

NOTE: The following Minutes are provided for informational purposes only.
If you would like to obtain an official copy of these Minutes, please contact
the State Board of Pharmacy at 614/466-4143 for instructions and fee.

STATE BOARD OF PHARMACY; 77 SOUTH HIGH STREET, ROOM 1702; COLUMBUS, OHIO 43215-6126
Tel: 614/466-4143 Fax: 614/752-4836 Email: exec@bop.state.oh.us

Minutes Of The Meeting

Ohio State Board of Pharmacy
January 3, 4, 5, 2005

MONDAY, JANUARY 3, 2005

10:00 a.m. ROLL CALL

The State Board of Pharmacy convened in Room East-B, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

Lawrence J. Kost, R.Ph. (President); Suzanne R. Eastman, R.Ph. (Vice-President); Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; and James E. Turner, R.Ph.

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

Mr. Rowland announced that the following settlement agreement had been signed by all parties and was now effective:

R-2005-109

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY

(Docket No. D-040510-068)

In The Matter Of:

DWAYNE STEVEN VARNER, R.Ph.

134 Windsor Drive
Johnstown, Pennsylvania 15904
(R.Ph. No. 03-2-13990)

This Settlement Agreement is entered into by and between Dwayne Steven Varner 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.

Dwayne Steven Varner voluntarily enters into this Agreement being fully informed of his 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. Dwayne Steven Varner acknowledges that by entering into this agreement he has waived his rights under Chapter 119. of the Revised Code.

Whereas, the Board is empowered by Section 4729.16 of the Ohio Revised Code to suspend, revoke, place on probation, refuse to grant or renew an identification card or enforce a monetary penalty on the license holder for violation of any of the enumerated grounds therein.

Whereas, Dwayne Steven Varner is licensed to practice pharmacy in the State of Ohio.

Whereas, on or about May 10, 2004 and May 12, 2004, pursuant to Chapter 119. of the Ohio Revised Code, Dwayne Steven Varner was notified of the allegations or charges against him, his right to a hearing, his rights in such hearing, and his right to submit contentions in writing. Dwayne Steven Varner requested a hearing; it was scheduled. The May 10, 2004, Notice of Opportunity for Hearing and May 12, 2004 Amendment, contain the following allegations or charges:

- (1) Records of the State Board of Pharmacy indicate that Dwayne Steven Varner was originally licensed by the State of Ohio as a pharmacist on March 24, 1981, pursuant to reciprocity, and is currently licensed to practice pharmacy in the State of Ohio.
- (2) Dwayne Steven Varner was, on or about October 10, 2002, convicted of one count of Failure to Keep Records, an "Upgraded Misdemeanor," and four counts of Theft by Unlawful Taking, misdemeanors of the first degree. Commonwealth of Pennsylvania vs. Dwayne Varner, Case No. 0508-2002, Cambria County Common Pleas Court (Pennsylvania). Dwayne Steven Varner was sentenced to six months probation and fined \$10,000.00 on the first count, and sentenced to six months house arrest with eleven months probation on the remaining four counts. Such conduct constitutes being guilty of gross immorality; guilty of dishonesty or unprofessional conduct in the practice of pharmacy; and/or convicted of a misdemeanor related to or committed in the practice of pharmacy within the meaning of Section 4729.16 of the Ohio Revised Code.
- (3) Dwayne Steven Varner was, on or about October 23, 2002, disciplined by the Pennsylvania Board of Pharmacy. Commonwealth of Pennsylvania, Bureau of Professional and Occupational Affairs vs. Dwayne Steven Varner, R.Ph. Docket No. 1290-54-03, File No. 01-54-06715. Dwayne Steven Varner admitted being impaired in that he "suffers from chemical abuse or dependence on narcotics" and, the Pennsylvania Board noted his criminal conviction. Such conduct constitutes abusing drugs to such a degree as to render Dwayne Steven Varner unfit to practice pharmacy within the meaning of Section 4729.16 of the Ohio Revised Code.

Whereas, the Board has evidence sufficient to sustain the allegations and hereby adjudicates the same.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of a formal hearing at this time, Dwayne Steven Varner knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

- (A) Dwayne Steven Varner must abide by the conditions as set forth in the Consent Agreement and Order of the Pennsylvania Board of Pharmacy dated September 16, 2003.
- (B) Until such time as the Pennsylvania Board of Pharmacy removes all conditions from Dwayne Steven Varner's license to practice pharmacy, Dwayne Steven Varner's license to practice pharmacy in the State of Ohio will be placed on probation.
- (C) Dwayne Steven Varner must notify the Ohio State Board of Pharmacy if he plans to return to Ohio to practice pharmacy in Ohio; whereupon, an administrative hearing will be held to determine Dwayne Steven Varner's compliance with his Consent Agreement and Order of the Pennsylvania Board.

If, in the judgment of the Board, Dwayne Steven Varner appears to have violated or breached any terms or conditions of this Agreement, the Ohio State Board of Pharmacy reserves the right to, at any time, revoke probation, modify the conditions of probation, and reduce or extend the period of probation, and/or the Board may institute formal disciplinary proceedings for any and all possible violations or breaches, including but not limited to, alleged violation of the laws of Ohio occurring before the effective date of this Agreement.

Dwayne Steven Varner acknowledges that he 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. Any action initiated by the Board based on alleged violation of this Agreement shall comply with the Administrative Procedure Act, Chapter 119. of the Ohio Revised Code.

Dwayne Steven Varner waives any and all claims or causes of action he may have against the State of Ohio or the Board, and members, officers, employees, and/or agents of either, arising out of matters which are the subject of this Agreement. Dwayne Steven Varner waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

This Settlement 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/ Dwayne Steven Varner R.Ph.</u>	<u>/d/ 12/14/2004</u>
Dwayne Steven Varner, R.Ph., Respondent	Date of Signature
<u>/s/ David W. Grauer</u>	<u>/d/ 12-20-2004</u>
David W. Grauer, Attorney for Respondent	Date of Signature
<u>/s/ Lawrence J. Kost</u>	<u>/d/ 1-3-05</u>
Lawrence J. Kost, President, Ohio State Board of Pharmacy	Date of Signature
<u>/s/ Sally Ann Steuk</u>	<u>/d/ 1/3/05</u>
Sally Ann Steuk, Ohio Assistant Attorney General	Date of Signature

10:09 a.m.

Board Member Gregory Braylock arrived and joined the meeting.

10:12 a.m.

Mrs. Gregg 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 and for the purpose of conferring with an attorney for the Board regarding pending or imminent court action pursuant to Section 121.22(G)(3) of the Revised Code. The motion was seconded by Mr. Braylock and a roll call vote was conducted by President Kost as follows: Braylock-Yes, Eastman-Yes, Gregg-Yes, Lipsyc-Yes, Mitchell-Yes, and Turner-Yes.

11:05 a.m.

Board Member Dorothy Teater arrived and joined the meeting in progress. The Executive Session ended and the meeting was opened to the public. The Board took a brief recess.

11:13 a.m.

Mr. Winsley distributed a letter that he had sent to the Drug Enforcement Administration (DEA) regarding policy statements made by DEA in a Federal Register document published in November. After discussion, it was determined that there was no other official action needed at this time.

11:34 a.m.

The Board recessed for lunch.

1:00 p.m.

The Board reconvened in Room East-B, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

Lawrence J. Kost, R.Ph. (President); Suzanne R. Eastman, R.Ph. (Vice-President); Gregory Braylock, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; Dorothy S. Teater, Public Member; and James E. Turner, R.Ph.

R-2005-110

Mr. Keeley presented a request for Board approval of an electronic prescribing system from Misys. After discussion, Mrs. Gregg moved that the Board find the Misys electronic prescribing system approvable pending final inspection of the installed product. The motion was seconded by Mr. Braylock and approved by the Board (Aye-7/Nay-0).

- R-2005-111** Mr. Keeley next presented a request for Board approval of an electronic prescribing system from E-MDs. After discussion, Mrs. Gregg moved that the Board find the E-MDs electronic prescribing system approvable pending final inspection of the installed product. The motion was seconded by Mr. Lipsyc and approved by the Board (Aye-7/-Nay-0).
- R-2005-112** A revision to proposed new rule 4729-21-06 was distributed to the Board members by Mr. Keeley. A letter had been sent to the Joint Committee on Agency Rule Review (JCARR) indicating the Board's intent to refile the rule due to comments received prior to the JCARR hearing. After discussion, Mrs. Gregg moved that the Board approve the revision made to the rule and that it be approved for filing at the earliest possible date. The motion was seconded by Mrs. Teater and approved by the Board (Aye-7/Nay-0).
- R-2005-113** Mr. Keeley announced that the remainder of the rules that had been proposed by the Board were through the Administrative Code rule process and only needed final approval and an implementation date by the Board. After discussion, Ms. Eastman moved that the following rules be approved for final filing with an implementation date of February 1, 2005. The motion was seconded by Mr. Braylock and approved by the Board (Aye-7/Nay-0).

4729-3-01 Definitions.

As used in Chapter 4729-3 of the Administrative Code:

- (A) "Pharmacy internship" means the supervised practical experience required for licensure as a registered pharmacist. The purpose of the pharmacy internship program is to provide those individuals, who intend to become registered pharmacists, with the knowledge and practical experience necessary for functioning competently and effectively upon licensure.
- (B) "Supervised practical experience" is the experience obtained at an internship site and which is conducted in accordance with the "National Association of Boards of Pharmacy - American Association of Colleges of Pharmacy" publication "The Internship Experience," or a similar outline and/or manual approved by the board of pharmacy.
- (C) "Internship site" means a pharmacy licensed as a terminal distributor of dangerous drugs pursuant to Chapter 4729. of the Revised Code, except as provided in paragraph (C) or (D) of rule 4729-3-05 of the Administrative Code, and whose license is in good standing.
- (D) "Preceptor" is the individual responsible for seeing that the intern is properly supervised and exposed to all aspects of the internship program defined as the supervised practical experience.
 - (1) A "preceptor" is a pharmacist who holds a current identification card which is in good standing; or, is a person who is of good moral character and is qualified to direct the approved experience in the area approved by the director of internship pursuant to paragraph (D) of rule 4729-3-05 of the Administrative Code.
 - (2) A person may serve as the preceptor for more than one intern. The number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty.
 - (3) A preceptor must report to the board on the progress and aptitude of an intern when requested by the director of internship.
- (E) "Director of internship" has the same meaning as provided in section 4729.11 of the Revised Code.

- (F) "In good standing" means that the licensee or registrant has not been denied the privilege of supervising interns by the board.
- (G) "Statement of Preceptor" is the form which must be received by the board of pharmacy for each pharmacy intern within thirty days of beginning internship under a preceptor's supervision. A "Statement of Preceptor" form is not required to be submitted to the board when using an academic experience affidavit.
- (1) No credit will be given for practical experience obtained prior to thirty days of the date that the "Statement of Preceptor" form is received by the board office; except, that in the event of extraordinary circumstances and when due to no fault of the intern, the board may accept a retroactive date of filing for the "Statement of Preceptor."
 - (2) The intern must file a "Statement of Preceptor" form whenever he/she changes internship sites and/or preceptors.
- (H) "Practical experience affidavit" is the form which must be used to submit **evidence of** practical experience for internship credit.
- (1) Practical experience reported on the affidavit shall be the total number of **actual clock** hours **obtained worked** during the reported time period rounded to the nearest hour. The hours reported must be able to be documented by payroll or other records which may be examined by the board of pharmacy upon reasonable notice.
 - (2) Practical experience affidavits must be signed by the preceptor on file with the board of pharmacy. In the event of the unavailability of the preceptor's signature due to extraordinary circumstances and due to no fault of the intern, the board may accept an alternative method for verification of a practical experience affidavit.
 - (3) Practical experience affidavits for a calendar year may be filed at any time, except that they must be received in the board office or postmarked no later than the first day of March of the following year.
- (I) "Academic experience affidavit" is the form that may be used to submit **evidence of** practical experience obtained from a **board approved** structured program where academic credit is awarded.
- (1) The academic experience coordinator at a school of pharmacy is responsible for assuring that during the time of the experience each practice site and preceptor are currently licensed and are in good standing with the appropriate professional licensing board or have been previously approved by the board of pharmacy.
 - (2) The preceptor at each practice site must sign the academic experience affidavit certifying the hours of practical experience obtained by the intern.
 - (3) The academic experience coordinator at a school of pharmacy must submit a signed academic experience affidavit certifying that the intern obtained a passing grade and that the practice sites and the preceptors are currently licensed and in good standing with the appropriate professional licensing board or have been previously approved by the board of pharmacy.
 - (4) The academic experience coordinator at a school of pharmacy is responsible for maintaining records of intern experience at each practice site.
 - (5) Academic experience affidavits may be filed at any time, except that they must be received in the board office or postmarked no later than the first day of the July that immediately follows the successful completion of the academic course.

- (J) "School of pharmacy" has the same meaning as a college of pharmacy or a department of pharmacy of a university, which has been recognized and approved by the state board of pharmacy.

4729-3-02 Registration as a pharmacy intern.

