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Minutes of the October 9-10, 2007 Meeting of the Ohio State Board of Pharmacy

Monday, October 9, 2007

9:07 a.m. The Ohio State Board of Pharmacy convened in room East B, 31st Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, with the following members present:

Gregory Braylock, R.Ph., *President*; Nathan S. Lipsyc, R.Ph., *Vice-President*; Elizabeth I. Gregg, R.Ph.; Richard F. Kolezynski, R.Ph.; Kevin J. Mitchell, R.Ph.; Heather L. Pasquale, R.Ph.; Dorothy S. Teater, Public Member; James E. Turner, R.Ph.; and Jerome J. Wiesenhahn, 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*; Danna Droz, *Prescription Drug Monitoring Program Director*; and Sally Ann Steuk, *Assistant Attorney General*.

R-2008-053 Mr. Rowland announced that the following Settlement Agreement with **Gene Alan Johnson**, R.Ph. (03-1-26043) Centerburg, Ohio, has been signed by all parties and is now effective.

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY

Docket Number D-070809-002

in the matter of:

GENE ALAN JOHNSON, R.Ph.

5655 County Road 13
Centerburg, Ohio 43011

R.Ph. Number 03-1-26043

This Settlement Agreement is entered into by and between Gene Alan Johnson 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.

Gene Alan Johnson 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. Gene Alan Johnson 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, Gene Alan Johnson is licensed to practice pharmacy in the State of Ohio.

Whereas, on or about August 9, 2007, pursuant to Chapter 119. of the Ohio Revised Code, Gene Alan Johnson 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. Gene Alan Johnson requested a hearing; it was scheduled. The August 9, 2007, Notice of Opportunity for Hearing contains the following allegations or charges:

- (1) Records of the State Board of Pharmacy indicate that Gene Alan Johnson was originally licensed by the State of Ohio as a pharmacist on March 17, 2004, pursuant to examination, and is currently licensed to practice pharmacy in the State of Ohio.
- (2) Gene Alan Johnson did, on or about February 18, 2006, misbrand a drug, to wit: when Gene Alan Johnson received a prescription for Provera 10 mg, #30, "one PO qd," Rx #530405, he dispensed megestrol 40 mg, "one tablet every day," which had not been specifically prescribed by the physician. The patient subsequently was harmed. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.
- (3) Gene Alan Johnson did, on or about August 6, 2006, misbrand a drug, to wit: when Gene Alan Johnson received a refill for Rx #530405, for Provera 10 mg, #30, "one PO qd," he again dispensed megestrol 40 mg, "one tablet every day," which had not been specifically prescribed by the physician. The patient was harmed. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.
- (4) Gene Alan Johnson did, on or about September 8, 2006, misbrand a drug, to wit: when Gene Alan Johnson received a refill for Rx #530405, for Provera 10 mg, #30, "one PO qd," he dispensed megestrol 40 mg, "one tablet every day," which had not been specifically prescribed by the physician. The patient was harmed. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

Gene Alan Johnson neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated August 9, 2007; however, 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, Gene Alan Johnson knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

- (A) Gene Alan Johnson agrees to the imposition of a monetary penalty of two hundred fifty dollars (\$250.00) due and owing within thirty days from the effective date of this Agreement. Checks should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126.

- (B) Gene Alan Johnson must obtain, within six months from the effective date of this Agreement, five hours of continuing pharmacy education (0.5 CEUs) on preventing medication errors, which may not also be used for license renewal

Gene Alan Johnson 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.

Gene Alan Johnson 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. Gene Alan Johnson 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.

/s/ Gene Alan Johnson, R.Ph. Date Signed: 09/29/07
Respondent

/s/ Gregory Braylock Date Signed: 10/09/07
President; Ohio State Board of Pharmacy

/s/ Sally Ann Steuk Date Signed: 10/09/07
Ohio Assistant Attorney General

9:09 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 Ohio Revised Code and to confer with an attorney for the Board regarding pending or imminent court action pursuant to Section 121.22(G)(3) of the Ohio Revised Code. The motion was seconded by Ms. Pasquale and a roll-call vote was conducted by President Braylock as follows: Gregg – *yes*; Kolezynski – *yes*; Lipsyc – *yes*; Mitchell – *yes*; Pasquale – *yes*; Teater – *yes*; Turner – *yes*; and Wiesenhahn – *yes*.

10:08 a.m. The Executive Session ended and the meeting was opened to the public.

R-2008-054 Mrs. Gregg moved that the settlement offer in the matter of **Kevin Kelly Sheets, R.Ph.** (03-3-11763) Portsmouth, Ohio, be accepted. The motion was seconded by Mr. Turner and approved by the Board: *Aye* – 8.

R-2008-055 Mr. Turner moved that the settlement offer in the matter of **Jae-Seung Lee, R.Ph.** (03-3-22050) Dublin, Ohio, be denied. The motion was seconded by Ms. Pasquale and approved by the Board: *Aye* – 8.

10:15 a.m. The Board recessed briefly.

10:21 a.m. The Board reconvened.

