2) If preprinted with multiple drug name and strength combinations:
 - (a) There are no controlled substances among the choices;
 - (b) There is only one prescription order selected per form.
- (B) No prescriber shall write and no pharmacist shall dispense controlled substances pursuant to a written outpatient prescription unless the following conditions are met:
 - (1) The prescription has been issued in compliance with rule 4729-5-30 of the Administrative Code.
 - (2) The prescription contains only one prescription order per prescription form, whether handwritten or preprinted.
 - (3) The quantity has been written both numerically and alphabetically.
 - (4) If preprinted, there is only one drug and strength combination printed on the form.
- (C) A prescription issued by a medical intern, resident, or fellow as defined in paragraph (B) of rule 4729-5-15 of the Administrative Code may not be dispensed unless the prescription is issued in compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 of the Administrative Code.
- (D) A prescription issued by a staff prescriber of a hospital may not be dispensed unless the prescription is issued in compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 of the Administrative Code.

4729-5-14 PRESCRIPTION FORMAT FOR A HOSPICE OUTPATIENT STARTER KIT.

- (A) FOR PURPOSES OF PREPRINTED PRESCRIPTIONS FOR HOSPICE OUTPATIENT STARTER KITS, THE FOLLOWING CONDITIONS APPLY:
- (1) NON-CONTROLLED DANGEROUS DRUGS MAY HAVE MULTIPLE ORDERS ON ONE SHEET AND THE PRESCRIBER MAY SELECT AS MANY DRUG ORDERS AS NECESSARY. THESE SHEETS MAY NOT CONTAIN ORDERS FOR ANY CONTROLLED SUBSTANCES. ORDERS FOR NON-CONTROLLED DANGEROUS DRUGS MAY BE MANUALLY ADDED TO THIS PREPRINTED SHEET.
 - (2) FOR CONTROLLED SUBSTANCES:
 - (a) THE PREPRINTED SHEET MAY HAVE MULTIPLE ORDERS ON ONE SHEET AND THE PRESCRIBER MAY SELECT AS MANY DRUG ORDERS AS NECESSARY FOR SCHEDULE III, IV, AND V DRUGS. NO ADDITIONAL ORDERS MAY BE MANUALLY ADDED TO THIS SHEET.
 - (b) PREPRINTED SHEETS CANNOT BE USED FOR SCHEDULE II DRUGS. ALL ORDERS FOR SCHEDULE II DRUGS MUST BE ORIGINAL, SIGNED PRESCRIPTIONS.
- (B) ALL ORDERS ON PREPRINTED STARTER KIT FORMS MAY NOT EXCEED A SEVENTY-TWO-HOUR SUPPLY OF EACH MEDICATION.
- (C) THE PRESCRIBER MUST MANUALLY INDICATE ON EACH PREPRINTED SHEET THE TOTAL NUMBER OF ORDERS FOR THAT SHEET.

4729-5-17 Labeling by prescribers who personally furnish dangerous drugs to their patients.

- (A) Whenever a prescriber personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, the prescriber shall affix to the container a label showing:
- (1) The name and address of the prescriber.
 - (2) The name of the patient for whom the drug is intended. If the patient is an animal, the name of the owner and ~~the species~~ IDENTIFICATION of the animal.
 - (3) Name and strength of the dangerous drug.
 - (4) Directions for use.
 - (5) Date furnished.
- (B) Whenever a prescriber personally furnishes a dangerous drug, labeled as a sample pursuant to section 3719.81 of the Revised Code and where the directions for use are different from the directions on or in the sample container, the prescriber shall also provide, in written format, the following:
- (1) Name of the prescriber.
 - (2) Name of the patient. If the patient is an animal, the name of the owner and ~~the species~~ IDENTIFICATION of the animal.
 - (3) Directions for use.

4729-5-30 Manner of issuance of prescription.

- (A) A prescription, to be effective, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding

responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law.