- (A) A certificate of registration as a pharmacy intern shall only be issued for the purpose of allowing those individuals who intend to become registered pharmacists the opportunity to obtain the practical experience required for examination and registration as a pharmacist.
- (B) If a person is actively working towards the requirements for licensure as a pharmacist and desires to work as a pharmacy intern in Ohio, he/she must:
- (1) (a) Have successfully completed ~~forty-eight~~ **at least sixty** semester or ~~seventy-two~~ **ninety** quarter hours of college and be enrolled in a school of pharmacy; or
 - (b) Have obtained a first professional degree in pharmacy from a program which has been recognized and approved by the state board of pharmacy; or
 - (c) Have established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Commission (FPGEC) certificate, and have established proficiency in spoken English by successfully completing the Test of Spoken English (TSE) or its **board approved** equivalent.
- (2) Apply to the state board of pharmacy for registration as a pharmacy intern.

4729-3-03 Application for registration as a pharmacy intern.

- (A) Every person desiring to register as a pharmacy intern shall submit the following to the state board of pharmacy:
- (1) A completed application form as provided by the board;
 - (2) A head and shoulders photograph taken within the previous six months;
 - (3) Fee;
 - (4) An original transcript certifying that the applicant has in fact successfully completed a minimum of ~~forty-eight~~ **sixty** semester or ~~seventy-two~~ **ninety** quarter hours of college work; and
 - (5) A certificate of enrollment into a school of pharmacy certifying that the person is enrolled in a school of pharmacy and is actively working towards the requirements for licensure as a pharmacist; or.
 - (6) All items listed in paragraphs (A)(1) to (A)(3) of this rule and:
 - (a) Certification of having obtained a first professional degree in pharmacy from a program that has been recognized and approved by the state board of pharmacy; or
 - (b) Certification of having established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and evidence of successful completion of the "Test of Spoken English (TSE)" or its **board approved** equivalent.

- (B) The state board of pharmacy may register an applicant as a pharmacy intern as soon as the state board of pharmacy receives all the required items set forth in paragraphs (A)(1) to (A)(5) or paragraph (A)(6) of this rule.
- (C) The state board of pharmacy may, pursuant to rule 4729-5-04 of the Administrative Code, deny the issuance of a certificate of registration or an identification card to practice as a pharmacy intern.

4729-3-04 Pharmacy intern identification card renewal.

A pharmacy intern may renew his/her identification card each year provided he/she is actively working toward the requirements for licensure as a pharmacist and otherwise meets the requirements and rules of the state board of pharmacy. The state board of pharmacy may, pursuant to rule 4729-5-04 of the Administrative Code, deny the issuance of an identification card to practice pharmacy as an intern.

- (A) An intern shall be considered to be actively working towards licensure as a pharmacist if he/she has complied with all of the statutes and rules regarding internship since registration as a pharmacy intern, and:
 - (1) He/she is enrolled in a school of pharmacy and is actively working towards the requirements for licensure as a pharmacist; or
 - (2) He/she is a member of the armed forces and can provide evidence that he/she has been accepted for enrollment in a school of pharmacy upon his/her release from the armed forces; or
 - (3) He/she is able to provide evidence of obtaining a first professional degree in pharmacy from a school of pharmacy; or
 - (4) He/she is able to provide evidence of obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and can provide evidence of successful completion of the "Test of Spoken English (TSE)" or its **board approved** equivalent.
- (B) An intern who has obtained a first professional degree in pharmacy from a school of pharmacy, or who has established equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, may renew his/her license only once. In the event of extraordinary circumstances and when due to no fault of the intern, the board may approve additional renewals.

4729-5-01 Definitions.

As used in Chapter 4729. of the Revised Code:

- (A) "Practice of pharmacy" is as defined in division (B) of section 4729.01 of the Revised Code.
- (B) The term "dispense" means the final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug. **In the case of an automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular patient will be deemed to have occurred when the pharmacist has given final approval to the patient specific prescription in the system.**
- (C) The term "compounding" has the same meaning as defined in division (C) of section 4729.01 of the Revised Code.

- (D) "Interpret prescriptions" means the professional judgment of a pharmacist when reviewing a prescription order of a prescriber for a patient.
- (E) "To participate in drug selection" means selecting and dispensing a drug product pursuant to sections 4729.38 and 4729.381 of the Revised Code.
- (F) "To participate with prescribers in reviews of drug utilization" means monitoring the appropriate use of drugs through communication with the prescriber(s) involved.
- (G) "Pharmacist" means an individual who holds a current pharmacist identification card pursuant to section 4729.08 or 4729.09 of the Revised Code; or, pursuant to section 4729.12 of the Revised Code.
- (H) "Original prescription" means the prescription issued by the prescriber in writing, an oral or electronically transmitted prescription recorded in writing by the pharmacist, a prescription transmitted by use of a facsimile machine, or a prescription transmitted by a ~~board-approved~~ **board approved** electronic prescription transmission system, each of which is pursuant to rule 4729-5-30 of the Administrative Code.
- (I) "Personal supervision" means a pharmacist shall be physically present in the pharmacy and provide personal review and approval of all professional pharmaceutical activities.
- (J) "Preprinted order" is defined as a ~~patient-specific~~ **patient specific**, definitive set of drug treatment directives to be administered to an individual patient who has been examined by a prescriber and for whom the prescriber has determined that the drug therapy is appropriate and safe when used pursuant to the conditions set forth in the preprinted order. Preprinted orders may be used only for inpatients in an institutional facility as defined in Chapter 4729-17 of the Administrative Code.
- (K) "Standing order" will mean the same as the term "protocol".
- (L) "Protocol" is defined as:
- (1) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy **pursuant to section 4729.54 of the Revised Code. A protocol may** be used **only** by licensed health care professionals when providing limited medical services to individuals in an emergency situation when the services of a prescriber are not immediately available; or
 - (2) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy **pursuant to section 4729.54 of the Revised Code. A protocol may** be used **only** by licensed health care professionals when administering biologicals or vaccines to individuals for the purpose of preventing diseases; or
 - (3) A definitive set of written treatment guidelines that include ~~patient-specific~~ **patient specific** and ~~dose-specific~~ **dose specific** orders for the administration of a specific drug that have been authorized by a prescriber to be used when the services of that prescriber are not immediately available. The state board of pharmacy must approve the treatment guidelines prior to implementation. A list of the ~~board-approved~~ **board approved** drugs used in the treatment guidelines shall be displayed on the ~~board's website~~ **(www.state.oh.us/pharmacy) pharmacy board web site (www.pharmacy.ohio.gov)**. To be considered for approval by the board, the treatment guidelines must meet the following requirements:

- (a) The drugs shall only be administered by an individual authorized by law to administer the drugs that are listed in the treatment guidelines.
- (b) A prescriber must complete an assessment and make a diagnosis prior to ordering a set of treatment guidelines.
- (c) The treatment guidelines:
 - (i) Can only be initiated upon the order of a prescriber, and the prescriber, utilizing positive identification, must create an order in the patient record to acknowledge and document an adjustment made pursuant to the treatment guidelines before another dose or frequency adjustment can be made;
 - (ii) Shall only apply to adjusting the dose or frequency of the administration of a specific drug that has been previously ordered by a prescriber;
 - (iii) Apply only to those drugs that may require calculations for specific dose and frequency adjustments which shall be based on objective measures;
 - (iv) Apply only to those drugs for which the therapeutic dose is significantly lower than the dose expected to cause detrimental adverse effects;
 - (v) Do not apply to those drugs for which a dosage change selected within the usual normal dose range could cause detrimental adverse effects;
 - (vi) Can be performed without requiring the exercise of medical judgment;
 - (vii) Will lead to results that are reasonably predictable and safe;
 - (viii) Can be performed safely without repeated medical assessments;
 - (ix) If performed improperly, would not present a danger of immediate and serious harm to the patient.

A protocol may be used only by individuals authorized by law to administer the drugs and to perform the procedures included in the protocol.

Protocols submitted for approval by the state board of pharmacy may be reviewed with the appropriate health care related board prior to any approval by the state board of pharmacy.

- (M) "Prescriber" means any person authorized by the Revised Code to prescribe dangerous drugs as part of their professional practice.
- (N) "Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug. ~~Such method must include a physical means of identification such as, but not limited to, the following:~~

(1) A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:

- ~~(1)~~ **(a)** A manual signature on a ~~hard-copy~~ **hard copy** record;
- ~~(2)~~ **(b)** A magnetic card reader;
- ~~(3)~~ **(c)** A bar code reader;

~~(4)~~ **(d)** A thumbprint reader or other biometric method; ~~or~~

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

~~(5)~~ **(g)** A ~~daily~~ printout of every transaction that is verified and manually signed within ~~twenty-four hours~~ **a reasonable period of time** by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; ~~or~~

(h) Other effective methods for identifying individuals that have been approved by the board.

~~A magnetic card reader or a bar code reader system of identification must also include a private personal identifier, such as a password, for entry into a mechanical or automated system.~~

(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

4729-5-11 Responsible person.

(A) For a pharmacy licensed as a terminal distributor of dangerous drugs:

- (1) Only a pharmacist may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for a pharmacy as defined in division (A) of section 4729.01 of the Revised Code. A pharmacist shall be the responsible person for no more than one such pharmacy except with written permission from the state board of pharmacy. A written request shall be submitted outlining the circumstances requiring a pharmacist to be responsible for more than one pharmacy and the period of time during which the circumstances will exist. A pharmacist shall not be designated the responsible person for a pharmacy unless he/she will be physically present in the pharmacy a sufficient amount of time to provide supervision and control.
- (2) The responsible person shall be responsible for the practice of the profession of pharmacy, including but not limited to "supervision and control" of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, "adequate safeguards" as required in division (C) of section 4729.55 of the Revised Code, and maintaining all drug records otherwise required.
- (3) The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of drugs and the practice of pharmacy.

(B) For all locations licensed as a terminal distributor of dangerous drugs:

- (1) A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times.

(2) The responsible person whose name appears on the terminal distributor of dangerous drugs license shall sign the license and shall maintain the license in a readily available place in the principal location of the business.

- ~~(2)~~(3) When there is a change of responsible person, the state board of pharmacy shall be notified by the new responsible person within thirty days on a ~~board-approved~~ **board approved** form. This notice to the state board of pharmacy shall be sent by certified mail, return receipt requested, or by verified facsimile transmission.
- ~~(3)~~(4) A complete inventory, pursuant to federal regulations and rule 4729-9-14 of the Administrative Code, shall be taken of the controlled substances on hand with the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the site of the terminal distributor of dangerous drugs.
- ~~(4)~~(5) The responsible person to whom the terminal distributor of dangerous drugs license has been issued is responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of drugs.

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 handwritten or typewritten, there are no more than three noncontrolled substance prescription orders per prescription form.**
- ~~(2)~~(3) 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, **typewritten**, 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.
- (E) If a ~~board-approved~~ **board approved** electronic prescription transmission system is used to fax a prescription to a pharmacy, the faxed order is exempt from paragraphs (A) and (B) of this rule. The faxed order must comply with rule 4729-5-30 of the Administrative Code and must be filed in the most restrictive file according to rule 4729-5-09 of the Administrative Code.

4729-5-15 Prescriber.

- (A) For purposes of division (Z) of section 3719.01 and division (I) of section 4729.01 of the Revised Code, the following persons, maintaining current licenses and in good standing, licensed pursuant to Chapters 4715., 4725., 4731., and 4741. of the Revised Code, are authorized by law to write prescriptions for drugs or dangerous drugs in the course of their professional practice:
 - (1) Chapter 4715. of the Revised Code: dentist.
 - (2) Chapter 4725. of the Revised Code: optometrist, if that person holds a current "therapeutic pharmaceutical agents certificate" as defined in division (H) of section 4725.01 of the Revised Code.
 - (3) Chapter 4731. of the Revised Code: doctor of medicine, doctor of osteopathic medicine and surgery, and doctor of podiatry.
 - (4) Chapter 4741. of the Revised Code: doctor of veterinary medicine.
- (B) Those persons pursuing an approved internship, residency, or fellowship program in this state are authorized to write prescriptions only when acting within their scope of employment in the hospital(s) or institution(s). Approved internship and residency programs are those accredited by the "Accreditation Council for Graduate Medical Education (ACGME)" or the "American Osteopathic Association (AOA)". Approved clinical fellowships are those at institutions which have a residency program in the same or a related clinical field which is accredited by the ACGME or the AOA.
- (C) A ~~non-resident~~ **nonresident** prescriber whose license is current and in good standing and who is authorized to issue prescriptions for drugs in the course of their professional practice in a state, as defined in division (G) of section 1.59 of the Revised Code, other than Ohio is authorized to write prescriptions in that state for drugs to be dispensed in the state of Ohio.
- (D) An advanced practice nurse approved pursuant to section 4723.56 of the Revised Code may prescribe those drugs which have been approved by the formulary committee for advanced practice nurses and that are included in the collaborative protocol established for that advanced practice nurse.
- (E) An advanced practice nurse approved pursuant to section 4723.48 of the Revised Code may prescribe those drugs which have been approved by the committee on prescriptive governance for advanced practice nurses and pursuant to the standard care agreement for that advanced practice nurse.

4729-5-18 Patient profiles.

All pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received prescriptions from that pharmacy.