10:24 a.m.
R-2008-056 Mr. Winsley asked for approval to have the following new and amended rules filed as soon as possible, becoming effective ten days after filing. Mrs. Gregg moved that approval be given and the motion was seconded by Mr. Turner: *Aye* – 8.

FULL TEXT SHOWING CHANGES

UNDERLINED = Add New Language

LINED THROUGH = ~~Remove~~ Old Language

4729-1-02 Notice of meetings.

Any person may obtain the time and place of all regularly scheduled meetings and the time, place, and purpose of all special meetings of the state board of pharmacy, as required by division (F) of section 121.22 of the Revised Code, by:

- (A) ~~Written~~ Regular mail, upon written request to the state board of pharmacy.
 - (1) Written requests shall include the name, mailing address, and telephone number of the person making the request.
 - (2) Written requests shall be accompanied by a service fee of twenty-five dollars which shall be valid for the fiscal year of July first through June thirtieth.
 - (3) Notice for the annual renewal of this request will be sent by the board of pharmacy by June first of each year and shall be due no later than July thirty-first of each year.
- (B) Calling the telephone number of the state board of pharmacy between the normal business hours of eight a.m. to four-thirty p.m., Monday through Friday, legal holidays excepted.
- (C) Consulting the official record of all board of pharmacy regularly scheduled and special meetings located at office of the state board of pharmacy.
- (D) Viewing the state board of pharmacy's world wide web home page.
- (E) Requesting the information to be sent by the state board of pharmacy by e-mail.

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 electronic prescription transmission system, each of which is pursuant to rule 4729-5-30 of the Administrative Code.
- (I) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, and provide personal review and approval of all professional ~~pharmaceutical~~ activities.
- (J) "Preprinted order" is defined as a 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 and 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 drugs used in the treatment guidelines shall be displayed on the 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.
 - (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:
 - (a) A manual signature on a hard copy record;
 - (b) A magnetic card reader;
 - (c) A bar code reader;
 - (d) A thumbprint reader or other biometric method;
 - (e) A proximity badge reader;
 - (f) A board approved system of randomly generated personal questions;
 - (g) A printout of every transaction that is verified and manually signed within 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.

(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.

(O) "Originating pharmacy", as it relates to central fill pharmacies, means the pharmacy that received the original prescription.

4729-5-08 Pharmacy intern professional functions. (NEW)

In addition to assisting a pharmacist with technical functions, a pharmacy intern may perform the following professional functions under the direct supervision of a pharmacist. These activities must be documented with positive identification of both the supervising pharmacist and the pharmacy intern.

(A) The sale of schedule V controlled substances pursuant to rule 4729-11-09 of the Administrative Code.

(B) The receipt of oral prescriptions pursuant to paragraph (D)(3) of rule 4729-5-30 of the Administrative Code.

(C) The transfer of a prescription copy pursuant to paragraph (G) of rule 4729-5-24 of the Administrative Code.

(D) The act of patient counseling pursuant to paragraph (B) of rule 4729-5-22 of the Administrative Code.

(E) The administration of influenza immunizations to individuals eighteen years of age and older pursuant to section 4729.41 of the Revised Code.

(F) The documentation of informed consent to administer an immunization pursuant to section 4729.41 of the Revised Code and paragraph (O) of rule 4729-5-27 of the Administrative Code.

4729-5-10 Prescription pick-up station.

(A) No pharmacist shall accept prescriptions obtained from a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled unless such place is a pharmacy as defined in section 4729.01 of the Revised Code, has received board approval to function in such a manner, and all of the following apply:

(1) The site is licensed with the state board of pharmacy as a terminal distributor of dangerous drugs;

(2) The receipt, storage, control, and distribution of prescriptions are in the full and actual charge of a pharmacist licensed pursuant to Chapter 4729. Of the Revised Code;

(3) An appropriate recordkeeping system is in place that will provide accountability for proper receipt, delivery, and return of all prescriptions;

- (4) There is a documented method in place to ensure compliance with rule 4729-5-22 of the Administrative Code.
- (B) No pharmacist shall dispense dangerous drugs to a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered unless such place is a pharmacy as defined in section 4729.01 of the Revised Code, has received board approval to function in such a manner, and paragraphs (B)(1) through (B)(4) of this rule apply or, if not a pharmacy, unless all of the following apply:
- (1) The site is licensed with the state board of pharmacy as a terminal distributor of dangerous drugs.
 - (2) The receipt, storage, control, and distribution of prescriptions or drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4715., 4723., 4729., 4730., ~~or 4731.~~ or 4741. of the Revised Code.
 - (3) An appropriate recordkeeping system is in place that will provide accountability for proper receipt, delivery, and return of all prescription medications.
 - (4) There is a documented method in place to ensure compliance with rule 4729-5-22 of the Administrative Code.
 - (5) The state board of pharmacy has approved the site for such activity due to clear and convincing evidence that delivery of prescription medication directly to the patient would result in:
 - (a) Danger to public health or safety, or
 - (b) Danger to the patient without increased involvement by a health care professional in the patient's drug therapy.

4729-5-13 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.
 - (3) If preprinted with multiple drug names or 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 for a controlled substance 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 for a controlled substance 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 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 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 4723.48 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.
- (E) A physician assistant approved pursuant to section 4730.44 of the Revised Code may prescribe those drugs approved in rule by the medical board and pursuant to the physician supervisory plan for that physician assistant.