- (B) All prescriptions shall be dated as of and signed on the day when issued, and shall bear the full name and address of the patient.
- (C) All written prescriptions issued by a prescriber shall bear the full name and address of the prescriber and shall be manually signed by the prescriber in the same manner as he/she would sign a check or legal document.
- (D) An original signed prescription (for other than a schedule II controlled substance except as noted in paragraph (N) of this rule and rules 4729-17-09 and 4729-19-02 of the Administrative Code) may be transmitted as an "other means of communication" to a pharmacist PHARMACY by the use of a facsimile machine only by a prescriber or the prescriber's agent. Such a facsimile shall only be valid as a prescription if a system is in place that will allow the pharmacist to maintain the facsimile as a part of the prescription record including the positive identification of the prescriber and his/her agent as well as positive identification of the origin of the facsimile. The pharmacist must record the prescription in writing pursuant to section 4729.37 of the Revised Code or store the facsimile copy in such a manner that will allow retention of the prescription record for three years from the date of the last transaction. The original signed prescription from which the facsimile is produced shall not be issued to the patient. The original signed prescription must remain with the patient's records at the prescriber's office or the institutional facility where it was issued. IF A BOARD-APPROVED ELECTRONIC PRESCRIPTION TRANSMISSION SYSTEM IS USED TO FAX THE PRESCRIPTION, THE COMPUTER DATA MUST BE RETAINED FOR A PERIOD OF THREE YEARS AT THE PRESCRIBER'S OFFICE. A facsimile of a prescription received by a pharmacist PHARMACY in any manner other than transmission directly from the prescriber or the prescriber's agent shall not be considered a valid prescription, except as a copy of a prescription pursuant to rule 4729-5-24 of the Administrative Code.
- (E) All prescriptions shall specify the number of times or the period of time for which the prescription may be refilled. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.
- (F) Prescriptions for dangerous drugs may not be dispensed for the first time beyond six months from the date of issuance by a prescriber.
- (G) Prescriptions for dangerous drugs and controlled substances in schedule V may not be authorized for refill beyond one year from the date of issuance. Prescriptions for controlled substances in schedules III and IV shall be authorized for refill only as permitted by section 3719.05 of the Revised Code. Prescriptions for controlled substances in schedule II may not be refilled.
- (H) A prescription may be refilled only as expressly authorized by the prescriber, either in writing or orally. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.281 of the Revised Code.
- (I) The drug(s) in a compounded prescription or drug product shall be identified by the product trade name or generic name.
- (J) No prescription shall be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice. A "coded prescription" is one which bears letters, numbers, words or symbols, or any other device used in lieu of the name, quantity, strength and directions for its use, other than those normal letters, numbers, words, symbols, or other media recognized by the profession of pharmacy as a means of conveying information by prescription. No symbol, word, or any other device shall be used in lieu of the name of said preparation.
- (K) The agent of a prescriber who transfers a facsimile of an original prescription or transmits an oral prescription or authorization of a refill for a dangerous drug must identify themselves by full name and the pharmacist shall make a record of the

prescriber's agent on the original prescription and, if used, on the alternate system of recordkeeping. A pharmacist who modifies a patient's drug therapy, pursuant to a consult agreement, must personally transmit the facsimile or oral order to another pharmacist, if the drug is not dispensed by the pharmacist who modified the drug order.

- (L) When forms are used that create multiple copies of a prescription issued to a patient by a prescriber, the original prescription which also bears the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.
- (M) A pharmacist may accept, without further verification of the prescriber's identity required, a prescription that has been transmitted by means of a ~~board approved~~ BOARD-APPROVED automated paperless system. The system shall require positive identification of the prescriber as defined in rule 4729-5-01 of the Administrative Code as well as the full name of any authorized agent of the prescriber who transmits the prescription.
- (N) A schedule II controlled substance prescription for a narcotic substance issued for a patient enrolled in a hospice may be transmitted by the prescriber or the prescriber's agent to the pharmacy by facsimile. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must meet all of the requirements in paragraph (D) of this rule for such a prescription.
- (O) When a pharmacist, acting as an agent of the physician, modifies a patient's drug therapy pursuant to a consult agreement, the pharmacist must comply with this rule in the same manner as a prescriber and include the name of the physician who originally prescribed the drug and sign the pharmacist's full name.
- (P) A PRESCRIPTION ORALLY TRANSMITTED BY TELEPHONE TO A PHARMACY BY A PRESCRIBER OR THE PRESCRIBER'S AGENT MAY BE PLACED ON A RECORDING DEVICE AT THE PHARMACY IF THE PHARMACIST IS UNAVAILABLE. THE PRESCRIBER OR PRESCRIBER'S AGENT MUST PROVIDE HIS/HER COMPLETE NAME. THE PHARMACIST MUST REMOVE THE PRESCRIPTION FROM THE RECORDER AND REDUCE IT TO WRITING. THE PHARMACIST IS RESPONSIBLE FOR ASSURING THE VALIDITY OF THE PRESCRIPTION REMOVED FROM THE RECORDER.

4729-5-33 Criteria for re-licensure by reciprocity.

A person who has been registered as a pharmacist pursuant to section 4729.07 or 4729.09 of the Revised Code, and whose identification card has lapsed, may obtain an identification card to practice pharmacy in Ohio pursuant to section 4729.09 of the Revised Code provided he/she:

- (A) Submits evidence of having ~~obtained four and one-half "C.E.U.s" of approved continuing pharmacy education pursuant to Chapter 4729-7~~ MET THE REQUIREMENTS OF RULE 4729-7-02 of the Administrative Code during the three-year period immediately preceding the date of application; or
- (B) Is reciprocating from a state where continuing pharmacy education is mandatory and submits evidence of having met the continuing pharmacy education requirements of that state.

4729-9-14 Records of controlled substances.

- (A) Each prescriber or terminal distributor of dangerous drugs shall keep a record of all controlled substances received, administered, dispensed, sold, or used.
 - (1) Records of receipt shall contain a description of all controlled substances received, the kind and quantity of controlled substances received, the name and address of the persons from whom received, and the date of receipt.