(A) The dispensing pharmacist shall be responsible for ensuring that a reasonable effort has been made to obtain, record, and maintain at least the following records:

(1) The patient's data record, which should consist of, but is not limited to, the following information:

- (a) Full name of the patient for whom the drug is intended;
- (b) Address and telephone number of the patient;
- (c) Patient's date of birth;
- (d) Patient's gender;
- (e) A list of current patient specific data consisting of at least the following:
 - (i) Known ~~drug-related~~ drug related allergies,
 - (ii) Previous drug reactions,
 - (iii) History of or active chronic conditions or disease states,
 - (iv) Other drugs and nutritional supplements, including ~~non-prescription~~ nonprescription drugs used on a routine basis, or devices;
- (f) The pharmacist's comments relevant to the individual patient's drug therapy, including any other information peculiar to the specific patient or drug;
- (g) Any information that is given to the pharmacist by the patient or care-giver to complete the patient data record shall be presumed to be accurate, unless there is reasonable cause to believe the information is inaccurate.

(2) The patient's drug therapy record, which shall contain at least the following information for all of the prescriptions that were filled at the pharmacy within the last twelve months showing:

- (a) Name and strength of the drug or device;
- (b) Prescription number;
- (c) Quantity dispensed;
- (d) Date dispensed;
- (e) Name of the prescriber;

(f) Directions for use.

(B) The patient profile shall be maintained for a period of not less than one year from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

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~~ **record keeping** system is being used pursuant to ~~rules rule~~ 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~~ **noncontrolled** 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~~ **record keeping** system is used, this information must also be maintained in that system.
- (D) In the case of a ~~board-approved~~ **board approved** central filling operation in which the pharmacies are accessing the same ~~real-time~~ **real time**, ~~on-line~~ **online** 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.

4729-5-21 Manner of processing a prescription. [NEW]

- (A) A prescription, to be valid, 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 bona fide treatment of a patient 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 of law.

(B) A pharmacist when dispensing a prescription must:

- (1) Ensure that patient information is profiled pursuant to rule 4729-5-18 of the Administrative Code;
- (2) Perform prospective drug utilization review pursuant to rule 4729-5-20 of the Administrative Code;
- (3) Ensure that the drug is labeled pursuant to rule 4729-5-16 of the Administrative Code;
- (4) Ensure that a patient is given an offer to counsel pursuant to rule 4729-5-22 of the Administrative Code;
- (5) Ensure that a prescription is filed pursuant to rule 4729-5-09 of the Administrative Code.

(C) Prescriptions:

- (1) A pharmacist may receive a signed hard copy prescription, an oral prescription, a facsimile of a signed prescription, or a prescription sent using a board approved electronic prescription transmission system.
- (2) When a pharmacist dispenses a drug pursuant to an original prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or, if approved by the state board of pharmacy, enter his/her positive identification into the computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code. If an alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, the record of dispensing must also be recorded in the alternate record keeping system.
- (3) When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or enter such information in an alternate record keeping system or, if approved by the state board of pharmacy, enter his/her positive identification into a computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code.

(D) Oral prescriptions:

- (1) The pharmacist shall make a record of the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, on the original prescription and, if used, on the alternate system of record keeping. The pharmacist is responsible for assuring the validity of the source of the oral prescription.
- (2) Upon receiving a prescription from a recording device, the pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist must document on the original prescription the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for assuring the validity of the prescription removed from the recorder.
- (3) A licensed pharmacy intern may receive telephone prescriptions if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to perform this function.

(a) The intern shall immediately reduce the prescription to writing, document the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the oral order.

(b) The supervising pharmacist on duty is responsible for the accuracy of the prescription.

(c) The supervising pharmacist on duty must be immediately available to answer questions or discuss the prescription with the caller.

(E) Facsimile prescriptions:

(1) 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 full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent as well as identification of the origin of the facsimile.

(2) 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.

(F) A pharmacist may not dispense a dangerous drug for the first time beyond six months from the date of issuance of a prescription.

(G) The quantity dispensed shall be considered the quantity prescribed unless the quantity dispensed on a:

(1) New prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription. If the quantity dispensed on a new prescription is greater than the quantity prescribed, the pharmacist shall also record on the original prescription the name of the authorizing prescriber, the full name of the agent of the prescriber if applicable, the quantity authorized to be dispensed, and the date that the authorization was obtained.

(2) Refill prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription or enter the quantity dispensed on an alternate record pursuant to paragraph (F) of rule 4729-5-27 of the Administrative Code. If the quantity dispensed on a refill prescription is greater than the quantity prescribed, the pharmacist shall also record the name of the authorizing prescriber, the full name of the agent of the prescriber if applicable, the quantity authorized to be dispensed, and the date that the authorization was obtained.

(H) Where a prescription is written using a generic name, or where the pharmacist dispenses an equivalent drug product pursuant to the provisions of sections 4729.38 and 4729.381 of the Revised Code, the brand name or drug name and name of the manufacturer or distributor of the drug or the national drug code (NDC) number of the drug dispensed must be recorded on the record of dispensing by the pharmacist.

(I) A pharmacist who modifies a patient's drug therapy pursuant to a consult agreement and is:

- (1) Also responsible for the dispensing of the drug to the patient must include on the drug order the name of the physician who originally prescribed the drug, sign the pharmacist's full name, and be in compliance with this rule in the same manner as the prescriber.
- (2) Not responsible for the dispensing of the drug to the patient may transmit the order to a pharmacy by acting as an agent of the physician. Such pharmacist must personally transmit the order verbally or by facsimile to another pharmacist and be in compliance with this rule.

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 except as provided in paragraph (G) of this rule; 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 real time, on-line online** 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 full name of the transferring pharmacist.
 - (3) Copies transferred for **non-refillable nonrefillable** 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) of, and name of the pharmacist at, the receiving pharmacy.
 - (c) Except, if an automated data processing system is being used as an alternate system of ~~recordkeeping~~ **record keeping** for prescriptions pursuant to ~~rules rule~~ 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~~ **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~~ **real time**, ~~on-line~~ **online** database pursuant to the operation of a ~~board-approved~~ **board approved** central filling operation shall not be considered a prescription copy and, therefore, is not subject to the requirements of this rule.
- (G) A licensed pharmacy intern may send or receive copies of prescriptions pursuant to the following:
- (1) The pharmacist on duty who is supervising the activity of the intern will determine if the intern is competent to send or receive a prescription copy.
 - (2) The pharmacist on duty who is supervising the activity of the intern is responsible for the accuracy of a prescription copy that is sent or received by an intern.
 - (3) The supervising pharmacist must be immediately available to answer questions or discuss the prescription copy that is sent or received by an intern.
 - (4) The intern may not send or receive a prescription copy for a controlled substance.
 - (5) The pharmacist or intern receiving a prescription copy from an intern must document the full names of the sending intern and his/her supervising pharmacist. The receiving intern shall immediately reduce the prescription copy to writing and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the copy.
 - (6) The pharmacist or intern sending a prescription copy to an intern must document the full names of the receiving intern and his/her supervising pharmacist. There must be documented positive identification of the sending intern and his/her supervising pharmacist who authorized the transfer of the prescription copy.
 - (7) The approved intern and the supervising pharmacist must meet all the requirements of this rule.

~~4729-5-27 Recordkeeping: [RESCINDED - see NEW 4729-5-27]~~

4729-5-27 Record keeping. [NEW]

The following record keeping requirements do not apply to records relating to the practice of pharmacy for an inpatient as defined in rule 4729-17-01 of the Administrative Code.

- (A) There must be positive identification of the pharmacist or pharmacists responsible for performing all activities relating to the practice of pharmacy including, but not limited to:
- (1) Prescription information entered into the record keeping system;
 - (2) Prospective drug utilization review;
 - (3) Dispensing;
 - (4) Patient counseling;
 - (5) Administering adult immunizations;
 - (6) Prescription information reduced to writing from an order received by telephone, facsimile, or recording device.
- (B) Records of dispensing must provide accountability and ensure that patients do not receive more drugs than intended by the prescriber.
- (C) All records relating to the practice of pharmacy shall be uniformly maintained for a period of three years, be readily available, and promptly produced upon request for inspection by a state board of pharmacy officer, agent, and/or inspector during regular business hours.
- (D) All prescriptions or other records relating to the practice of pharmacy, which are required to be kept for three years according to section 4729.37 of the Revised Code, may be microfilmed or placed on electronic, magnetic media. The microfilm or electronic, magnetic media used for this purpose must comply with the "International Standards Organization" standards of quality approved for permanent records. Such records are subject to all other paragraphs of this rule.
- (E) Any pharmacy intending to maintain records relating to the practice of pharmacy at a location other than the place licensed with the state board of pharmacy must first send written notification to the state board of pharmacy by mail or facsimile. The state board of pharmacy office will send written notification of the approval or disapproval of the request. Only after receiving the notice of the board's approval may the records be placed in the new location.
- (F) Alternate record keeping systems include, but are not limited to, the following:
- (1) A system that utilizes the original hard copy prescription to document the initial dispensing of a prescription, but utilizes a computerized system to dispense refills that does not document the positive identification of the pharmacist responsible for the practice of pharmacy. In order to document positive identification, this system would require the manual signature or initials of a pharmacist on a hard copy record as indicated in paragraph (I) of this rule.
 - (2) A computerized system that documents the positive identification of the pharmacist responsible for the practice of pharmacy. If this method is used, it must be approved by the board and provide a daily backup.
 - (3) Any record keeping system approved by the board.

(G) All computerized record keeping systems must be capable of providing immediate retrieval (via CRT display and hard copy printout or other mutually agreeable transfer medium) of patient profile information for all prescriptions filled within the previous twelve months and retrieval within three working days, excluding week-ends and holidays, of all prescriptions dispensed within the previous three years. This information shall include at least, but is not limited to, the following data:

- (1) The original prescription number;
- (2) Date of issuance of the original prescription order by the prescriber;
- (3) Date of dispensing by the pharmacist;
- (4) Full name and address of the patient;
- (5) Full name and address of the prescriber;
- (6) Directions for use;
- (7) The name, strength, dosage form, and quantity of the drug prescribed;
- (8) The quantity dispensed if different from the quantity prescribed;
- (9) If utilizing a board approved system pursuant to paragraph (F)(2) of this rule, there must be positive identification documented within the system of the pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code, and the pharmacist responsible for dispensing;
- (10) The total number of refills authorized by the prescriber;
- (11) The refill history of the prescription as defined in paragraph (H) of this rule.

(H) The refill history of the prescription must include, but is not limited to:

- (1) The prescription number;
- (2) The name and strength of the drug dispensed;
- (3) The date of refill;
- (4) The quantity dispensed;
- (5) If utilizing a board approved system pursuant to paragraph (F)(2) of this rule, there must be positive identification documented within the system of the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code and the pharmacist responsible for dispensing for each refill;
- (6) The total number of refills dispensed to date for that prescription order.

(I) Hard copy documentation as required pursuant to paragraph (F)(1) of this rule must be provided by each individual pharmacist who makes use of such system by one of the following methods:

- (1) A hard copy printout of each day's prescription refill data that shall include, at a minimum, the following data:
 - (a) Date of dispensing;
 - (b) Prescription number;

(c) Patient name;

(d) Name, strength (if applicable), and quantity of drug;

(e) Identification of pharmacy and pharmacist;

(f) Identification of controlled substances.

This printout must be verified, dated, and signed by each individual pharmacist who dispensed a prescription that day. The pharmacist must verify that the data on the printout is complete and correct and sign a statement to that effect on the document as he/she would sign a check or legal document (e.g., J. H. Smith or Jane H. Smith). These documents must be maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing. If the printout is prepared at a location other than that where the drug was dispensed, the printout must be provided to the licensed location within three working days, excluding holidays and weekends, of the date on which the drugs were dispensed. Such printouts must be verified and signed by each pharmacist who dispensed drugs within twenty-four hours of the date the printout is received;

(2) A tamper evident log book in which shall be entered, at a minimum, the date of dispensing and prescription number. The dispensing pharmacist must manually record his/her name or initials on each log book entry at the time of dispensing each refill; or

(3) Each individual pharmacist involved in dispensing drugs must enter into a tamper evident log book, at a minimum, the following data for each prescription refilled:

(a) Date of dispensing;

(b) Prescription number;

(c) Patient name;

(d) Name, strength (if applicable), and quantity of drug;

(e) Identification of the pharmacist;

(f) Identification of controlled substances.

Each individual pharmacist involved in dispensing drugs must review this information at the end of each day and then must sign a statement in the log book attesting to the fact that the prescription information entered into the computer that day and recorded in the log book has been reviewed by him/her and is correct as shown.

(J) Any computerized record keeping system must have the capability of producing a printout by any data field which the user pharmacy is responsible for maintaining pursuant to federal and state laws and their implementing regulations and rules within three working days of a request being submitted by an individual authorized by law to access such records.

(K) In the event that the computerized record keeping system experiences down time, a record of all refills dispensed during such time must be recorded on the back of the original prescription. The refill information must be entered into the computerized record keeping system as soon as it is available for use. During the time the computerized record keeping system is not available, prescriptions may be refilled only if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.

(L) A pharmacy purging a computerized record keeping system of prescription records must develop a method of record keeping capable of providing retrieval (via CRT display, hard copy printout, or other mutually agreeable transfer medium) within three working days, excluding holidays and weekends, of prescription order information for all prescriptions filled or refilled within the previous three years. This information shall include, at a minimum, the following data:

- (1) Pharmacy name and address;
- (2) Original prescription number;
- (3) Date of issuance of the original prescription order by the prescriber;
- (4) Date of original dispensing by the pharmacist;
- (5) Full name and address of the patient;
- (6) Full name and address of the prescriber;
- (7) Directions for use;
- (8) Name, strength, dosage form, and quantity of the drug prescribed;
- (9) Quantity dispensed if different from the quantity prescribed;
- (10) Total number of refills authorized by the prescriber;
- (11) Total number of refills dispensed to date for that prescription order;
- (12) Date of each refill;
- (13) Name or initials of each individual dispensing pharmacist.