4729-5-27 Record keeping.

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 request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy office will send written notification of the approval or ~~disapproval~~ denial of the request. ~~Only after receiving the notice of the board's approval may the records be placed in the new location.~~ A copy of the board's approval shall be maintained with other records relating to the practice of pharmacy. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.
- (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 weekends 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. In addition to the immediate retrieval and production of patient profile information required by paragraph (G) of this rule, a pharmacy that utilizes a computerized record keeping system must be able to:~~

(1) Produce:

- (a) An electronic record in a character-delimited or fixed-width ASCII text file or other mutually acceptable format that contains any requested data fields the user pharmacy is responsible for maintaining pursuant to all federal and state laws, rules, and regulations; and
- (b) A hardcopy printout sorted by any requested data fields that the user pharmacy is responsible for maintaining pursuant to all federal and state laws, rules, and regulations.

(2) Provide, within three working days of a request by an individual authorized by law to access such records, any requested:

- (a) Printout; or
- (b) Electronic record and a definition file describing the file layout and column width, if applicable.

(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 or the administering pharmacy intern and supervising pharmacist;
 - (11) ~~Documentation~~ Positive identification of the patient, parent, or legal guardian of the patient who gives informed consent to administer an immunization.
- (P) A pharmacist or pharmacy intern under the direct supervision of a pharmacist who administers adult immunizations an immunization 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.

4729-5-30 Manner of issuance of a prescription.

- (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, professional title, 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) For a controlled substance, indicate the drug enforcement administration registration number of the prescriber pursuant to Title 21 CFR 1306.05.
 - (16) If issued by a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner with prescriptive authority, contain the nurse's prescriber number found on the certificate to prescribe issued by the state board of nursing pursuant to rule 4723-9-09 of the Administrative Code.
 - (17) 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.
 - (5) The facsimile of the prescription must include header information identifying the origin of the facsimile.
- (F) A prescription may be transmitted by means of a board approved electronic prescription transmission system provided that:

- (1) The system requires 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 is retained for a period of three years at the prescriber's office.

(G) Pursuant to section 4729.38 of the Revised Code if a prescriber does not want a pharmacist to select a generically equivalent drug the prescriber must handwrite "dispense as written" or "DAW" on the prescription, or if ordering electronically or orally the prescriber specifies that the prescribed drug is medically necessary.

4729-5-36 Course requirements in the administration of ~~adult~~ immunizations.

- (A) A course in the administration of ~~adult~~ immunizations developed pursuant to division (B)(1) of section 4729.41 of the revised code shall meet at least the following requirements:
- (1) The instructor shall be a licensed health care professional and have the appropriate education and experience to teach a course in the administration of ~~adult~~ immunizations.
 - (2) The content must meet the standards established for such courses by the centers for disease control and prevention in the public health service of the united states department of health and human services.
 - (3) The course must be a minimum of five hours in length and include at least the following:
 - (a) A review of immunology that includes a discussion of the body's immune system reaction to the immunizations.
 - (b) A review of each ~~immunization~~ medication listed in division (A) of section 4729.41 of the revised code that includes the following:
 - (i) Disease states associated with the immunization;
 - (ii) Type or nature of activity of the immunization;
 - (iii) Appropriate administration schedules;
 - (iv) Appropriate routes of administration;
 - (v) Appropriate injection sites;
 - (vi) Appropriate dosages;
 - (vii) Appropriate monitoring and treatment of the patient for adverse reactions;
 - (viii) Appropriate patient populations;
 - (ix) Precautions and contraindications;
 - (x) Proper storage requirements for the immunization.
 - (c) A review of sterile technique in injectable dosage preparation and administration.
 - (d) A minimum of one hour of instruction and physical participation in administration techniques.

- (e) A review of the proper disposal procedures for contaminated needles and immunizations.
 - (f) A review of the proper procedures for accidental needle sticks.
- (4) The course must provide a method to evaluate the successful mastery of the content.
- (B) All courses in ~~adult~~ immunizations must be submitted to the state board of pharmacy for approval. The courses may be reviewed with the state medical board and the board of nursing, as appropriate. Any subsequent revisions to the course, after the initial approval, must be submitted to the state board of pharmacy for approval.

4729-5-37 Protocols for the administration of ~~adult~~ immunizations.

- (A) To be considered an approved protocol pursuant to division (B)(3) of section 4729.41 of the revised code, the physician-established protocol for the administration of ~~adult~~ immunizations must include at least the following:
- (1) For each ~~immunization~~ medication listed in division (A) of section 4729.41 of the revised code:
 - (a) Name and strength;
 - (b) Precautions and contraindications;
 - (c) Intended audience or patient population;
 - (d) Appropriate dosage;
 - (e) Appropriate administration schedules;
 - (f) Appropriate routes of administration;
 - (g) Appropriate injection sites.
 - (2) The length of time the pharmacist or pharmacy intern under the direct supervision of a pharmacist must observe an individual for adverse effects, which shall be based on appropriate standards of care established by the physician. The location of the observation shall be in the general vicinity of the administering pharmacist or pharmacy intern to allow for on-going evaluation.
 - (3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.
 - (4) A method to notify an individual's physician or the applicable board of health within thirty days after administering an immunization a medication, except for influenza immunizations administered to individuals eighteen years of age and older.
 - (5) The locations that a pharmacist or pharmacy intern under the direct supervision of a pharmacist may engage in the administration of immunizations.
- (B) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the administering pharmacist. The pharmacist must renew the protocol annually with the physician.