- (2) Records of administering, dispensing, or using controlled substances shall contain a description of the kind and quantity of the controlled substance administered, dispensed, or used, the date, the name and address of the person to whom, or for whose use, or the owner and ~~species~~ IDENTIFICATION of the animal for which, the controlled substance was administered, dispensed, or used.
 - (3) Records of drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the name and address requirements of paragraph (A)(2) of this rule.
- (B) Each prescriber or terminal distributor of dangerous drugs shall maintain an inventory of all controlled substances as follows:
- (1) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.
 - (a) The name of the substance.
 - (b) The total quantity of the substance.
 - (i) Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter).
 - (ii) The number of units or volume of each finished form in each commercial container (e.g., one-hundred-tablet bottle or ten-milliliter vial).
 - (iii) The number of commercial containers of each such finished form (e.g., three one-hundred-tablet bottles or ten one-milliliter vials).
 - (c) If the substance is listed in schedule I or II, the prescriber or terminal distributor of dangerous drugs shall make an exact count or measure of the contents.
 - (d) If the substance is listed in schedule III, IV, or V, the prescriber or terminal distributor of dangerous drugs shall make an estimated count or measure of the contents, unless the container holds more than one thousand tablets or capsules in which an exact count of the contents must be made.
 - (2) A separate inventory shall be made for each place or establishment where controlled substances are in the possession or under the control of the prescriber or terminal distributor. Each inventory for each place or establishment shall be kept at the place or establishment.
 - (3) An inventory of all stocks of controlled substances on hand on the date the prescriber or terminal distributor first engages in the administering, dispensing, or use of controlled substances. In the event the prescriber or terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory.
 - (4) Each prescriber or terminal distributor of dangerous drugs shall take a new inventory of all stocks of controlled substances on hand every two years following the date on which the initial inventory is taken.
 - (5) When a substance is added to the schedule of controlled substances by the federal drug enforcement administration or the state board of pharmacy, each prescriber or terminal distributor of dangerous drugs shall take an inventory of all stock of such substance on hand at that time.
 - (6) All records of receipt, distribution, administering, dispensing, inventory, or using controlled substances shall be kept for a period of three years at the place where the controlled substances are located. Any prescriber or terminal distributor of dangerous drugs intending to maintain such records at a location

other than this place must first send notification to the state board of pharmacy; if not contested by the board within sixty days, it will stand as approved.

4729-9-22 Records of dangerous drugs.

Each prescriber or terminal distributor of dangerous drugs shall keep a record of all dangerous drugs received, administered, dispensed, distributed, sold, or used.

- (A) Records of receipt shall contain a description of all dangerous drugs received, the kind and quantity of dangerous drugs received, the name and address of the persons from whom received, and the date of receipt.
- (B) Records of administering, dispensing, or using dangerous drugs shall contain a description of the kind and quantity of the dangerous drugs administered, dispensed, sold, or used, the date, the name and address of the person to whom, or for whose use, or the owner and ~~species~~ IDENTIFICATION of the animal for which, the dangerous drug was administered, dispensed, or used.
- (C) Records of dangerous drugs, other than controlled substances, administered, dispensed, or used which become a permanent part of the patient's medical record shall be deemed to meet the requirements of paragraph (B) of this rule.
- (D) All records of receipt, distribution, administering, dispensing, selling, or using dangerous drugs shall be kept for a period of three years at the place where the dangerous drugs are located. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send notification to the state board of pharmacy by certified mail, return receipt requested; if not contested by the board within sixty days, it will stand as approved. A copy of the request with the return receipt shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor.

4729-11-01 Controlled substance schedule I.

4729-11-02 Controlled substance schedule II.

4729-11-03 Controlled substance schedule III.

4729-11-04 Controlled substance schedule IV.

Rules 4729-11-01 through 4729-11-04 are proposed to be rescinded to remove duplication of the Revised Code. These rules were adopted and effective in 1978. The rescission of these rules will NOT affect the "Ohio's Schedules of Controlled Substances" list as it is currently in effect.

4729-11-09 Sale of schedule V controlled substance products without a prescription.

A schedule V controlled substance product which is not a prescription drug as determined under the "Federal Food, Drug and Cosmetic Act" may be sold at retail by a pharmacist without a prescription to a purchaser at retail; provided that:

- (A) The sale is made only by a pharmacist OR A PHARMACY INTERN UNDER THE DIRECT SUPERVISION OF A PHARMACIST and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities in this section, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist).
- (B) The purchaser is at least eighteen years of age.
- (C) The pharmacist requires every purchaser of a controlled substance under this rule not known to him to furnish suitable identification (including proof of age where appropriate).

- (D) A bound record book is maintained which contains the true name and complete address of the purchaser, the legible signature of the purchaser, the name and quantity of controlled substances sold, the date of each sale, and the name and legible initials of the pharmacist who sold the controlled substance at retail. This book shall be maintained for a period of three years from the date of the last transaction and must be made available for inspection and copying by persons authorized to enforce the federal and state drug laws.
- (E) The schedule V controlled substance product is sold at retail.
- (F) Not more than two hundred forty milliliters (eight ounces) nor more than forty-eight solid dosage units of any schedule V controlled substance product containing opium, nor more than one hundred twenty milliliters (four ounces) nor more than twenty-four solid dosage units of any other narcotic controlled substance may be sold at retail to the same purchaser in any consecutive forty-eight-hour period.
- (G) Not more than one hundred solid dosage units of any schedule V controlled substance stimulant product may be sold to any one person in any consecutive thirty-day period.
- (H) The schedule V controlled substance is sold at retail for a legitimate medical need and the purchaser furnishes information to the pharmacist which establishes the legitimate medical need for the controlled substance.

4729-12-02 Registration and licensure.