(M) A log must be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. The log must contain at least, but is not limited to, the following:

- (1) Date and time of change;
- (2) Changes made;
- (3) Pharmacist making the change.

(N) Prescriptions entered into a computer system but not dispensed must meet all of the following conditions:

- (1) The complete prescription information must be entered in the computer system;
- (2) The information must appear in the patient's profile;
- (3) There is positive identification, in the computer system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system; and
- (4) The original prescription is filed according to rule 4729-5-09 of the Administrative Code.

(O) Records shall be maintained for three years on all adult immunizations administered pursuant to section 4729.41 of the Revised Code and must include at least the following information:

- (1) Full name and address of the patient;
- (2) Patient's date of birth or age;
- (3) Patient's gender;
- (4) Patient's applicable allergy information;
- (5) Date of administration by the pharmacist;
- (6) Name, strength, and dose of the adult immunization administered;
- (7) Lot number and expiration date of the immunization;
- (8) Route of administration;
- (9) Location of the injection site;
- (10) Positive identification of the administering pharmacist;
- (11) Documentation of patient informed consent.

(P) A pharmacist who administers adult immunizations pursuant to section 4729.41 of the Revised Code shall maintain and immediately make available, upon the request of the state board of pharmacy, the following records:

- (1) Documentation of the successful completion of a board approved course in the administration of adult immunizations;
- (2) Documentation of current certification to perform basic life support procedures pursuant to division (B)(2) of section 4729.41 of the Revised Code.

~~**4729-5-28 Computerized recordkeeping systems.**
[RESCINDED - see NEW 4729-5-27]~~

~~**4729-5-30 Manner of issuance of a prescription.**
[RESCINDED - see NEW 4729-5-30]~~

4729-5-30 Manner of issuance of a prescription. [NEW]

(A) A prescription, to be valid, 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 bona fide treatment of a patient 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 of law.

(B) All prescriptions issued by a prescriber shall:

- (1) Be dated as of and on the day when issued.
- (2) Contain the manually printed, typewritten, or preprinted full name and address of the prescriber.
- (3) Indicate a telephone number where the prescriber can be personally contacted during normal business hours.

- (4) Indicate the full name and address of the patient.
 - (5) Indicate the drug name and strength.
 - (6) Indicate the quantity to dispense.
 - (7) Indicate the appropriate directions for use.
 - (8) Specify the number of times or the period of time for which the prescription may be refilled. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.281 of the Revised Code. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.
 - (9) Not authorize any refills for schedule II controlled substances.
 - (10) Authorize refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code.
 - (11) Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances and for dangerous drugs that are not controlled substances.
 - (12) Identify the trade name or generic name of the drug(s) in a compounded prescription.
 - (13) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice.
 - (14) For prescriptions issued to a patient by a prescriber, be:
 - (a) Manually signed on the day issued by the prescriber in the same manner as he/she would sign a check or legal document.
 - (b) Issued in compliance with rule 4729-5-13 of the Administrative Code.
 - (15) Be issued in compliance with all applicable federal and state laws, rules, and regulations.
- (C) When forms are used that create multiple copies of a prescription issued to a patient by a prescriber, the original prescription that bears the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.
- (D) Oral transmission by the prescriber or the prescriber's agent of original prescriptions and refills authorized by a prescriber, pursuant to the requirements of this rule, may be transmitted by telephone only to:
- (1) A pharmacist.
 - (2) A recording device within the pharmacy if the pharmacist is unavailable. 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.
 - (3) A licensed pharmacy intern if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to receive telephone prescriptions.
- The prescriber's agent must provide his/her full name when transmitting an oral prescription.

- (E) Original written prescriptions authorized and signed by a prescriber may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy pursuant to the following:
- (1) The facsimile of the prescription must include the full name of the prescriber and if applicable the full name of the prescriber's agent transmitting the prescription to the pharmacy.
 - (2) The original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.
 - (3) Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for:
 - (a) A resident of a long term care facility pursuant to rule 4729-17-09 of the Administrative Code.
 - (b) A narcotic substance issued for a patient enrolled in a hospice. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must also meet the other requirements of this rule.
 - (c) A compounded sterile product prescription for a narcotic substance pursuant to rule 4729-19-02 of the Administrative Code.
 - (4) A facsimile of a prescription received by a pharmacy in any manner other than transmission directly from the prescriber or the prescriber's agent shall not be considered a valid prescription.
- (F) A prescription may be transmitted by means of a board approved electronic prescription transmission system, without further verification by the pharmacist of the prescriber's identity, provided that:
- (1) The system shall require positive identification of the prescriber as defined in rule 4729-5-01 of the Administrative Code and the full name of any authorized agent of the prescriber who transmits the prescription.
 - (2) The computer data must be retained for a period of three years at the prescriber's office.

4729-5-35 Automated drug delivery systems.

All automated drug delivery systems intended for use by a terminal distributor of dangerous drugs **to assist in the dispensing of a drug** pursuant to ~~rule~~ **rules 4729-5-01 and** 4729-17-01 of the Administrative Code must meet the following requirements:

- (A) Each automated drug delivery system must be approved by the board of pharmacy prior to its implementation by the terminal distributor of dangerous drugs;
- (B) The automated drug delivery system shall have a documented and **on-going** **ongoing** quality assurance program that monitors total system performance and includes the requirement for one hundred per cent accuracy in drug and strength delivered;
- (C) The automated drug delivery system shall have adequate security to prevent unauthorized individuals from accessing or obtaining dangerous drugs;
- (D) The records kept by the automated drug delivery system shall comply with all board requirements.

4729-9-21 Drugs compounded in a pharmacy.

- (A) In order to compound prescriptions, a pharmacy shall meet the minimum standards for a pharmacy pursuant to rule 4729-9-02 of the Administrative Code.
- (B) Parenteral and sterile product prescriptions shall be compounded in accordance with Chapter 4729-19 and/or Chapter 4729-15 of the Administrative Code.
- (C) For all compounded prescriptions, the pharmacist shall:
 - (1) Inspect and approve the compounding process;
 - (2) Perform the final check of the finished product.
- (D) For all compounded prescriptions, the pharmacist shall be responsible for:
 - (1) All compounding records;
 - (2) The proper maintenance, cleanliness, and use of all equipment used in compounding.
- (E) Personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.
- (F) A prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
- (G) A compounded prescription that is dispensed to a patient must be labeled according to rule 4729-5-16 of the Administrative Code.
- (H) Labels for a compounded prescription that is prepared in anticipation of a prescription drug order shall contain, but not be limited to, the following:
 - (1) The name, strength, and quantity of each drug used in the compounded prescription;
 - (2) The identification of the repackager by name or by the final six digits of its terminal distributor of dangerous drugs license number;
 - (3) Pharmacy control number;
 - (4) The pharmacy's expiration date or ~~beyond-use~~ beyond use date.

4729-15-01 Definitions.

As used in Chapter 4729-15 of the Administrative Code:

- (A) "Nuclear pharmacy" is a pharmacy where prescriptions for radiopharmaceuticals are filled or where radiopharmaceuticals are compounded or dispensed by a pharmacist licensed by the proper authorities to receive, possess, and use such drugs. A nuclear pharmacy shall be licensed by the United States "Nuclear Regulatory Commission" or the appropriate state nuclear regulatory agencies, other appropriate state agencies, and by the state board of pharmacy.

- (B) "Radiopharmaceutical," a dangerous drug as defined in division (D) of section 4729.01 of the Revised Code, shall include any article that exhibits spontaneous decay or disintegration of an unstable atomic nucleus, usually accompanied by the emission of ionizing radiation and any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such article.
- (C) "Nuclear pharmacist" shall be a licensed pharmacist holding a current identification card in the state of Ohio, and meets the following standards:
- (1) Be certified as a nuclear pharmacist by the "Board of Pharmaceutical Specialties"; or
 - (2) Meet minimal standards of training for an "authorized user" of radioactive material or for an "authorized nuclear pharmacist (ANP)" designation by the proper nuclear regulatory agency, the United States Nuclear Regulatory Commission, or the appropriate state agency including:
 - (a) Have received a minimum of two hundred contact hours of didactic instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an accredited college of pharmacy or a program approved by the nuclear regulatory commission, with emphasis in the following areas:
 - (i) Radiation physics and instrumentation (eighty-five hours);
 - (ii) Radiation protection (forty-five hours);
 - (iii) Mathematics of radioactivity (twenty hours);
 - (iv) Radiation biology (twenty hours);
 - (v) Radiopharmaceutical chemistry (thirty hours).
 - (b) Attain a minimum of five hundred hours of clinical nuclear pharmacy training under the supervision of a pharmacist trained in nuclear pharmacy and who is an "authorized user" or an "authorized nuclear pharmacist" as defined by the nuclear regulatory commission.

(D) "Class 100 environment" has the same meaning as in rule 4729-19-01 of the Administrative Code.

(E) "Class 100,000 environment" means an atmospheric environment that contains no more than 100,000 particles of 0.5 microns in diameter or larger per cubic foot of air according to "Federal Standard 209E". A class 100,000 environment is equivalent to ISO class 8.

4729-15-03 Minimum standards for a nuclear pharmacy. [NEW]

- (A) A nuclear pharmacy shall comply with all applicable local, state, and federal requirements. If a nuclear pharmacy compounds parenteral or sterile product prescriptions other than radiopharmaceuticals or biohazardous materials, the pharmacy shall also comply with rule 4729-19-04 of the Administrative Code.
- (B) A policy and procedure manual shall be prepared and maintained regarding the compounding, dispensing, and delivery of sterile radiopharmaceutical prescriptions. The policy and procedure manual shall include at a minimum:
- (1) A quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education;

- (2) Justification for the chosen beyond use dates of compounded products;
- (3) Proper handling, storage, and disposal of drugs, radiopharmaceuticals, and radioactive waste;
- (4) Proper handling, storage, and disposal of biohazardous materials, if applicable;
- (5) Handling of spills and exposure to radioactive and biohazardous materials;
- (6) Proper documentation and reporting of adverse events;
- (7) Procedures to resolve conflicts when sterile product preparation may interfere with radiation safety practices and equipment. These procedures should use the principle of as clean as reasonably achievable. For example, class 100,000 conditions will be employed in the area where generator elution is performed with a terminal sterilization filter to obtain as reasonably achievable class 100 conditions.

The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy agent.

(C) Physical requirements

- (1) The facility shall have a designated area with access limited to authorized personnel for preparing sterile radiopharmaceutical products. This area shall be isolated from other areas and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area. It shall be used only for the preparations of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
- (2) The facility compounding radiopharmaceutical prescriptions shall have appropriate:
 - (a) Environmental control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; furthermore, these devices are to be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air. Environmental control devices for handling biohazardous substances such as human blood, if applicable. At a minimum, there shall be a physical barrier separating the area where biohazardous products are prepared;
 - (b) Shielding of radioactive materials;
 - (c) Compounding devices and equipment;
 - (d) Storage conditions for drugs, radiopharmaceuticals, and biohazardous materials;
 - (e) Appropriate disposal containers for used needles, syringes, etc.
- (3) The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.
- (4) The compounding of sterile products shall be done within a class 100 environment except in an emergency situation when the product is required to meet the immediate needs of a patient whose health would otherwise be jeopardized.

(D) Delivery service

The responsible nuclear pharmacist shall ensure that all employees comply with all applicable local, state, and federal requirements to assure the proper labeling, environmental controls, integrity, and safety of all products transported.

(E) Disposal of radioactive and/or biohazardous waste

The responsible nuclear pharmacist shall ensure that all employees comply with all applicable local, state, and federal requirements to assure that there is a system for the disposal of radioactive and/or biohazardous waste in a manner so as not to endanger the public health.

(F) Health care professional counseling

When appropriate, a nuclear pharmacist shall be involved in discussing with each health care professional responsible for receiving, storing, and administering a radiopharmaceutical product, the following matters:

- (1) Dosage form, dosage, calibrated activity, route of administration, and duration of therapy;
- (2) Special directions and precautions for preparation and administration;
- (3) Proper storage; and
- (4) Stability or incompatibilities of the medication.

(G) Quality assurance

- (1) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, finished compounded drug products, and facilities.
- (2) At a minimum, there shall be written quality assurance programs developed that address:
 - (a) Adequate training and continuing competency monitoring of all personnel in personal cleansing, proper attire, aseptic technique, proper clean room conduct, and clean room disinfecting procedures. Instructors shall have the appropriate knowledge and experience necessary to conduct the training;
 - (b) Continued verification of compounding accuracy including physical inspection of end products;
 - (c) Continued verification of automated compounding devices;
 - (d) Continued verification that appropriate beyond use dates are being assigned to compounded products;
 - (e) End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected. If bulk compounding of sterile products is being performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine;
 - (f) All clean rooms and laminar flow hoods shall have environmental monitoring performed at least every six months to certify operational efficiency. There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operation efficiency shall be maintained for at least three years.

4729-17-01 Definitions.