- (C) Upon the request of the state board of pharmacy, a pharmacist shall immediately provide the protocols for adult immunizations pursuant to division (B)(3) of section 4729.41 of the revised code. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has approved it. The state board of pharmacy may review the protocols with the state medical board and the board of nursing, as appropriate.

4729-9-11 Security and control of dangerous drugs.

A pharmacist, prescriber, or responsible person pursuant to paragraph (C) of rule 4729-13-01 or paragraph (C) of rule 4729-14-01 of the Administrative Code, who has signed as being responsible for a terminal distributor of dangerous drugs license, shall provide "supervision and control" of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, and "adequate safeguards" to assure that dangerous drugs are being distributed in accordance with all state and federal laws as required in section 4729.55 of the Revised Code, by the following procedures:

- (A) In a pharmacy.
- (1) Personal supervision by a pharmacist of the dangerous drugs at all times to deter and detect theft or diversion; except,
 - (2) Whenever personal supervision of the dangerous drugs is not provided by a pharmacist, physical or electronic security of the dangerous drugs must be provided according to the following requirements:
 - (a) The prescription department or stock of dangerous drugs must be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time the pharmacist is not present. Such a barrier, before being put into use, must be approved by the state board of pharmacy.
 - (b) The prescription department must contain all dangerous drugs, exempt narcotics, hypodermics, poisons, and every other item or product that requires the personal supervision or sale by a pharmacist.
 - (c) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the prescription department.
 - (d) Except as provided in rule 4729-17-03 of the Administrative Code, only a pharmacist may have access to the prescription department or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, exempt narcotics, hypodermics, poisons, and any other item or product that requires the personal supervision or sale by a pharmacist.
 - (e) No prescription, dangerous drug, exempt narcotic, hypodermic, nor any other item or product that requires the personal supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the prescription department is closed.
 - (f) New or refill prescription orders may be deposited into a secured area within the building where the pharmacy is located when a pharmacist is not present. Only a pharmacist may have access to this secured area.
 - (g) Notice to the public of operating hours of the prescription department must be posted.

- (3) Areas designated for the dispensing, compounding, and storage of dangerous drugs shall meet the security requirements in rule 4729-9-05 of the Administrative Code. No person may be within the physical confines of the area designated for the dispensing, compounding, and storage of dangerous drugs unless under the personal supervision of a pharmacist.
- (B) In other terminal distributors of dangerous drugs, including but not limited to, emergency medical services pursuant to division (C) of section 4729.54 of the Revised Code, first-aid departments pursuant to rule 4729-9-04 of the Administrative Code, approved laboratories pursuant to paragraph (A) of rule 4729-13-01 of the Administrative Code, and animal shelters pursuant to paragraph (A) of rule 4729-14-01 of the Administrative Code, dangerous drugs must be stored in an area secured by either a physical barrier with suitable locks and/or an electronic barrier to deter and detect unauthorized access.
- (C) A pharmacist, prescriber, or responsible person for a terminal distributor of dangerous drugs license pursuant to paragraph (C) of rule 4729-13-01 or paragraph (C) of rule 4729-14-01 of the Administrative Code who has signed as being responsible for a terminal distributor of dangerous drugs license is responsible to monitor for suspicious orders, unusual usage, or questionable disposition of dangerous drugs.
- (D) All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board.

4729-9-14 Records of controlled substances.

- (A) Each prescriber or terminal distributor of dangerous drugs shall keep a record of all controlled substances received, administered, dispensed, sold, or used. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.
 - (1) Records of receipt shall contain a description of all controlled substances received, the kind and quantity of controlled substances received, the name and address of the persons from whom received, and the date of receipt.
 - (2) Records of administering, dispensing, or using controlled substances shall contain a description of the kind and quantity of the controlled substance administered, dispensed, or used, the date, the name and address of the person to whom or for whose use, or the owner and identification of the animal for which, the controlled substance was administered, dispensed, or used.
 - (3) Records of drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the name and address requirements of paragraph (A)(2) of this rule.
- (B) Each prescriber or terminal distributor of dangerous drugs shall maintain an inventory of all controlled substances as follows:
 - (1) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.
 - (a) The name of the substance.
 - (b) The total quantity of the substance.