- (A) Any person who manufactures, sells at wholesale or retail, dispenses, imports or exports products containing ephedrine, its salts or isomers, or who proposes to engage in such activities, shall submit an application for registration as a wholesaler of dangerous drugs and controlled substances or for licensure as a category III terminal distributor of dangerous drugs to conduct such activities in accordance with Chapters 3719. and 4729. of the Revised Code.
- (B) THIS SECTION DOES NOT APPLY IF THE EPHEDRINE PRODUCT IS A FOOD PRODUCT OR A DIETARY SUPPLEMENT THAT IS SPECIFICALLY EXCEPTED IN DIVISION (K)(2) OF SECTION 3719.44 OF THE REVISED CODE.

4729-12-03 Security, storage, and sale.

- (A) Schedule V products containing ephedrine may be sold at wholesale or retail, and must be maintained in accordance with Chapters 3719. and 4729. of the Revised Code and Chapters 4729-9 and 4729-11 of the Administrative Code.
- (B) THIS SECTION DOES NOT APPLY IF THE EPHEDRINE PRODUCT IS A FOOD PRODUCT OR A DIETARY SUPPLEMENT THAT IS SPECIFICALLY EXCEPTED IN DIVISION (K)(2) OF SECTION 3719.44 OF THE REVISED CODE.

4729-12-04 Inventory.

- (A) Every registrant or licensee required to keep records who possesses any quantity of ephedrine or schedule V drug products containing ephedrine shall take an inventory pursuant to rules 4729-9-14 and 4729-9-16 of the Administrative Code.
- (B) THIS SECTION DOES NOT APPLY IF THE EPHEDRINE PRODUCT IS A FOOD PRODUCT OR A DIETARY SUPPLEMENT THAT IS SPECIFICALLY EXCEPTED IN DIVISION (K)(2) OF SECTION 3719.44 OF THE REVISED CODE.

4729-12-05 Records.

- (A) All practitioners, registrants, and licensees required to keep records pursuant to Chapter 3719. of the Revised Code and Chapters 4729-9 and 4729-11 of the

Administrative Code shall maintain such records for ephedrine and schedule V drug products containing ephedrine.

- (B) THIS SECTION DOES NOT APPLY IF THE EPHEDRINE PRODUCT IS A FOOD PRODUCT OR A DIETARY SUPPLEMENT THAT IS SPECIFICALLY EXCEPTED IN DIVISION (K)(2) OF SECTION 3719.44 OF THE REVISED CODE.

4729-12-08 Petitions for exception of ephedrine-containing products.

- (A) A petition requesting that a drug product containing ephedrine be excepted by the board of pharmacy from being legally classified as a schedule V controlled substance stimulant may be submitted by any person engaged in the legitimate manufacture or wholesale sale of such products in the United States. The petition shall include the following information:

- ~~(A)~~ (1) Full name, address, and telephone number of the manufacturer.
- ~~(1)~~ (a) If incorporated, the petition must include copies of the incorporation papers and the names, dates of birth, addresses, and social security numbers of the officers of the corporation and all stockholders holding more than ten percent of the stock.
- ~~(2)~~ (b) If a proprietorship, the petition must include the name, address, date of birth, and social security number of the owner(s).
- ~~(3)~~ (c) If a partnership, the petition must include the names, addresses, dates of birth, and social security numbers of the partners.
- ~~(B)~~ (2) A description of the package sizes and the manner of packaging the drug product.
- ~~(C)~~ (3) A limited number of samples of each dosage form marketed in the final marketed packages.
- ~~(D)~~ (4) The manner of distribution, advertising, and promotion of the product, including but not limited to:
- ~~(1)~~ (a) The full name and address of all accounts located in Ohio to which the products have been or will be distributed at wholesale based on other products marketed by the petitioner.
- ~~(2)~~ (b) Copies of all advertisements used to promote the product within the last twelve months shall be included with the petition. A list of the publications in which the advertisements appeared or will appear if not presently marketed. If the product has not yet been marketed, copies of other products marketed by the petitioner shall be submitted with the petition.
- ~~(E)~~ (5) A listing of all ingredients in the product, indicating the quantity of each ingredient, whether or not it has any therapeutic value, and its purpose for being included in the product. Documentation of the therapeutic value of all active ingredients in the product shall be included with the petition.
- ~~(F)~~ (6) A list of all names the product is marketed or will be marketed under in the United States or any other country.
- ~~(G)~~ (7) Any information regarding the product's abuse or potential for abuse in the United States or other countries where the product is marketed or will be marketed under any of the names listed in paragraph ~~(F)~~ (A)(6) of this rule.

- (B) THIS SECTION DOES NOT APPLY IF THE EPHEDRINE PRODUCT IS A FOOD PRODUCT OR A DIETARY SUPPLEMENT THAT IS SPECIFICALLY EXCEPTED IN DIVISION (K)(2) OF SECTION 3719.44 OF THE REVISED CODE.

4729-22-04 Prescriber's order.

Before making an initial sale of medical oxygen to a patient, the retail seller must have an order issued by a person authorized to prescribe oxygen in the course of the prescriber's professional practice. The order must include the full name and address of the patient, the name and address of the prescriber, and documentation of need. THIS ORDER MUST BE RENEWED AT LEAST ANNUALLY.

4729-33-01 DEFINITIONS.