As used in Chapter 4729-17 of the Administrative Code:

- (A) "Institutional facility" means a facility licensed by the Ohio state board of pharmacy and ~~either~~ the Ohio department of health, ~~or~~ the Ohio department of rehabilitation and correction, or the Ohio department of mental retardation and developmental disabilities at which medical care is provided on site and a medical record documenting episodes of care, including medications ordered and administered, is maintained, including but not limited to:
- (1) Convalescent homes;
 - (2) Developmental facilities;
 - (3) Hospitals;
 - (4) ~~Long-term~~ Long term care facilities;
 - (5) Nursing homes;
 - (6) Psychiatric facilities;
 - (7) Rehabilitation facilities;
 - (8) Mental retardation facilities.
- (B) "Inpatient" means any person who receives drugs for use while within the institutional facility.
- (C) "Inpatient prescription" means a written, electronic, or oral order for a drug to be dispensed for use in treating an inpatient.
- (D) "Dispensing of a drug pursuant to an inpatient prescription" means the professional review by a pharmacist required to place a specific drug in final association with the name of a particular inpatient pursuant to the lawful order of a prescriber. In the case of ~~a computerized an~~ automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular inpatient will be deemed to have occurred when the pharmacist has given final approval to the ~~patient-specific~~ patient specific order in the system.
- (E) "Contingency drugs" are those drugs which may be required to meet the therapeutic needs of inpatients when a licensed pharmacist is not available and personally in full and actual charge of the institutional pharmacy.
- (F) "Emergency drugs" are those drugs which are required to meet the immediate therapeutic needs of inpatients in order to sustain life in an emergency crisis.
- (G) "Outpatient" means any person who receives drugs for use outside of the institutional facility.

4729-17-09 Drug orders for patients of an institutional facility.

- (A) Drugs shall be dispensed by a pharmacist for inpatients pursuant to an original ~~patient-specific~~ patient specific order issued by a prescriber.

- (1) Oral orders issued by a prescriber for inpatients of an institutional facility may be transmitted to a pharmacist by personnel authorized by, and in accordance with, written policies and procedures of the facility. Such orders shall be recorded by the pharmacist, noting the full name(s) of the authorized personnel transmitting the order. Oral orders issued by a prescriber and transmitted by authorized personnel shall be verified by the prescriber using positive identification within a reasonable time and as required by the written policies and procedures of the facility.
 - (2) Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of a facsimile machine to facsimile machine transfer shall be transmitted by personnel authorized by, and in accordance with, written policies and procedures of the facility. The pharmacist receiving the facsimile shall have in place written policies and procedures allowing only authorized personnel access to the drug order facsimile. The pharmacist shall maintain the facsimile showing the origin of the order as a part of the drug order record. This facsimile must be maintained if it is the only record showing the pharmacist responsible for dispensing the drug.
 - (3) Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of a state board of pharmacy approved paperless automated data processing system may be considered an original order for the dispensing of drugs. Access to such system for entering and transmitting original orders shall be restricted to licensed health care professionals using positive identification. If the licensed health care professional entering the order into the system is not the prescriber, there shall be a system in place requiring the positive identification of the prescriber for each order which shall be available in a readily retrievable fashion. With such a system, the institutional pharmacy director or responsible pharmacist shall have in place written policies and procedures allowing only authorized personnel in the pharmacy access to the drug orders.
- (B) All orders for drugs for inpatients shall include, but are not limited to, at least the following:
- (1) Name of patient;
 - (2) Name, strength, and dosage form of drug;
 - (3) Directions for use, including route of administration if other than oral;
 - (4) Date prescribed; and
 - (5) Prescriber's positive identification.
- (C) Drugs shall be dispensed for outpatients pursuant to an original order of a prescriber. All orders for the dispensing of drugs to outpatients shall, at a minimum, conform to rule 4729-5-30 of the Administrative Code, shall be labeled in accordance with rule 4729-5-16 of the Administrative Code, and the records shall be maintained in accordance with rule 4729-5-27 of the Administrative Code.
- (D) An original signed prescription for a schedule II controlled substance prepared in accordance with federal and state requirements and issued for a resident in a long term care facility may be transmitted by the prescriber or the prescriber's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be received and maintained ~~as in paragraph (D) of rule pursuant to rules 4729-5-21 and~~ 4729-5-30 of the Administrative Code. The original signed prescription must remain with the patient's records at either the prescriber's office or the long term care facility.

4729-19-01 Definitions.

- (A) As used in the Administrative Code:
- (1) "Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment according to "National Sanitation Foundation (NSF) Standard 49".
 - (2) "Class 100 environment" means an atmospheric environment which contains **less no more** than one hundred particles of 0.5 microns in diameter **or larger** per cubic foot of air according to "Federal Standard ~~209D~~ 209E." **A class 100 environment is equivalent to ISO class 5.**
 - (3) "Compounding facility" means a site licensed as a terminal distributor of dangerous drugs where the compounding of sterile product prescriptions occurs.
 - (4) "Cytotoxic" means a drug that has been shown to be carcinogenic or mutagenic to humans through active or passive exposure.
 - (5) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of the skin.
 - (6) "Sterile product" means a dosage form free of living microorganisms (aseptic).
- (B) Compounded sterile product prescriptions include, but are not limited to, the following preparations:
- (1) Total parenteral nutrition (TPN) solutions;
 - (2) Parenteral analgesic drugs;
 - (3) Parenteral antibiotics;
 - (4) Parenteral antineoplastic agents;
 - (5) Parenteral electrolytes;
 - (6) Parenteral vitamins;
 - (7) Irrigating fluids;
 - (8) Ophthalmic preparations.
- (C) Sterile product prescriptions shall not include commercially manufactured products that do not require compounding prior to dispensing.

4729-19-02 Prescriptions for sterile products.

- (A) Sterile product prescriptions must meet the requirements of rule 4729-5-30 of the Administrative Code, except that a sterile product prescription prepared in accordance with federal and state requirements that is for a schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the prescriber or the prescriber's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be received and maintained ~~as in paragraph (F) of rule~~ **pursuant to rules 4729-5-21 and** 4729-5-30 of the Administrative Code. The original signed prescription must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.
- (B) The requirements for sterile product prescriptions received by a fluid therapy pharmacy are as specified in rule 4729-31-02 of the Administrative Code.

4729-19-04 Minimum standards for compounding parenteral or sterile product prescriptions.

- (A) A compounding facility shall meet the minimum standards for institutional facility pharmacies pursuant to rule 4729-17-08 of the Administrative Code.
- (B) A policy and procedure manual shall be prepared and maintained regarding the compounding, dispensing, and delivery of sterile product prescriptions. **The policy and procedure manual shall include at a minimum:**

- (1) ~~The policy and procedure manual shall include a~~ **A** quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education.

(2) Justification for the chosen beyond use dates of compounded products.

- ~~(2)~~ **(3) The policy and procedure manual shall include policies and procedures for Handling of cytotoxic waste, if applicable.**

- ~~(3)~~ The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy designated agent.

(C) Physical requirements

- (1) The facility shall have a designated area with access limited to authorized personnel for preparing parenteral and sterile products. This area shall be isolated from other areas and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area. It shall be used only for the preparations of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
- (2) The facility compounding parenteral and sterile product prescriptions shall have:
- (a) Appropriate environmental control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; furthermore, these devices are to be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air;
- (b) Appropriate disposal containers for used needles, syringes, etc. and, if applicable, for cytotoxic waste from the preparation of chemotherapy agents;
- (c) Appropriate environmental control including approved biohazard cabinetry when cytotoxic drug products are prepared;
- (d) Infusion devices and equipment, if appropriate;
- (e) Appropriate ~~temperature-controlled~~ **temperature controlled** transport containers.
- (3) The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.
- (4) The facility shall have sufficient current reference materials related to sterile products to meet the needs of the facility staff.

- (5) The compounding of sterile products shall be done within a class 100 environment except in an emergency situation when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized.

(D) Delivery service

The responsible person shall assure the environmental control of all products shipped to the patient.

(E) Disposal of cytotoxic and/or hazardous waste

The responsible person shall assure that there is a system for the disposal of cytotoxic and/or hazardous waste in a manner so as not to endanger the public health.

(F) Cytotoxic drugs

The following requirements are necessary for those facilities that prepare cytotoxic drugs to ensure the protection of the personnel involved:

- (1) All cytotoxic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet. Other products should not be compounded in this cabinet.
- (2) Protective apparel shall be worn by personnel compounding cytotoxic drugs. This shall include at least gloves and gowns with tight cuffs.
- (3) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.
- (4) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.
- (5) Written procedures for handling both major and minor spills of cytotoxic agents shall be developed and shall be included in the policy and procedure manual.
- (6) Prepared doses of cytotoxic drugs shall be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(G) Patient training

Whenever possible, a pharmacist shall be involved in discussing with each patient receiving an outpatient parenteral or sterile product prescription, or the caregiver of such individual, the following matters:

- (1) Dosage form, dosage, route of administration, and duration of drug therapy;
- (2) Special directions and precautions for preparation and administration;
- (3) Proper storage; and
- (4) Stability or incompatibilities of the medication.

(H) Quality assurance

There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, **finished compounded drug products**, and facilities.

- (1) ~~All clean rooms and laminar flow hoods shall be certified for operational efficiency at least every six months. Appropriate records shall be maintained. At a minimum, there shall be written quality assurance programs developed that address:~~
 - (a) Adequate training and continuing competency monitoring of all personnel in personal cleansing, proper attire, aseptic technique, proper clean room conduct, and clean room disinfecting procedures. Instructors shall have the appropriate knowledge and experience necessary to conduct the training;
 - (b) Continued verification of compounding accuracy including physical inspection of end products;
 - (c) Continued verification of automated compounding devices;
 - (d) Continued verification that appropriate beyond use dates are being assigned to compounded products;
 - (e) End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected. Additionally, if bulk compounding of parenteral or sterile products is being performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.
- (2) ~~There shall be written procedures developed requiring appropriate sampling if microbial contamination is suspected. All clean rooms and laminar flow hoods shall have environmental monitoring performed at least every six months to certify operational efficiency. There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operational efficiency shall be maintained for at least three years.~~
- (3) ~~If bulk compounding of parenteral or sterile products is performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.~~
- (4) ~~There shall be written justification for the chosen beyond use dates of compounded products.~~

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 **positive identification of the prescriber, the manually printed, typewritten, or preprinted full** name and address of the prescriber, **the telephone number where the prescriber can be personally contacted during normal business hours**, and documentation of need. This order must be renewed at least annually.

4729-29-02 Pharmacist as agent.

For the purpose of implementing any actions initiated as a result of a consult agreement whereby the consulting pharmacist is not the dispensing pharmacist or the person administering the dosage ordered, the consulting pharmacist shall be deemed to be acting as the agent of the consulting physician as the term agent is used in ~~rule~~ **rules 4729-5-21 and 4729-5-30** of the Administrative Code unless the physician has specified otherwise in the consult agreement. The pharmacist's copy of the signed consult agreement shall be made available to the dispensing pharmacist or the person administering the dosage ordered if it is requested in order to prove the right of the pharmacist to act in this manner.

4729-35-08 ~~Recordkeeping~~ Record keeping.

- (A) Donor forms must be maintained for a minimum of three years by a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility.
- (B) Recipient forms must be maintained for a minimum of three years by a pharmacy, hospital, or nonprofit clinic.
- (C) An invoice must be created by the donor location, which includes a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility where the donor resides. The invoice must include at least the following information:
 - (1) The name and address of the donor location.
 - (2) The brand name of the drug donated, or the generic name and list either the name of the manufacturer or the national drug code number (NDC#).
 - (3) The strength of the drug.
 - (4) The quantity of the drug.
 - ~~(5) The lot number of the drug.~~
 - ~~(6) The expiration of the drug.~~
 - ~~(7)~~(5) The date the drug was sent to a pharmacy, hospital, or nonprofit clinic.
 - ~~(8)~~(6) The name and address of the recipient pharmacy, hospital, or nonprofit clinic.
- (D) A copy of the invoice must be maintained for a minimum of three years by both the donor location, which includes a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility, and the recipient location, which includes a pharmacy, hospital, or nonprofit clinic.

Mr. Keeley discussed his Legislative Report with the Board. There was no official action needed by the Board at this time.

1:26 p.m.

The Board took a brief recess.

1:39 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 Joseph M. Rukse, Jr., R.Ph., Barboursville, WV.

2:27 p.m.

The hearing ended. The record was left open until 5 p.m. to allow for the admission of a letter to be used as part of the respondent's evidence.

The Board began to discuss the formation of an Ad Hoc Committee to consider the rules contained in Chapter 4729-17 of the Administrative Code (AC) and the Board's definition of positive identification as defined in paragraph (N) of AC Rule 4729-5-01. The discussion was tabled until later in the meeting to allow more information to be made available.

R-2005-114 The Board next considered a request for an exemption from the pick-up station prohibition in AC Rule 4729-5-10 received from the following sites:

Teregen Laboratories (02-1235150)
Various Physician Offices contained in the letter of request

After discussion, Mrs. Gregg moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Ms. Eastman and approved by the Board (Aye-7/Nay-0).

Mr. Braylock reported that the Committee on Prescriptive Governance had not met since the last Board meeting.

2:54 p.m.

The Board meeting was recessed until Tuesday, January 4, 2005.