- (i) Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter).
 - (ii) The number of units or volume of each finished form in each commercial container (e.g., one-hundred-tablet bottle or ten-milliliter vial).
 - (iii) The number of commercial containers of each such finished form (e.g., three one-hundred-tablet bottles or ten one-milliliter vials).
- (c) If the substance is listed in schedule I or II, the prescriber or terminal distributor of dangerous drugs shall make an exact count or measure of the contents.
 - (d) If the substance is listed in schedule III, IV, or V, the prescriber or terminal distributor of dangerous drugs may make an estimated count or measure of the contents, unless the container holds more than one thousand tablets or capsules in which an exact count of the contents must be made.
- (2) A separate inventory shall be made for each place or establishment where controlled substances are in the possession or under the control of the prescriber or terminal distributor. Each inventory for each place or establishment shall be kept at the place or establishment.
 - (3) An inventory of all stocks of controlled substances on hand on the date the prescriber or terminal distributor first engages in the administering, dispensing, or use of controlled substances. In the event the prescriber or terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory.
 - (4) Each prescriber or terminal distributor of dangerous drugs shall take a new inventory of all stocks of controlled substances on hand every two years following the date on which the initial inventory is taken.
 - (5) When a substance is added to the schedule of controlled substances by the federal drug enforcement administration or the state board of pharmacy, each prescriber or terminal distributor of dangerous drugs shall take an inventory of all stock of such substance on hand at that time.
 - (6) All records of receipt, distribution, administering, dispensing, inventory, or using controlled substances shall be kept for a period of three years at the place where the controlled substances are located. Any prescriber or terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send notification a written request to the state board of pharmacy; ~~if not contested by the board within sixty days, it will stand as approved.~~ The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of controlled substances. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

4729-9-22 Records of dangerous drugs.

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

be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.

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

4729-10-01 Definitions.

As used in Chapter 4729-10 of the Administrative Code:

- (A) "Nonresident pharmacy" means any pharmacy, as defined in section 4729.01 of the Revised Code, located outside of Ohio that ships, mails, or delivers, in any manner, drugs at retail into Ohio;
- (B) "Nonresident terminal distributor of dangerous drugs" means any person, as defined in section 4729.01 of the Revised Code, located outside of Ohio that ships, mails, or delivers in any manner, dangerous drugs at retail into Ohio;
- (C) "Pharmacist," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice pharmacy in the state where he/she is practicing.
- ~~(D) "Dentist," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice dentistry in the state where he is practicing.~~
- ~~(E) "Optometrist," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice optometry in the state where he is practicing.~~
- ~~(F) "Physician," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice medicine in the state where he is practicing.~~

- ~~(C) "Veterinarian," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice veterinary medicine in the state where he is practicing.~~
- (D) "Licensed health professional authorized to prescribe drugs" or "prescriber" as used in division (B) of section 4729.55 means an individual who is authorized by law to prescribe drugs or dangerous drugs in the state where the individual is practicing.
- ~~(H)~~(E) "Dangerous drug" has the same meaning as given that term in section 4729.01 of the Revised Code.

4729-10-02 Licensure.

Each nonresident terminal distributor of dangerous drugs that sells dangerous drugs at retail in the state of Ohio shall obtain a terminal distributor of dangerous drugs license pursuant to sections 4729.54 and 4729.55 of the Revised Code and Chapter 4729-10 of the Administrative Code.

- (A) Conditions of licensure. The nonresident terminal distributor of dangerous drugs shall provide the following information relative to the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code:
- (1) Full name, address, and telephone number of the person who desires to be licensed as a nonresident terminal distributor of dangerous drugs.
 - (a) If incorporated, the application for licensure must include copies of the incorporation papers; and names, dates of birth, addresses, and social security numbers of the officers of the corporation and all stockholders holding more than ten percent of the stock.
 - (b) If a proprietorship, the application for licensure must include the name, address, date of birth, and social security number of the owner(s).
 - (c) If a partnership, the application for licensure must include the names, addresses, dates of birth, and social security numbers of the partners.
 - (d) If the entity applying for a license is a private investment group, the application for licensure must include the names, addresses, dates of birth, and social security numbers of the investors.
 - (2) Certification from the appropriate licensing authority that the applicant maintains at all times a valid, unexpired license, permit, or registration to properly carry on the business of a distributor of dangerous drugs in the state in which the facility is located and from where dangerous drugs are being sold at retail to residents in Ohio. The certification(s) must include licenses, permits, or registrations required to cover the categories of dangerous drugs which the nonresident terminal distributor of dangerous drugs will be selling at retail to persons in the state of Ohio (i.e., controlled substance drug products as well as noncontrolled substance drug products).
 - (3) A copy of the most recent inspection report, any warning notices, notice of deficiency reports, or any other related reports issued by the regulatory licensing agency and drug law enforcement agencies of the state in which it is located or any federal agencies regulating and enforcing laws governing the legal distribution of drugs.
 - (4) A narrative description of the type of business the nonresident terminal distributor of dangerous drugs will ~~be carrying on~~ conduct within the category of licensure requested. The description shall include the type of professional services that will be provided in

accordance with federal and state laws governing the legal distribution of drugs and professional pharmacy practice.