AS USED IN THIS CHAPTER:

- (A) "DANGEROUS DRUG" HAS THE SAME MEANING AS IN SECTION 4729.01 OF THE REVISED CODE.
- (B) "CONTROLLED SUBSTANCE" HAS THE SAME MEANING AS IN SECTION 4729.01 OF THE REVISED CODE.
- (C) "TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS" HAS THE SAME MEANING AS IN SECTION 4729.01 OF THE REVISED CODE.
- (D) "EMERGENCY MEDICAL SERVICE (EMS) ORGANIZATION" HAS THE SAME MEANING AS IN SECTION 4765.01 OF THE REVISED CODE.
- (E) "MUTUAL AID" MEANS A FORMAL AGREEMENT BETWEEN TWO OR MORE EMS ORGANIZATIONS TO ASSIST IN EMERGENCY MEDICAL COVERAGE IN THE OTHER'S USUAL AREA OF COVERAGE INCLUDING HAVING ACCESS TO DANGEROUS DRUGS DURING THE EMERGENCY SITUATION.
- (F) "POSTING UP" MEANS LOCATING AN EMS UNIT CONTAINING DANGEROUS DRUGS AT A LOCATION OTHER THAN A LOCATION LICENSED BY THE BOARD OF PHARMACY.
- (G) "POSTING UP AT A SPECIAL EVENT" MEANS LOCATING AN EMS UNIT CONTAINING DANGEROUS DRUGS AT A LOCATION OTHER THAN A LOCATION LICENSED BY THE BOARD OF PHARMACY PURSUANT TO A FORMAL AGREEMENT WITH THE SPONSORS OF THE SPECIAL EVENT.
- (H) "SPECIAL EVENT" MEANS AN EVENT REQUIRING EMS COVERAGE FOR MORE THAN TWENTY-FOUR HOURS INCLUDING, BUT NOT LIMITED TO, THE FOLLOWING:
 - (1) A COUNTY FAIR.
 - (2) A WEEKEND FESTIVAL.
- (I) "SCOPE OF PRACTICE" SHALL BE AS DEFINED IN SECTION 4765.35 OF THE REVISED CODE FOR A FIRST RESPONDER, SECTION 4765.37 OF THE REVISED CODE FOR AN EMERGENCY MEDICAL TECHNICIAN-BASIC, SECTION 4765.38 OF THE REVISED CODE FOR AN EMERGENCY MEDICAL TECHNICIAN-INTERMEDIATE, AND SECTION 4765.39 OF THE REVISED CODE FOR AN EMERGENCY MEDICAL TECHNICIAN-PARAMEDIC.
- (J) "CERTIFICATION" MEANS THE LEVEL TO WHICH AN INDIVIDUAL IS TRAINED AND LICENSED AS DEFINED IN SECTION 4765.01 OF THE REVISED CODE AND RULE 4765-1-01 OF THE ADMINISTRATIVE CODE.
- (K) "MEDICAL DIRECTOR" HAS THE SAME MEANING AS IN RULE 4765-10-06 OF THE ADMINISTRATIVE CODE.
- (L) "RESPONSIBLE PERSON" HAS THE SAME MEANING AS IN RULE 4729-13-01 OF THE ADMINISTRATIVE CODE.
- (M) "STANDING ORDER" AND "PROTOCOL" HAVE THE SAME MEANINGS AS IN RULE 4729-5-01 OF THE ADMINISTRATIVE CODE.

- (N) "SATELLITE" MEANS AN ADDRESS LICENSED BY THE BOARD AS A TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS THAT IS SEPARATE FROM THE LICENSED HEADQUARTERS ADDRESS OF THE EMS ORGANIZATION.
- (O) "TAMPER-EVIDENT" MEANS THE PACKAGE IS SEALED IN SUCH A WAY THAT ACCESS TO THE DRUGS STORED WITHIN IS NOT POSSIBLE WITHOUT LEAVING VISIBLE PROOF THAT SUCH ACCESS HAS BEEN ATTEMPTED OR MADE.
- (P) "READILY RETRIEVABLE" MEANS ALL RECORDS WHICH ARE REQUIRED TO BE MAINTAINED MUST BE PROVIDED UPON REQUEST TO THE INSPECTOR OR AGENT OF THE BOARD OF PHARMACY WITHIN THREE WORKING DAYS.

4729-33-02 LICENSURE.