TUESDAY, JANUARY 4, 2005

8:35 a.m. ROLL CALL

The State Board of Pharmacy convened in Room East-B, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

Lawrence J. Kost, R.Ph. (President); Suzanne R. Eastman, R.Ph. (Vice-President); Gregory Braylock, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; and James E. Turner, R.Ph.

8:36 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 Alan Patrick Horvath, R.Ph., Hilliard.

8:40 a.m.

Mrs. Teater arrived and, with the agreement of Mr. Horvath, joined the hearing in progress.

9:38 a.m.

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

9:50 a.m.

Mr. Benedict discussed the last meeting of the Medical Board's Prescribing Committee with the Board members.

The Board continued the discussion of the members needed for the review of the Administrative Code Chapter 4729-17 rules. Several members were selected and Board staff was instructed to review the need for additional members.

The draft minutes from the December, 2004 Board meeting were reviewed. After discussion, Mrs. Gregg moved that the December, 2004 minutes be approved as amended. The motion was seconded by Ms. Eastman and approved by the Board (Aye-7/Nay-0).

10:14 a.m.

Mrs. Gregg 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. Lipsyc and a roll call vote was conducted by President Kost as follows: Braylock-Yes, Eastman-Yes, Gregg-Yes, Lipsyc-Yes, Mitchell-Yes, Teater-Yes, and Turner-Yes.

11:25 a.m.

R-2005-115

The Executive Session ended and the meeting was opened to the public. Mrs. Gregg moved that the Board adopt the following Order in the matter of Alan Horvath, R.Ph.:

ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-040726-005)

In The Matter Of:

ALAN PATRICK HORVATH, R.Ph.

2762 Wynnerock Court

Hilliard, Ohio 43026

(R.Ph. No. 03-3-21869)

INTRODUCTION

THE MATTER OF ALAN PATRICK HORVATH CAME FOR HEARING ON JANUARY 4, 2005, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: LAWRENCE J. KOST, R.Ph. (presiding); GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; NATHAN S. LIPSYC, R.Ph.; KEVIN J. MITCHELL, R.Ph.; DOROTHY S. TEATER, PUBLIC MEMBER; AND JAMES E. TURNER, R.Ph.

ALAN PATRICK HORVATH WAS NOT REPRESENTED BY COUNSEL AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

State's Witnesses

None

Respondent's Witnesses

1. Alan Patrick Horvath, R.Ph., Respondent
2. James Scott Patton, R.Ph.
3. Nick A. Kallis, R.Ph.

State's Exhibits

1. Reinstatement Hearing Request letter from Alan Horvath [06-25-04]
- 1A-1B. Procedurals
2. Rx #2216610 [03-07-02]
- 2A. State Board of Pharmacy Order in re Alan Patrick Horvath, R.Ph. [12-10-03]
3. Notarized Statement of Alan P. Horvath [07-01-02]
4. Notarized Statement of Alan P. Horvath [07-31-02]
5. Notarized Statement of Alan P. Horvath [08-01-02]
6. Rx #2217705 [06-22-02]
8. Notarized Statement of Charles W. Sindeldecker [08-06-02]
9. Indictment, State of Ohio vs. Alan P. Horvath, Case No. 03CR 02-1171, Franklin County Common Pleas Court [02-25-03]
10. Entry of Guilty Plea [06-24-03]
11. Judgment Entry [06-24-03]

Respondent's Exhibits

- A. Two PRO Pharmacist's Recovery Contracts for Alan Horvath [10-05-02 and 12-10-03]
- B. Calendar pages with Support Group Meeting Notes [August 2002 to December 2004]; Support Group Attendance Records [08-11-02 to 01-02-05]
- C. Drug Screen Reports [10-29-02 to 12-13-04]; Compass Vision Licensee Summary Report [01-16-03 to 11-18-04]; Compass Vision Drug Panel [not dated]
- D. Notice (Community Control Imposed) [06-23-03]; Judgment Entry (Community Control Imposed) [06-24-03]; Conditions of Supervision [06-27-03]; Receipt No. 164941 [12-02-03]; Receipt No. 158355 [08-11-03]; copy of two bank checks, No. 521111537 and No. 520340770, payable to Franklin County Clerk of Courts [12-01-03 and 08-09-03]; Early Termination of Probation [12-28-04]. State of Ohio vs. Alan P. Horvath, Case No. 03CR02-1171, Franklin County Common Pleas Court.

- E. Copy of bank check, No. 121905837, payable to Kroger [08-12-02]
- F. Two-page Summary Report of Continuing Pharmacy Education Credits [02-13-01 to 12-03-04]; Continuing Pharmaceutical Education Credit Statements and Certificates [07-20-00 to 12-03-04]
- G. Twenty-three Letters of Support [02-25-03 to 12-16-04]; OSU College of Pharmacy Nomination Letter for "Preceptor-of-the-Year Award" for 2001 [05-31-01]

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 that Alan Patrick Horvath has complied with the terms set forth in the Order of the State Board of Pharmacy, Docket No. D-020808-004, effective December 10, 2003.

DECISION OF THE BOARD

On the basis of the Finding of Fact set forth above, and after consideration of the record as whole, the State Board of Pharmacy hereby approves the reinstatement of the pharmacist identification card, No. 03-3-21869, held by Alan Patrick Horvath to practice pharmacy in Ohio and places Alan Patrick Horvath on probation for five years beginning on the effective date of this Order, with the following conditions:

(A) Alan Patrick Horvath must enter into a new contract, signed within thirty days after the effective date of this Order with an Ohio Department of Alcohol and Drug Addiction Services (ODADAS) treatment provider or a treatment provider acceptable to the Board for a period of not less than five years and submit a copy of the signed contract to the Board office before his pharmacist identification card is issued. The contract must provide that:

(1) Random, observed urine drug screens shall be conducted at least once each month for the first year and then at least once every three months for the remaining four years.

(a) The urine sample must be given within twelve hours of notification. The urine drug screen must include testing for creatinine or specific gravity of the sample as the dilutional standard.

(b) Results of all drug screens must be negative. Refusal of a drug screen or a diluted urine screen is equivalent to a positive result. Any positive results, including those that may have resulted from ingestion of food, but excluding false positives that resulted from medication legitimately prescribed, indicate a violation of probation.

(2) The intervener/sponsor shall provide copies of all drug screen reports to the Board in a timely fashion.

(3) Attendance is required a minimum of three times per week at an Alcoholics Anonymous, Narcotics Anonymous, and/or similar support group meeting.

(4) The program shall immediately report to the Board any violations of the contract and/or lack of cooperation.

(B) Alan Patrick Horvath must submit quarterly progress reports to the Board (due January 10, April 10, July 10, and October 10 of each year of probation) that include:

(1) The written report and documentation provided by the treatment program pursuant to the contract, and

(2) A written description of Alan Patrick Horvath's progress towards recovery and what Alan Patrick Horvath has been doing during the previous three months.

(C) Other terms of probation are as follows:

(1) The State Board of Pharmacy hereby declares that Alan Patrick Horvath'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) Alan Patrick Horvath may not serve as a responsible pharmacist.

(3) Alan Patrick Horvath may not destroy, assist in, or witness the destruction of controlled substances.

(4) Alan Patrick Horvath may not, during the first six months of practice, work in a pharmacy more than 40 hours per week.

(5) Alan Patrick Horvath must, during the first six months of practice, work only with a pharmacist whose license is in good standing.

(6) Alan Patrick Horvath must abide by the contract with his treatment provider and must immediately report any violation of the contract to the Board.

(7) Alan Patrick Horvath must not violate the drug laws of Ohio, any other state, or the federal government.

(8) Alan Patrick Horvath must abide by rules of the State Board of Pharmacy.

(9) Alan Patrick Horvath must comply with the terms of this Order.

(D) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.

Alan Patrick Horvath is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

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

MOTION CARRIED.

SO ORDERED.

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

R-2005-116 Mr. Turner then moved that the Board adopt the following Order in the matter of Joseph Rukse, R.Ph.:

ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-040426-067)

In The Matter Of:

JOSEPH MARTIN RUKSE, JR., R.Ph.

23 Colonial Court

Barboursville, West Virginia 25504

(R.Ph. No. 03-2-15318)

INTRODUCTION

THE MATTER OF JOSEPH MARTIN RUKSE, JR. CAME FOR HEARING ON JANUARY 3, 2005, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: LAWRENCE J. KOST, R.Ph. (presiding); GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; NATHAN S. LIPSYC, R.Ph.; KEVIN J. MITCHELL, R.Ph.; DOROTHY S. TEATER, PUBLIC MEMBER; AND JAMES E. TURNER, R.Ph.

JOSEPH MARTIN RUKSE, JR. WAS REPRESENTED BY DOUGLAS E. GRAFF AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

State's Witnesses

1. None

Respondent's Witnesses

1. Joseph Martin Rukse, Jr., R.Ph., Respondent
2. Michael D. Quigley, R.Ph.

State's Exhibits

1. Reinstatement Hearing Request letter from Joseph M. Rukse, Jr. [03-31-04]
- 1A-1C. Procedurals
2. State Board of Pharmacy Order in re Joseph Martin Rukse, Jr. [07-21-03]
3. State Board of Pharmacy Order in re Joseph Martin Rukse, Jr. [05-05-99]
4. Information, United States of America v. Joseph M. Rukse, Jr. Case No. 3:00-00219, United States District Court For The Southern District of West Virginia, Huntington [10-11-00]; Letter of Agreement in re United States v. Joseph M. Rukse, Jr. [07-18-00]; Order [11-13-00]; Judgment in a Criminal Case [01-24-01]
5. KMart Loss Control Report of Investigation [03-01-97]
6. Criminal Affidavit, Complaint By Prosecuting Attorney Upon Affidavit, and Judgment Entry of Plea and Sentencing, for Theft. State of Ohio vs. Joseph Rukse, Case No. 97-CRA-393, Lawrence County Municipal Court [04-29-97 to 06-02-97]
7. Renewal Application for Pharmacist License of Joseph M. Rukse, Jr. [07-15-97]
8. Complaint, State of Ohio v. Rukse, Case No. 98/013821, Franklin County Municipal Court [05-29-98]; Sentencing Entry [11-24-98]
9. Copy of letter from William T. Douglass, Jr. [04-23-02]

Respondent's Exhibits

- A. Letter from Michael D. Quigley, R.Ph. [11-18-04]; Three PRO Pharmacist's Recovery Contracts for Joseph Rukse [08-25-00, 06/21/02, and 07-25-03]
- B. Treatment Progress Report for Joseph M. Rukse from Frederick N. Karaffa, M.D. [12-29-00]; Shepherd Hill Hospital Counselor Discharge Summary [05-24-00]; Marshall University Psychiatric Evaluation report [02-24-00] and clinical records (02/29/00 to 10/03/00) for Joe Rukse
- C. Calendar Pages for June 2000 to November 2004; Support Group Attendance Records [06-23-00 to 12-30-04]
- D. Letter from Lola I. Toney [11-16-04]; Drug Screen Reports [04-10-00 to 10-06-04]; Facsimile Transmission cover sheet and Letter from Lola I. Toney [01-03-05] with two Drug Screen Reports [11-29-04 and 12-09-04]
- E. Conditions of Probation and Supervised Release [01-24-01]; Criminal Docket [10-11-00 to 10-29-04]; Entirety of Agreement [11-13-00]; Information [not dated]. United States of America v. Joseph M. Rukse, Jr., Case No. 3:00CR00219-01, U.S. District Court for the Southern District of West Virginia.
- F. U.S. District Court: WVSD - Docket Report of Restitution [01-24-01 to 10-29-04]
- G. State Board of Pharmacy Order in re Joseph Martin Rukse, Jr. [07-21-03]

- H. Eighteen Letters of Support and Recommendation [12-15-00 to 11-23-04]
- I. Continuing Pharmaceutical Education Credit Statements and Certificates [05-21-02 to 07-28-04]
- J. Federal Correctional Institution Certificate of Achievement for Joseph Rukse [07-13-01]; Four Program Review Reports [03-07-01 to 11-15-01]
- K. Ohio State Board of Pharmacy Jurisprudence Examination (MPJE) grade letter [12-13-04]

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 that Joseph Martin Rukse, Jr. has complied with the terms set forth in the Order of the State Board of Pharmacy, Docket No. D-001226-027, effective July 21, 2003.

DECISION OF THE BOARD

On the basis of the Finding of Fact set forth above, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the reinstatement of the pharmacist identification card, No. 03-2-15318, held by Joseph Martin Rukse, Jr. to practice pharmacy in Ohio and places Joseph Martin Rukse, Jr. on probation for five years beginning on the effective date of this Order, with the following conditions:

(A) Joseph Martin Rukse, Jr. must enter into a new contract, signed within thirty days after the effective date of this Order, with an Ohio Department of Alcohol and Drug Addiction Services (ODADAS) treatment provider or a treatment provider acceptable to the Board for a period of not less than five years and submit a copy of the signed contract to the Board office before his pharmacist identification card is issued. The contract must provide that:

(1) Random, observed urine drug screens shall be conducted at least once each month for the first year and then at least once every three months for the remaining four years.

(a) The urine sample must be given within twelve hours of notification. The urine drug screen must include testing for creatinine or specific gravity of the sample as the dilutional standard.