- (5) If the nonresident terminal distributor is a pharmacy, the application shall be accompanied by:
 - (a) The name and license number of the responsible pharmacist (pharmacist-in-charge).
 - (b) Certification from the appropriate licensing authority that the responsible pharmacist's license is current and in good standing.
 - (c) The telephone number where the responsible pharmacist may be reached during normal business hours.
 - (d) A list of all pharmacists employed by the pharmacy who are dispensing dangerous drugs pursuant to prescriptions to residents of this state. The list shall include each pharmacist's license number and the date that the license will expire.
 - (e) A description of the following:
 - (i) Normal delivery protocols and times;
 - (ii) Any special packaging or procedures used in delivering temperature-sensitive drug products;
 - (iii) The procedure to be followed if the patient's prescription drug is not available at the nonresident pharmacy, or if delivery will be delayed beyond the normal delivery time;
 - (iv) The procedure to be followed upon receipt of a prescription for an acute illness that assures the patient the opportunity to obtain the medication immediately.
 - (v) The procedure to be followed that will ensure that the patient's medication therapy is not interrupted when the nonresident pharmacy has been advised by the patient or patient's caregiver that the patient's prescription medication has not been received within the normal delivery time.
- (6) Nonresident terminal distributors of dangerous drugs where the responsible person is a ~~dentist, optometrist, physician, or veterinarian~~ prescriber shall submit the following information with their application:
 - (a) The name and license number of the responsible ~~dentist, optometrist, physician, or veterinarian~~ prescriber.
 - (b) Certification from the appropriate licensing authority that the responsible person's license is current and in good standing.
 - (c) The telephone number where the responsible ~~dentist, optometrist, physician, or veterinarian~~ prescriber may be reached during normal business hours.
 - (d) A list of all ~~dentists, optometrists, physicians, or veterinarians~~ prescribers employed by the nonresident terminal distributor who are selling dangerous drugs at retail to residents of this state. The list shall include the license numbers and the date that the licenses to practice will expire.

4729-10-03 Compliance.

Each nonresident terminal distributor of dangerous drugs shall:

- (A) Maintain, in readily retrievable form, records of all dangerous drugs sold at retail to persons in Ohio.
- (B) Comply with all the statutory and regulatory requirements of the state of Ohio for controlled substances, including those that are different from federal law, unless such compliance would cause the nonresident terminal distributor of dangerous drugs to violate the statutory or regulatory requirements of the state in which it is located.
- (C) Supply upon request and in a timely manner all information needed by the board of pharmacy to carry out its responsibilities as a licensing, regulatory, and drug law enforcement agency of the state of Ohio.
- (D) Supply upon request and in a timely manner all information needed by the board of pharmacy and any local, state, or federal agency to carry out its responsibilities in enforcing the federal and state laws governing the distribution of drugs in the state of Ohio.
- (E) ~~Supply upon request and in a timely manner all information needed by the board of pharmacy to carry out its responsibilities in licensing and regulating professional practice in the state of Ohio.~~
- (F) If the nonresident terminal distributor is a pharmacy, there must be an offer to counsel the patient issued with every prescription filled. The offer shall be made by telephone or in writing on a separate document and shall accompany the prescription. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population. The pharmacy shall have sufficient telephone service to provide reasonable access to incoming callers.

4729-36-04 Sample drug distribution to a charitable pharmacy.

- (A) An eligible sample drug shall only be distributed directly to a charitable pharmacy by a:
 - (1) Manufacturer;
 - (2) Manufacturer's representative;
 - ~~(2)~~(3) Wholesale distributor of dangerous drugs acting on behalf of a manufacturer; or
 - ~~(3)~~(4) Prescriber practicing in a location that is licensed as a terminal distributor of dangerous drugs.
- (B) If a sample drug is furnished by a prescriber:
 - (1) A record must be created by the prescriber documenting the sample drug transfer. The record shall contain the: (a) Name and address of the supplying prescriber; (b) Name, strength, and quantity of the sample drug supplied; (c) Date of the sample drug transfer; (d) Name and address of the charitable pharmacy receiving the sample drug.
 - (2) ~~A copy of the original record issued by the manufacturer or the wholesale distributor documenting the transfer of the sample drug to the prescriber must be furnished to the charitable pharmacy upon receiving a sample drug.~~ (3) A copy of all required records documenting the transfer of a sample drug must be kept by the prescriber and the charitable pharmacy for a minimum of three years and be stored in a readily retrievable

manner. ~~(4)~~(3) The prescriber shall not transfer a sample drug to a charitable pharmacy unless the sample drug was received directly from a manufacturer, a manufacturer's representative, or by a wholesaler acting on behalf of a manufacturer and meets the eligibility requirements pursuant to rule 4729-36-05 of the Administrative Code. ~~(5)~~(4) The sample drug must not have any physical signs of tampering. ~~(6)~~(5) The sample drug packaging must not have any physical signs of tampering.

4729-37-03 Entities required to submit information.