- (A) ANY EMERGENCY MEDICAL SERVICE (EMS) ORGANIZATION THAT DESIRES TO STOCK DANGEROUS DRUGS SHALL APPLY FOR AND MAINTAIN A LICENSE AS A TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS. THE ONE LOCATION THAT SERVES AS THE MAIN STATION WILL BE DEEMED THE HEADQUARTERS LOCATION. ANY OTHER LOCATIONS ASSOCIATED WITH THIS HEADQUARTERS WHERE DANGEROUS DRUGS WILL BE STORED WILL BE LICENSED AS "SATELLITES". ONLY THE HEADQUARTERS LOCATION WILL BE CHARGED A LICENSE FEE OR RENEWAL LICENSE FEE.
- (B) EACH LOCATION, HEADQUARTERS AND SATELLITES, MUST BE LICENSED AS A LIMITED TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS AND MUST MAINTAIN A CURRENT TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE AND DRUG ADDENDUM.
- (C) AN APPLICATION FOR LICENSURE MUST INCLUDE ALL OF THE FOLLOWING:
 - (1) A COMPLETED APPLICATION;
 - (2) A COMPILATION OF ALL PROTOCOLS INVOLVING DANGEROUS DRUGS THAT HAVE BEEN SIGNED BY THE MEDICAL DIRECTOR AND NOTARIZED;
 - (3) A LIST OF DRUGS REFERENCED IN THE PROTOCOLS TO BE STOCKED BY THE EMS ORGANIZATION, SIGNED BY THE MEDICAL DIRECTOR AND NOTARIZED;
 - (4) A LIST OF PERSONNEL EMPLOYED BY THE EMS ORGANIZATION WHO MAY ACCESS AND ADMINISTER DANGEROUS DRUGS, WHICH INCLUDES THE NAME OF THE INDIVIDUAL, LEVEL OF CERTIFICATION, THEIR CERTIFICATION NUMBER, AND EXPIRATION DATE;
 - (5) A LIST OF ANY AND ALL FORMAL MUTUAL AID AGREEMENTS WITH OTHER EMS ORGANIZATIONS;
 - (6) THE FEE FOR THE APPROPRIATE CATEGORY OF LICENSURE.
- (D) EACH LOCATION, HEADQUARTERS AND SATELLITE, MAY ONLY POSSESS THOSE DANGEROUS DRUGS THAT ARE LISTED ON THE DRUG ADDENDUM AND ONLY AT LOCATIONS LICENSED BY THE BOARD OF PHARMACY.
 - (1) A MEDICAL DIRECTOR MAY ADD DANGEROUS DRUGS TO THE DRUG LIST BY SUBMITTING REVISED, SIGNED AND NOTARIZED PROTOCOLS AND LIST OF MEDICATIONS, AND THE ADDENDUM UPDATE FEE.
 - (2) A MEDICAL DIRECTOR MAY DELETE DANGEROUS DRUGS FROM THE DRUG LIST BY SUBMITTING A LETTER LISTING THE DRUGS TO BE DELETED.
- (E) A NEW APPLICATION AND FEE IS REQUIRED PRIOR TO ANY CHANGE OF LOCATION, ADDITION OF A SATELLITE LOCATION, CHANGE OF CATEGORY, NAME CHANGE, OR CHANGE OF OWNERSHIP. THESE CHANGES MAY BE MADE DURING THE ANNUAL RENEWAL PERIOD WITH NO ADDITIONAL FEE OTHER THAN THE RENEWAL FEE.
- (F) THE RESPONSIBLE PERSON SHALL PROVIDE SUPERVISION AND CONTROL OF ALL LOCATIONS WHERE DANGEROUS DRUGS ARE STORED. THE RESPONSIBLE PERSON

MUST BE A PHYSICIAN LICENSED PURSUANT TO CHAPTER 4731. OF THE REVISED CODE OR A PHARMACIST LICENSED PURSUANT TO CHAPTER 4729. OF THE REVISED CODE.

- (1) TO CHANGE THE RESPONSIBLE PERSON, THE NEW RESPONSIBLE PERSON MUST COMPLETE AND RETURN A NOTIFICATION OF CHANGE OF RESPONSIBLE PERSON FORM WITHIN THIRTY DAYS.
 - (2) TO CHANGE THE MEDICAL DIRECTOR, THE NEW MEDICAL DIRECTOR MUST SUBMIT A SIGNED AND NOTARIZED LETTER STATING THAT HE/SHE IS ACCEPTING RESPONSIBILITY FOR THE EMS ORGANIZATION.
 - (a) IF THE NEW MEDICAL DIRECTOR APPROVES OF THE CURRENT PROTOCOL AND DRUG LIST, A SIGNED AND NOTARIZED LETTER MUST BE SUBMITTED STATING THE CURRENT PROTOCOLS AND DRUG LIST ON FILE HAVE BEEN REVIEWED AND ARE APPROVED BY THE MEDICAL DIRECTOR FOR USE BY THIS EMS ORGANIZATION, OR
 - (b) IF THE NEW MEDICAL DIRECTOR DESIRES TO CHANGE THE PROTOCOLS OR DRUG LIST, THE MEDICAL DIRECTOR MUST SUBMIT THE REVISED, SIGNED, AND NOTARIZED PROTOCOLS AND DRUG LIST, AND THE ADDENDUM UPDATE FEE.
- (G) ANY CHANGES IN PROTOCOLS THAT INVOLVE DANGEROUS DRUGS MUST BE SUBMITTED TO THE STATE BOARD OF PHARMACY PRIOR TO THE IMPLEMENTATION OF THE PROTOCOLS INVOLVED. THE STATE BOARD OF PHARMACY MAY DISCUSS SUCH PROTOCOLS WITH THE STATE EMERGENCY MEDICAL SERVICES BOARD, STATE MEDICAL BOARD, OR OTHER GOVERNMENTAL AGENCIES AS NEEDED TO ASSURE THEIR VALIDITY.
- (H) ANY CHANGE OF PERSONNEL REQUIRES A LETTER FROM THE ORGANIZATION WITHIN THIRTY DAYS OF THE CHANGE LISTING THE TYPE OF CHANGE (ADDITION, UPDATE, OR DELETION), NAMES OF THE PERSONNEL INVOLVED, LEVEL OF CERTIFICATION, THEIR CERTIFICATION NUMBER, AND EXPIRATION DATE.