(b) Results of all drug screens must be negative. Refusals of urine screens or diluted urine screens are equivalent to a positive result. Any positive results, including those that may have resulted from ingestion of food, but excluding false positives that resulted from medication legitimately prescribed, indicate a violation of probation.

(2) The intervener/sponsor shall provide copies of all drug and alcohol screen reports to the Board in a timely fashion.

(3) Attendance is required a minimum of three times per week at an Alcoholics Anonymous, Narcotics Anonymous, and/or similar support group meeting.

(4) The program shall immediately report to the Board any violations of the contract and/or lack of cooperation.

(B) Joseph Martin Rukse, Jr. must submit quarterly progress reports to the Board (due January 10, April 10, July 10, and October 10 of each year of probation) that include:

(1) The written report and documentation provided by the treatment program pursuant to the contract, and

(2) A written description of Joseph Martin Rukse, Jr.'s progress towards recovery and what Joseph Martin Rukse, Jr. has been doing during the previous three months.

(C) Other terms of probation are as follows:

(1) The State Board of Pharmacy hereby declares that Joseph Martin Rukse, Jr.'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) Joseph Martin Rukse, Jr. may not serve as a responsible pharmacist.

(3) Joseph Martin Rukse, Jr. may not destroy, assist in, or witness the destruction of controlled substances.

(4) Joseph Martin Rukse, Jr. may not, during the first six months of practice, work in a pharmacy more than 40 hours per week.

(5) Joseph Martin Rukse, Jr. must, during the first six months of practice, work only with a pharmacist whose license is in good standing.

(6) Joseph Martin Rukse, Jr. must abide by the contract with his treatment provider and must immediately report any violation of the contract to the Board.

(7) Joseph Martin Rukse, Jr. must not violate the drug laws of Ohio, any other state, or the federal government.

(8) Joseph Martin Rukse, Jr. must abide by the rules of the State Board of Pharmacy.

(9) Joseph Martin Rukse, Jr. must comply with the terms of this Order.

(D) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.

Joseph Martin Rukse, Jr. is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

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

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mr. Lipsyc and approved by the Board (Aye-6/Nay-1).

11:30 a.m.

The Board recessed for lunch.

1:30 p.m.

The Board convened in Room South-A, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, for the purpose of meeting with the candidates for licensure by reciprocity with the following members present:

Lawrence J. Kost, R.Ph. (President); Suzanne R. Eastman, R.Ph. (Vice-President); Gregory Braylock, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; Dorothy S. Teater, Public Member; and James E. Turner, R.Ph.

R-2005-117 Following presentations by Board members and self-introductions by the candidates for licensure by reciprocity, the following candidates participated in a discussion of pharmacy laws and rules with Mr. McMillen and were then presented with their pharmacist identification cards.

ROBERT LEE BECK, JR.
ELIZABETH JANE DAVIES

03-2-26576
03-2-26587

PENNSYLVANIA
ILLINOIS

JEFFREY ANTHONY DIETRICH	03-2-26574	PENNSYLVANIA
KAMMIE LEE DOUGLAS	03-2-26579	INDIANA
DAWN RAVASIO FITT	03-2-26585	GEORGIA
MARIE P. MURRAY	03-2-26582	INDIANA
NIKESH CHANDU PATEL	03-2-26578	TEXAS

1:58 p.m.

The Board reconvened in Room East-B. 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 Eric Shawn Youngblood, Wadsworth.

3:08 p.m.

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

3:15 p.m.

Mr. Turner 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. Braylock and a roll call vote was conducted by President Kost as follows: Braylock-Yes, Eastman-Yes, Gregg-Yes, Lipsyc-Yes, Mitchell-Yes, Teater-Yes, and Turner-Yes.

3:35 p.m.

R-2005-118

The Executive Session ended and the meeting was opened to the public. Mr. Braylock moved that the Board adopt the following Order in the matter of Eric Shawn Youngblood:

ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-040715-016)

In The Matter Of:

ERIC SHAWN YOUNGBLOOD

10380 Rischel Road
Wadsworth, Ohio 44281
(D.O.B. 07/11/84)

INTRODUCTION

THE MATTER OF ERIC SHAWN YOUNGBLOOD CAME FOR HEARING ON JANUARY 4, 2005, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: LAWRENCE J. KOST, R.Ph. (presiding); GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; NATHAN S. LIPSYC, R.Ph.; KEVIN J. MITCHELL, R.Ph.; DOROTHY S. TEATER, PUBLIC MEMBER; AND JAMES E. TURNER, R.Ph.

ERIC SHAWN YOUNGBLOOD WAS REPRESENTED BY RONALD SCOTT SPEARS AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

State's Witnesses

1. Thomas Miksch, Ohio State Board of Pharmacy

Respondent's Witnesses

1. Eric Shawn Youngblood, Respondent

State's Exhibits

1. Proposal to Deny/Notice of Opportunity For Hearing letter [07-15-04]
1A-1B. Procedurals
2. Summons and Complaint No. 0901 and Minor Misdemeanor Citation No. 0902, State of Ohio vs. Eric S. Youngblood, Case No. 03CRB01112, Medina Municipal Court [08-20-03]
3. Montville Township Police Incident Report, No. 03-1797 [08-19-03]
4. Waiver of Trial By Jury; Waiver of Attorney; Waiver of Reading of the Facts/Circumstances, State of Ohio vs. Youngblood, Eric S., Case No. 03CRB01112, Medina Municipal Court [08-25-03]
5. Dismissal of Minor Misdemeanor Possession of Marijuana Charge [11-21-03]
6. Judgment Entry and Sentence [11-26-03]
7. Letter from Eric Youngblood [04-26-04]; Application for Pharmacy Intern Registration submitted by Eric Youngblood [04-28-04]

Respondent's Exhibits

- A. Summons and Complaint No. 0901 and Minor Misdemeanor Citation No. 0902, State of Ohio vs. Eric S. Youngblood, Case No. 03CRB01112, Medina Municipal Court [08-19-03]
- B. Charge: Drug Paraphernalia; and Waiver of Trial By Jury; Waiver of Attorney; Waiver of Reading of the Facts/Circumstances [08-25-03] State of Ohio vs. Eric S. Youngblood, Case No. 03CRB01112, Medina Municipal Court
- C. Dismissal of Minor Misdemeanor Possession of Marijuana Charge [11-21-03]
- D. Judgment Entry and Sentence [11-26-03]; Judgment Entry and Order [12-29-04]; Receipt No. 294289, Medina Municipal Court showing zero balance due [11-26-03]
- E. Proposal to Deny/Notice of Opportunity for Hearing letter [07-15-04]
- F. Hearing Request letter from Ronald Scott Spears [08-12-04]
- G. Hearing Schedule letter [08-16-04]
- H. Ohio Northern University Profession of Pharmacy 9, PHPR 303 curriculum requirements [not dated]
- I. Ohio Northern University Raabe College of Pharmacy Learning Objectives for The Profession of Pharmacy, PHPR 303 [2005]
- J. Letter from Eric Youngblood [04-26-04]; Application for Pharmacy Intern Registration submitted by Eric Youngblood [04-28-04]; Drug Screen Report [11-26-03]
- K. Two letters of support [12-27-04 and 12-30-04]

FINDINGS OF FACT

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

(1) Records of the State Board of Pharmacy indicate that Eric Shawn Youngblood applied to the Board for registration as a pharmacy intern in Ohio on April 28, 2004.

(2) Eric Shawn Youngblood did, on or about August 18, 2003, knowingly possess a Schedule I controlled substance when not in accordance with Chapters 3719., 4729., and 4731. of the Ohio Revised Code, to wit: Eric Shawn Youngblood possessed less than 200 gm of marijuana for his own personal abuse. Such conduct is in violation of Section 2925.11 of the Ohio Revised Code.

(3) Eric Shawn Youngblood did, on or about August 18, 2003, possess with purpose to use drug paraphernalia, to wit: Eric Shawn Youngblood possessed a glass smoking device and a pill bottle containing marijuana. Eric Shawn Youngblood pled guilty to Possession of Drug Paraphernalia, a misdemeanor of the fourth degree, in violation of Section 2925.14 of the Ohio Revised Code, and was sentenced to a fine and court costs. State of Ohio vs. Eric Youngblood, Case No. 03 CRB 01112, Medina Municipal Court.

CONCLUSION OF LAW

The State Board of Pharmacy concludes that paragraph (3) of the Findings of Fact constitutes being convicted of violating any state or federal pharmacy or drug law as provided in paragraph (B) of Rule 4729-5-04 of the Ohio Administrative Code.

DECISION OF THE BOARD

Pursuant to Section 4729.11 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the Application for Pharmacy Intern Registration submitted by Eric Shawn Youngblood.

Further, the Board places Eric Shawn Youngblood on probation for one year beginning on the effective date of this Order. The terms of probation are as follows:

(A) Eric Shawn Youngblood must notify his employer in writing, within thirty days of the effective date of this Order, of his marijuana possession and conviction. A copy of the letter must be submitted to the Board.

(B) Eric Shawn Youngblood must notify Ohio Northern University in writing, within thirty days of the effective date of this Order, of his marijuana possession and conviction. A copy of the letter must be submitted to the Board.

(C) Eric Shawn Youngblood must not violate the drug laws of Ohio, any other state, or the federal government.

(D) Eric Shawn Youngblood must abide by the rules of the State Board of Pharmacy.

(E) Eric Shawn Youngblood must comply with the terms of this Order.

(F) Eric Shawn Youngblood's license is deemed not in good standing until successful completion of the probationary period.

(G) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.

Eric Shawn Youngblood is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

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

MOTION CARRIED.

SO ORDERED.

3:37 p.m.

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

The meeting was recessed until Wednesday, January 5, 2005.

WEDNESDAY, JANUARY 5, 2005

10:00 a.m. ROLL CALL

The State Board of Pharmacy convened in Room East-B, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

Lawrence J. Kost, R.Ph. (President); Gregory Braylock, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; Dorothy S. Teater, Public Member; and James E. Turner, R.Ph.

10:07 a.m.

Suzanne Eastman arrived and joined the meeting in progress. 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 Michael Rebeck, R.Ph., Norton.

11:33 a.m.

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

11:38 a.m.

Mrs. Gregg 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. Teater and a roll call vote was conducted by President Kost as follows: Braylock-Yes, Eastman-Yes, Gregg-Yes, Lipsyc-Yes, Mitchell-Yes, Teater-Yes, and Turner-Yes.

11:50 a.m.

R-2005-119

The Executive Session ended and the meeting was opened to the public. Mr. Braylock moved that the Board adopt the following Order in the matter of David Michael Rebeck, R.Ph.:

ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-040802-007)

In The Matter Of:

DAVID MICHAEL REBECK, R.Ph.

3791 Reimer Road
Norton, Ohio 44203
(R.Ph. No. 03-2-15681)

INTRODUCTION

THE MATTER OF DAVID MICHAEL REBECK CAME FOR HEARING ON JANUARY 5, 2005, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: LAWRENCE J. KOST, R.Ph. (presiding); GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; NATHAN S. LIPSYC, R.Ph.; KEVIN J. MITCHELL, R.Ph.; DOROTHY S. TEATER, PUBLIC MEMBER; AND JAMES E. TURNER, R.Ph.

DAVID MICHAEL REBECK WAS REPRESENTED BY PETER T. CAHOON AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

State's Witnesses

1. Thomas Miksch, Ohio State Board of Pharmacy

Respondent's Witnesses

1. David Michael Rebeck, R.Ph., Respondent
2. Beverly Rebeck

State's Exhibits

1. Summary Suspension Order/Notice of Opportunity For Hearing letter [08-02-04]
1A-1C. Procedurals
2. Constructive Advice Notice to David Rebeck [05-08-04]
3. Drug & Alcohol Test Consent Agreement of Dave Rebeck to Marc Glassman, Inc. [05-19-04]
4. Alcohol Testing Form (Non-DOT) in re David M. Rebeck [05-19-04]
5. Medtox Laboratories Inc. Computer-Generated Laboratory Report for David Rebeck [05-19-04]
6. Ohio State Board of Pharmacy Written Statement Requesting the Release of Records Issued to Marcs Pharmacy [06-03-04]

7. Notarized Statement of Marla Waldman [06-09-04]
8. Notarized Statement of Naomi Bennett [06-09-04]
9. Notarized Statement of Alvin S. Moses, R.Ph. [06-09-04]
10. Eighteen Accountability Statements completed at Marcs Fairlawn Inc. for the following drugs: alprazolam 0.25 mg, alprazolam 0.5 mg, alprazolam 2 mg, Ativan 0.5 mg, clonazepam 0.5 mg, clonazepam 2 mg, clorazepate 3.75 mg, clorazepate 7.5 mg, clorazepate 15 mg, diazepam 5 mg, diazepam 10 mg, flurazepam 30 mg, Halcion 0.25 mg, Klonopin 1 mg, lorazepam 0.5 mg, Tranxene 3.75 mg, Tranxene 7.5 mg, Xanax 1 mg [07-26-04]
11. Statement of David M. Rebeck [12-30-04]