The following entities are required to submit the specified dispensing and wholesale sale information to the board of pharmacy for the drug database:

- (A) All pharmacies located outside this state and licensed as a terminal distributor of dangerous drugs that dispense shall report all drugs identified in rule 4729-37-02 of the Administrative Code that are dispensed to outpatients residing in this state.
- (B) All pharmacies located within this state and licensed as a terminal distributor of dangerous drugs shall report all drugs identified in rule 4729-37-02 of the Administrative Code that are dispensed to all outpatients.
- ~~(B)~~(C) All wholesalers licensed as a wholesale distributor of dangerous drugs that sell drugs identified in rule 4729-37-02 of the Administrative Code at wholesale to individual prescribers within this state, or to _____ locations other than institutional facilities that are licensed as a terminal distributor of dangerous drugs where prescribers practice shall report those drug transactions.
- ~~(C)~~(D) All pharmacies licensed as a terminal distributor of dangerous drugs that sell drugs identified in rule 4729-37-02 of the Administrative Code at wholesale to prescribers within this state, or to locations other than institutional facilities that are licensed as a terminal distributor of dangerous drugs where prescribers practice shall report those drug transactions.

The board of pharmacy shall identify the terminal distributors of dangerous drugs locations where prescribers practice and provide this information to all entities required to report sales at wholesale.

4729-37-04 Information required for submission.

- (A) Pharmacies pursuant to ~~paragraph~~ paragraphs (A) and (B) of rule 4729-37-03 of the Administrative Code that dispense drugs identified in rule 4729-37-02 of the Administrative Code to outpatients residing in this state must report the following dispensing information to the board of pharmacy:
 - (1) Pharmacy drug enforcement administration registration number;
 - (2) Pharmacy name;
 - (3) Pharmacy address;
 - (4) Pharmacy telephone number;
 - (5) Patient full name;
 - (6) Patient address;

- (7) Patient telephone number;
 - (8) Patient date of birth;
 - (9) Patient gender;
 - (10) Prescriber's drug enforcement administration registration number;
 - (11) Date prescription was issued by the prescriber;
 - (12) Date the prescription was dispensed by the pharmacy;
 - (13) Indication of whether the prescription dispensed is new or a refill;
 - (14) Number of the refill being dispensed;
 - (15) National drug code of the actual drug dispensed;
 - (16) Quantity of drug dispensed;
 - (17) Number of days' supply of drug dispensed;
 - (18) Serial or prescription number assigned to the prescription order;
 - (19) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial pharmacy benefit manager (PBM) insurance, major medical, or workers' compensation.
- (B) Wholesalers and pharmacies pursuant to paragraphs ~~(B)~~ and (C) and (D) of rule 4729-37-03 of the Administrative Code that sell drugs identified in rule 4729-37-02 of the Administrative Code at wholesale must report the following information to the board of pharmacy in the following sequence:
- (1) Wholesaler or pharmacy drug enforcement administration registration number;
 - (2) Purchaser's drug enforcement administration registration number;
 - (3) National drug code number of the actual drug sold;
 - (4) Quantity of the drug sold;
 - (5) Date of sale.

4729-37-06 Electronic format required for the transmission of wholesale drugs.

- (A) All wholesale data required to be submitted to the board of pharmacy pursuant to paragraph (B) of rule 4729-37-04 of the Administrative Code must be transmitted ~~on a mutually acceptable format such as, but not limited to ASCII delimited, ASCII fixed length, excel spreadsheet~~ in a comma-delimited ASCII text file or other mutually acceptable format.
- (B) In the event that a wholesaler or pharmacy cannot electronically transmit the required information pursuant to paragraph (B) of rule 4729-37-04 of the Administrative Code they must immediately contact the board of pharmacy to determine a mutually acceptable method of reporting. The wholesaler or pharmacy must document in writing to the board of pharmacy the reasons for their inability to submit the required information.

4729-37-07 Frequency requirements for submitting drug database information.

- (A) All drug dispensing ~~and wholesale drug sale~~ information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code must be submitted twice a month as follows:
- (1) During the first through the fifth day of each month; and
 - (2) During the fifteenth through the twentieth day of each month; and
- ~~(B)~~ (3) ~~Information~~ The information reported to the board of pharmacy shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than twenty-one days after the date of the dispensing ~~or wholesale sale~~.
- (B) All wholesale drug sale information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code must be submitted monthly as follows:
- (1) During the first through the tenth day of each month; and
 - (2) The information shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than forty days after the date of the wholesale sale.
- (C) In the event that a wholesaler or pharmacy cannot submit the required information as described in this rule they must immediately contact the board of pharmacy to determine a mutually acceptable time for submission of information. The wholesaler or pharmacy must document in writing to the board of pharmacy the reasons for their inability to submit the required information.

Mr. Benedict discussed the Medical Board's draft rule 4731-11-04 (Controlled substances: Utilization for weight reduction) with the Board. The Board's concerns will be expressed to the Medical Board at the next meeting of the Medical Board Prescribing Committee.

10:35 a.m. Mr. Wiesenhahn and Mr. Kolezynski left the meeting to have their State identification photos taken.

R-2008-057 Mr. McMillen presented a request from pharmacy intern **Mathilda Theresa De Beer** (06-0-06116) Mason, Ohio for permission to extend her internship one additional year due to extraordinary circumstances pursuant to Rule 4729-3-04 (Pharmacy Intern Identification Card Renewal). After discussion, Mr. Mitchell moved that **Ms. De Beer's** request be approved. The motion was seconded by Mrs. Gregg and approved by the Board: *Aye* – 6.

Mrs. Droz discussed the Prescription Drug Monitoring Program with the Board.