4729-33-03 SECURITY AND STORAGE OF DANGEROUS DRUGS.

- (A) OVERALL SUPERVISION AND CONTROL OF DANGEROUS DRUGS IS THE RESPONSIBILITY OF THE RESPONSIBLE PERSON. THE RESPONSIBLE PERSON MAY DELEGATE THE DAY-TO-DAY TASKS TO THE EMERGENCY MEDICAL SERVICE (EMS) ORGANIZATION PERSONNEL WHO HOLD APPROPRIATE CERTIFICATION TO ACCESS THE DANGEROUS DRUGS FOR WHICH THEY ARE RESPONSIBLE.
- (B) ALL DANGEROUS DRUGS MUST BE SECURED IN A TAMPER-EVIDENT SETTING WITH ACCESS LIMITED TO EMS PERSONNEL BASED ON THEIR CERTIFICATION STATUS EXCEPT FOR SEALED, TAMPER-EVIDENT SOLUTIONS LABELED FOR IRRIGATION USE. ALL REGISTRANTS SHALL PROVIDE EFFECTIVE AND APPROVED CONTROLS AND PROCEDURES TO DETER AND DETECT THEFT AND DIVERSION OF DANGEROUS DRUGS.
- (C) ONLY PARAMEDICS, REGISTERED NURSES, PHYSICIANS, AND PHARMACISTS WHO ARE ASSOCIATED WITH THAT EMS ORGANIZATION MAY HAVE ACCESS TO ANY CONTROLLED SUBSTANCES MAINTAINED BY THE EMS ORGANIZATION.
- (D) ADMINISTRATION OF DANGEROUS DRUGS BY AN EMS EMPLOYEE IS LIMITED TO THE SCOPE OF PRACTICE, AS DETERMINED BY THE STATE EMERGENCY MEDICAL SERVICES BOARD, FOR THE INDIVIDUAL'S CERTIFICATION LEVEL AND THE PROTOCOLS AS ESTABLISHED BY THE MEDICAL DIRECTOR OR WHEN THE INDIVIDUAL IS ACTING WITHIN THEIR CERTIFICATION LEVEL PURSUANT TO DIRECT PRESCRIBER'S ORDERS RECEIVED OVER AN ACTIVE COMMUNICATION LINK.
- (E) ALL DANGEROUS DRUGS WILL BE MAINTAINED IN A CLEAN AND TEMPERATURE-CONTROLLED ENVIRONMENT.

- (F) ANY DANGEROUS DRUG THAT REACHES ITS EXPIRATION DATE IS CONSIDERED ADULTERATED AND MUST BE SEPARATED FROM THE ACTIVE STOCK TO PREVENT POSSIBLE ADMINISTRATION TO PATIENTS.
- (G) ANY NON-CONTROLLED DANGEROUS DRUG THAT IS OUTDATED MAY BE RETURNED TO THE SUPPLIER WHERE THE DRUG WAS OBTAINED OR MAY BE DISPOSED OF IN THE PROPER MANNER.
- (H) ANY CONTROLLED SUBSTANCE THAT IS OUTDATED MAY BE RETURNED TO THE SUPPLIER WHERE THE DRUG WAS OBTAINED.
- (I) DESTRUCTION OF OUTDATED CONTROLLED SUBSTANCES MAY ONLY BE DONE BY A STATE BOARD OF PHARMACY AGENT OR BY PRIOR WRITTEN PERMISSION FROM THE STATE BOARD OF PHARMACY OFFICE.
- (J) DESTRUCTION OF PARTIALLY USED CONTROLLED SUBSTANCES CAN BE ACCOMPLISHED, WITH THE APPROPRIATE DOCUMENTATION, BY TWO LICENSED HEALTH CARE PERSONNEL, ONE OF WHICH MUST HAVE AT LEAST A PARAMEDIC LEVEL OF TRAINING.
- (K) ANY LOSS, THEFT, OR TAMPERING OF DANGEROUS DRUGS MUST BE REPORTED UPON DISCOVERY, BY TELEPHONE, TO THE STATE BOARD OF PHARMACY, LOCAL LAW ENFORCEMENT AND, IF CONTROLLED SUBSTANCES ARE INVOLVED, TO THE DRUG ENFORCEMENT ADMINISTRATION. A REPORT MUST BE FILED WITH THE STATE BOARD OF PHARMACY OF ANY LOSS OR THEFT OF THE VEHICLE OR STORAGE CABINETS CONTAINING DANGEROUS DRUGS USED BY THE EMS ORGANIZATION.
- (L) ANY DANGEROUS DRUG SHOWING EVIDENCE OF DAMAGE OR TAMPERING SHALL BE REMOVED FROM STOCK AND REPLACED IMMEDIATELY.

4729-33-04 RECORDKEEPING.