Respondent's Exhibits

- A. Edwin Shaw Hospital for Rehabilitation Certificate of Achievement for David Rebeck [11-06-04]
- B. Letter from Kevin L. Reid [12-10-04]
- C. Letter from Bill Plumley [12-16-04]
- D. SMART Recovery® Attendance Record for David Rebeck [06-16-04 to 10-27-04]
- E. Support Group Attendance Records [06-18-04 to 12-29-04]
- F. Sixteen Drug Screen Reports [06-18-04 to 10-07-04]
- G-H. Complaint; State of Ohio vs. David Rebeck, Case No. 04CRA16489, Akron Municipal Court [12-20-04]
- I. Edwin Shaw Hospital for Rehabilitation Chemical Dependency Continued Care Plan for David Rebeck [11-02-04]
- J. Continued Care Progress Report from Cheryl Shuttleworth, M.Ed, CCDC III-E [12-29-04]
- K. PRO Pharmacist's Recovery Contract for David Rebeck [10-18-04]
- L. Continuing Pharmaceutical Education Credit Statements and Certificate [04-01-03 to 01-02-05]
- M. Calendar pages from June 2004 to December 2004
- N. Letter from Ralph W. Meyer, Jr. [12-30-04]
- O. Letter from Julie A. Stone [12-29-04]

FINDINGS OF FACT

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

- (1) Records of the State Board of Pharmacy indicate that David Michael Rebeck was originally licensed by the State of Ohio as a pharmacist on August 8, 1984, pursuant to examination, and was summarily suspended effective August 8, 2004.
- (2) David Michael Rebeck is addicted to or abusing drugs or impaired physically or mentally to such a degree as to render him unfit to practice pharmacy within the meaning of Section 4729.16 of the Ohio Revised Code, to wit: David Michael Rebeck has been observed falling asleep while engaged in the practice of pharmacy; and, on May 19, 2004, David Michael Rebeck tested positive for having benzodiazepines in his system.
- (3) David Michael Rebeck did, on or about May 19, 2004, knowingly possess or use a controlled substance when the conduct was not in accordance with Chapters 3719., 4729., and 4731. of the Ohio Revised Code, to wit: without a valid prescription, David Michael Rebeck consumed benzodiazepines which were confirmed by a urine screen. Such conduct is in violation of Section 2925.11 of the Ohio Revised Code.
- (4) David Michael Rebeck did, from May 1, 2003, through June 2, 2004, with purpose to deprive, knowingly obtain or exert control over dangerous drugs, the property of Marc's Pharmacy in Fairlawn, beyond the express or implied consent of the owner, to wit: David Michael Rebeck stole the following controlled substances:

Drug	Shortage
alprazolam 0.25 mg	29
alprazolam 0.5 mg	90
alprazolam 2 mg	1108
Ativan 0.5 mg	17
clonazepam 0.5 mg	110
clonazepam 2 mg	94
clorazepate 3.75 mg	8
clorazepate 7.5 mg	14
clorazepate 15 mg	1286
diazepam 5 mg	368
diazepam 10 mg	2072
flurazepam 30 mg	19
Halcion 0.25 mg	7
Klonopin 1 mg	5
lorazepam 0.5 mg	306
Tranxene 3.75 mg	300
Tranxene 7.5 mg	50
Xanax 1 mg	79
Total:	<u>5962 unit doses</u>

Such conduct is in violation of Section 2913.02 of the Ohio Revised Code.

CONCLUSIONS OF LAW

(1) The State Board of Pharmacy concludes that paragraphs (3) and (4) 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) The State Board of Pharmacy concludes that paragraphs (3) and (4) 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) The State Board of Pharmacy concludes that paragraph (2) of the Findings of Fact constitutes being addicted to or abusing liquor or drugs and 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) The State Board of Pharmacy concludes that paragraph (3) of the Findings of Fact constitutes being guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of provisions of Chapter 2925. of the Revised Code as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.

DECISION 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 to David Michael Rebeck on August 2, 2004.

Pursuant to Section 4729.16 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby suspends indefinitely the pharmacist identification card, No. 03-2-15681, held by David Michael Rebeck and such suspension is effective as of the date of the mailing of this Order.

(A) David Michael Rebeck, pursuant to Rule 4729-9-01(F) of the Ohio Administrative Code, may not be employed by or work in a facility licensed by the State Board of Pharmacy to possess or distribute dangerous drugs during such period of suspension.

(B) David Michael Rebeck, pursuant to Section 4729.16(B) of the Ohio Revised Code, must return his identification card and license (wall certificate) to the office of the State Board of Pharmacy within ten days after receipt of this Order unless the Board office is already in possession of both. The identification card and wall certificate should be sent by certified mail, return receipt requested.

Further, after one year from the effective date of this Order, the Board will consider any petition filed by David Michael Rebeck for a hearing, pursuant to Ohio Revised Code Chapter 119., for reinstatement. The Board will only consider reinstatement of the license to practice pharmacy in Ohio if the following conditions have been met:

(A) David Michael Rebeck must enter into a new contract, signed within thirty days after the effective date of this Order, with an Ohio Department of Alcohol and Drug Addiction Services (ODADAS) treatment provider or a 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 that:

(1) Random, observed urine drug screens shall be conducted at least once each month.

(a) The urine sample must be given within twelve hours of notification. The urine drug screen must include testing for creatinine or specific gravity of the sample as the dilutional standard.

(b) Benzodiazepines must be added to the standard urine drug screen.

(c) Results of all drug screens must be negative. Refusal of a drug screen or a diluted drug screen is equivalent to a positive result. 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.

(2) Attendance is required a minimum of three times per week at an Alcoholics Anonymous, Narcotics Anonymous, and/or similar support group meeting.

(3) The program shall immediately report to the Board any violations of the contract and/or lack of cooperation.

(B) David Michael Rebeck must demonstrate satisfactory proof to the Board that he is no longer addicted to or abusing drugs or impaired physically or mentally to such a degree as to render him unfit to practice pharmacy.

(C) David Michael Rebeck must provide, at the reinstatement petition hearing, documentation of the following:

(1) Compliance with the contract required above (e.g.-proof of giving the sample within twelve hours of notification and copies of all drug screen reports, meeting attendance records, treatment program reports, etc.);

(2) Compliance with the continuing pharmacy education requirements set forth in Chapter 4729-7 of the Ohio Administrative Code as applicable and in effect on the date of petitioning the Board for reinstatement;

(3) Compliance with the terms of this Order.

(D) If reinstatement is not accomplished within three years of the effective date of this Order, David Michael Rebeck must also show successful completion of the NAPLEX examination or an equivalent examination approved by the Board.

Upon such time as the Board may consider reinstatement, David Michael Rebeck will be afforded a Chapter 119. hearing. At such time, the Board may consider reinstatement with or without restrictions and/or conditions as the Board deems appropriate under the circumstances.

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

MOTION CARRIED.

SO ORDERED.

- 11:52 a.m. The motion was seconded by Mr. Mitchell and approved by the Board (Aye-6/Nay-1).
- 1:34 p.m. The Board recessed for lunch.
- The Board reconvened in Room East-B, 31st Floor, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:
- Lawrence J. Kost, R.Ph. (President); Suzanne R. Eastman, R.Ph. (Vice-President); Gregory Braylock, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; Dorothy S. Teater, Public Member; and James E. Turner, R.Ph.
- 1:35 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 Sharon Malspeis, R.Ph., Columbus.
- 3:20 p.m. The hearing ended and the record was closed. The Board took a brief recess.
- 3:25 p.m. Mr. Braylock 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. Teater and a roll call vote was conducted by President Kost as follows: Braylock-Yes, Eastman-Yes, Gregg-Yes, Lipsyc-Yes, Mitchell-Yes, Teater-Yes, and Turner-Yes.
- 3:45 p.m. **R-2005-120** The Executive Session ended and the meeting was opened to the public. Mr. Braylock moved that the Board adopt the following Order in the matter of Sharon Malspeis, R.Ph.:

ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-041008-030)

In The Matter Of:

SHARON JUETT MALSPEIS, R.Ph.

1466 Oakbourne Drive
Columbus, Ohio 43235
(R.Ph. No. 03-2-08977)

INTRODUCTION

THE MATTER OF SHARON JUETT MALSPEIS CAME FOR HEARING ON JANUARY 5, 2005, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: LAWRENCE J. KOST, R.Ph. (presiding); GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; NATHAN S. LIPSYC, R.Ph.; KEVIN J. MITCHELL, R.Ph.; DOROTHY S. TEATER, PUBLIC MEMBER; AND JAMES E. TURNER, R.Ph.

SHARON JUETT MALSPEIS WAS NOT REPRESENTED BY COUNSEL AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

State's Witnesses

1. Christopher K. Reed, Ohio State Board of Pharmacy

Respondent's Witnesses

1. Sharon Juett Malspeis, R.Ph., Respondent

State's Exhibits

1. Notice of Opportunity For Hearing letter [10-08-04]
1A-1D. Procedurals

Respondent's Exhibits

- A. Social Security Earnings Record [1958 to 2002]; Three Employee's Pay Statements from The Roosevelt Hospital [03-08-64]; Cochran's Pharmacy Inc. [01-02-73]; Super-X, Sav-On and Gasen Drug Stores [09-14-74]
- B. Copy of The Merck Manual, Eighth Edition, pages 304 through 307 re Periodontal Disease and pages 320 and 321 re Prescriptions [not dated]; copy of article by Carla Davis, "The Question of Wine", www.vegetariantimes.com, November/December 2004; Copy of West and Todd Textbook of Biochemistry, 3rd Edition © 1951, 1955, 1961 (...of calcium and phosphorus and the Ca:P ratio of food); Copy of Table 1. - "Nutritive values for household measures and market units of foods" from Diet and Exercise Made Easy ©1975,1977, 1978, 1979, 1980; Copy of pages 1188 and 1189 of West and Todd Textbook of Biochemistry, 3rd Edition © 1951, 1955, 1961 (Formation of collagen fibers); Copy of page 197 of The New York Times Cookbook ©1961; Copy of purchase order from Chef's for Sharon Malspeis [04-10-03]; Copy of purchase order from Hammacher Schlemmer for Sharon Malspeis [07-17-02]; Color photocopy of two dental images from Oak Creek Dental Care for Sharon Malspeis [12-14-04]; Copy of dental x-ray from Oak Creek Dental Care for Sharon Malspeis [12-14-04]

FINDINGS OF FACT

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

(1) Records of the State Board of Pharmacy indicate that Sharon Juett Malspeis was originally licensed by the State of Ohio as a pharmacist on April 16, 1968, pursuant to reciprocity, and is currently licensed to practice pharmacy in the State of Ohio.

(2) There is reason to believe that Sharon Juett Malspeis is impaired physically or mentally to such a degree as to render her unfit to practice pharmacy, to wit: an anonymous source has indicated that Sharon Juett Malspeis is paranoid schizophrenic, and that Sharon Juett Malspeis is not under the care of a physician for this condition. During two separate interviews by Board agents, Sharon Juett Malspeis exhibited signs of mental impairment. Specifically, Sharon Juett Malspeis indicated to Board agents that everyone wearing the color blue is a federal agent investigating her; Sharon Juett Malspeis stated that her neighbor looks like her and that she's trying to steal her identity; that her pharmaceutical reference books were stolen, but showed up later in her house covered with dust; and, that federal agents have been in her house several times and had forced their way into her home recently.

DECISION OF THE BOARD

Pursuant to Section 4729.16 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby continues the hearing of Sharon Juett Malspeis to a date to be determined after compliance with the Order herein:

- (A) Sharon Juett Malspeis must obtain, within sixty days after the effective date of this Order, a full psychiatric evaluation by a licensed, board-certified psychiatrist.
- (B) Prior to obtaining said evaluation, Sharon Juett Malspeis must submit to the Board the name and address of the psychiatrist she will utilize so the Board can forward documentation of its concerns that must be addressed by the psychiatrist.
- (C) The psychiatrist must provide an initial evaluation and status report, which includes any recommended treatment plan, directly to the Board office within 10 days after completing the assessment.
- (D) Sharon Juett Malspeis must sign any appropriate waivers so the psychiatrist can present the final report and recommendation directly to the Board.
- (E) Pending the next hearing in this matter, Ms. Malspeis must abide by any treatment plan as designed by the psychiatrist.

Upon receipt of the psychiatrist's report, or upon the conclusion of one hundred days after the effective date of this Order, whichever comes first, the Board will reschedule this matter to reconvene the Chapter 119. hearing. At such time, the Board may take action pursuant to Section 4729.16 of the Ohio Revised Code.

NOTICE: Failure to obtain the psychiatric evaluation, under the terms, conditions, and time frames set forth in this Order, shall be deemed a violation of the Board's Order and a violation of Divisions (A)(3) and (E) of Section 4729.16 of the Ohio Revised Code. Such failure shall be deemed reason to take action pursuant to Section 4729.16 of the Ohio Revised Code.

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

MOTION CARRIED.

SO ORDERED.

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

3:48 p.m.

Mr. Lipsyc moved that the Board receive Per Diem as follows:

PER DIEM	<u>1/3</u>	<u>1/4</u>	<u>1/5</u>	<u>Total</u>
Braylock	1	1	1	3
Eastman	1	1	1	3
Giacalone	-	-	-	0
Gregg	1	1	1	3
Kost	1	1	1	3
Lipsyc	1	1	1	3
Mitchell	1	1	1	3
Teater	1	1	1	3
Turner	1	1	1	3

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

3:49 p.m.

Mr. Braylock moved that the meeting be adjourned. The motion was seconded by Mr. Lipsyc and approved by the Board (Aye-7/Nay-0).

<p>THE BOARD APPROVED THESE MINUTES FEBRUARY 8, 2005</p>