- (A) ALL EMERGENCY MEDICAL SERVICE (EMS) ORGANIZATIONS ARE REQUIRED TO KEEP COMPLETE AND ACCURATE RECORDS FOR AT LEAST THREE YEARS OF RECEIPT, USE, ADMINISTRATION, DESTRUCTION, AND WASTE OF DANGEROUS DRUGS. THESE RECORDS MUST BE READILY AVAILABLE FOR INSPECTION BY STATE BOARD OF PHARMACY AGENTS OR INSPECTORS AS PER SECTION 3719.27 OF THE REVISED CODE AND RULE 4729-5-29 OF THE ADMINISTRATIVE CODE.
- (B) RECORDS FROM SATELLITES MAY BE STORED AT THE HEADQUARTERS IF PRIOR NOTICE IS SENT TO THE BOARD OFFICE. A LETTER REQUESTING STORAGE OF RECORDS AT THE HEADQUARTERS MUST BE SENT TO THE STATE BOARD OF PHARMACY OFFICE BY VERIFIABLE DELIVERY. THE BOARD WILL NOTIFY THE ORGANIZATION OF THE BOARD'S APPROVAL OR DENIAL OF THE REQUEST WITHIN SIXTY DAYS.
- (C) RECORDS OF OXYGEN TRANSFILLING SHALL INCLUDE THE MANUFACTURER'S LOT NUMBER OF THE OXYGEN USED FOR TRANSFILLING THE PORTABLE OXYGEN TANKS.
- (D) IF THERE IS A RECALL OF OXYGEN BY THE MANUFACTURER, ALL PORTABLE OXYGEN TANKS THAT MAY HAVE ANY OF THAT LOT NUMBER SHALL BE DEALT WITH ACCORDING TO THE MANUFACTURER'S RECOMMENDATIONS; BUT, IN ALL SUCH CASES, SUCH PORTABLE OXYGEN TANKS MUST BE PURGED AND THEN REFILLED.
- (E) A READILY RETRIEVABLE RECORD OF CONTROLLED SUBSTANCES SHALL BE KEPT CONTAINING DOCUMENTATION OF ADMINISTRATION, USE, OR WASTE OF THE CONTROLLED SUBSTANCES. SUCH RECORDS SHALL CONTAIN AT LEAST THE FOLLOWING INFORMATION:
 - (1) THE NAME, STRENGTH, AND QUANTITY OF THE CONTROLLED SUBSTANCE ADMINISTERED, USED, OR WASTED;
 - (2) THE DATE OF ADMINISTRATION, USE, OR WASTE;

- (3) THE NAME OR OTHER MEANS OF IDENTIFYING THE PATIENT, SUCH AS MEDICAL RECORD NUMBER OR RUN NUMBER;
- (4) THE SIGNATURE AND IDENTIFICATION NUMBER OF THE INDIVIDUAL ADMINISTERING THE CONTROLLED SUBSTANCE;
- (5) IN THE CASE OF WASTE, THE SIGNATURES AND IDENTIFICATION NUMBERS OF BOTH INDIVIDUALS INVOLVED IN WASTING THE CONTROLLED SUBSTANCE.

4729-33-05 POSTING UP.

- (A) EXCEPT WHEN "POSTING UP AT A SPECIAL EVENT", "POSTING UP" MUST BE A TEMPORARY, SHORT-TERM LOCATION OF THE VEHICLE FOR LESS THAN TWENTY-FOUR HOURS WHERE THE EMS UNIT IS UNDER CONSTANT SUPERVISION OF THE EMS PERSONNEL ON DUTY, INCLUDING BUT NOT LIMITED TO:
 - (1) LOCAL SCHOOL SPORTS EVENT;
 - (2) COVERAGE OF A STATION PURSUANT TO A MUTUAL AID AGREEMENT.
- (B) "POSTING UP AT A SPECIAL EVENT" REQUIRES PRIOR WRITTEN NOTIFICATION TO, AND APPROVAL FROM, THE STATE BOARD OF PHARMACY OFFICE. THIS NOTIFICATION MUST INCLUDE THE NAME AND LOCATION OF THE EVENT, DATES OF THE EVENT, AND NAME AND TELEPHONE NUMBER OF THE CONTACT PERSON OF THE EMS UNIT.

The motion was seconded by Ms. Eastman and approved by the Board (Aye-7/Nay-0).

RES. 2000-085 The following rules were reviewed by the Board in accordance with Section 119.032 of the Revised Code and the Board determined that no changes are currently needed:

Continuing Pharmacy Education

- 4729-7-01 Definitions.
- 4729-7-02 Requirements for renewal of a pharmacist identification card.
- 4729-7-03 Evidence of continuing pharmacy education experiences.
- 4729-7-05 Procedure for approval as a provider of continuing pharmacy education.
- 4729-7-06 Criteria for in-state approved providers of continuing pharmacy education.
- 4729-7-07 Probation or revocation of approval as a provider.

Controlled Substances

- 4729-11-07 Standard pharmaceutical references.

Ephedrine

- 4729-12-01 Definition of ephedrine.
- 4729-12-09 Exceptions.
- 4729-12-10 Criteria to be considered in denying a petition for exemption or removing a drug product exemption.

Compressed Medical Gas

- 4729-21-01 Registration/licensure.
- 4729-21-02 Compressed medical gas fillers.
- 4729-21-03 Records.

Retail Sellers of Oxygen

- 4729-22-01 Licensure.
- 4729-22-02 Security, storage, and sale.
- 4729-22-03 Records.