R-2008-058 The Board considered a request for an exemption to Ohio Administrative Code Rule 4729-5-10 (Prescription pick-up station) received for the following sites:

Teregen Laboratories, Willoughby, Ohio (02-1235150)
Various Physician Offices on the letter or 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 Mr. Turner and approved by the Board: *Aye* – 6.

Mr. Braylock said there was no Nursing Board Committee on Prescriptive Governance Report this month.

11:00 a.m. Mr. Wiesenhahn and Mr. Kolezynski returned and joined the meeting in progress.

R-2008-059 The Board considered a request for an exemption to Ohio Administrative Code Rule 4729-5-10 (Prescription pick-up station) received for the following sites:

**The Medicine Shoppe, New Philadelphia, Ohio (02-0786250)
Various Physician Offices on the letter of request**

After discussion, Mr. Turner 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 Mr. Kolezynski and approved by the Board: *Aye – 8.*

R-2008-060 After discussion, Mrs. Gregg moved that the Conference Call minutes of September 21, 2007, be approved as amended. Ms. Pasquale seconded the motion and it was approved by the Board: *Aye – 8.*

R-2008-061 After discussion, Mrs. Gregg moved that the Board minutes of September 10-12, be approved as amended. Mr. Turner seconded the motion and it was approved by the Board: *Aye – 8.*

11:30 a.m. The Board recessed for lunch.

1:19 p.m. The Board reconvened and discussed topics of general interest that required no official action by the Board.

1:30 p.m. Mr. Mitchell left the meeting to attend the Medical Board Prescribing Committee meeting.

The Board reconvened in Room South A, 31st Floor of the Vern Riffe Center with the following members present:

Gregory Braylock, R.Ph., *President*; Nathan S. Lipsyc, R.Ph., *Vice-President*; Elizabeth I. Gregg, R.Ph.; Richard F. Kolezynski, R.Ph.; Heather L. Pasquale, R.Ph.; Dorothy S. Teater, Public Member; James E. Turner, R.Ph.; and Jerome J. Wiesenhahn, R.Ph.

R-2008-062 The following candidates for licensure by reciprocity introduced themselves and participated in a discussion of pharmacy laws and rules with Mr. McMillen. They were then presented their pharmacist identification cards.

Bo Cheng	03-2-28341
Kerry Michael Eberly	03-2-28330
Mohamad Haidar Dakdouk	03-2-28306
Karen Marie Herold	03-2-28344
Douglas Joyce	03-2-28275
Wael Mahmoud Khalifa	03-2-28345
Rebecca Louise Lander	03-2-28346
Anthony William Martinelli	03-2-28353
Nancy Beth Meadors	03-2-28332
Alan Howard Mutnick	03-2-28324
Tracy Jo Peters	03-2-28352
Richard John Shaw	03-2-28303
Kelly Marie Shields	03-2-28340
James B. Tighe	03-2-28336
Nasr A. Mansour	03-2-28342
Patricia Ann Zagami	03-2-28327

1:50 p.m. Mr. Wiesenbahn recused himself from the hearing in the matter of Richard M. Magliano, R.Ph. and left the meeting.

1:54 p.m. Mr. Keeley discussed two proposed revisions to the immunization training program from **Kroger's Great Lakes Division**. The first is a complete course that covers everything a participant would need to be certified to administer all of the current and new immunizations and drugs pursuant to the passage of SB58. The second is an update to Kroger's previously approved program to cover the administration of the new immunizations and drugs pursuant to the passage of SB58.

R-2008-063 Following the discussion, Mr. Turner moved that the revisions be accepted. The motion was seconded by Mr. Lipsyc and approved by the Board: *Aye* – 6.

Mr. Keeley discussed his Legislative Report with the Board.

2:00 p.m. The Board was joined by Assistant Attorney General Sally Ann Steuk to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Richard M. Magliano**, R.Ph. (03-2-17865) Loveland, Ohio.

3:14 p.m. The hearing ended and the record was closed.

3:14 p.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 Ohio Revised Code. The motion was seconded by Ms. Pasquale and a roll-call vote was conducted by President Braylock as follows: Gregg – *yes*; Kolezynski – *yes*; Lipsyc – *yes*; Pasquale – *yes*; Turner – *yes*; Teater – *yes*.

3:28 p.m. The Executive Session ended and the meeting was opened to the public.

3:29 p.m.

R-2008-064 Mrs. Gregg moved that the Board adopt the following order in the matter of **Richard M. Magliano**, R.Ph. (03-2-17865) Loveland, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY

Docket Number D-070406-038

in the matter of:

RICHARD M. MAGLIANO, R.Ph.

2687 Columbia Trail
Loveland, Ohio 45140

R.Ph. Number 03-2-17865

INTRODUCTION

The matter of Richard M. Magliano came for hearing on October 9, 2007, before the following members of the Board: Gregory Braylock, R.Ph. (*presiding*); Elizabeth I. Gregg, R.Ph.; Richard F. Kolezynski, R.Ph.; Nathan S. Lipsyc, R.Ph.; Heather L. Pasquale, R.Ph.; Dorothy S. Teater, Public Member; and James E. Turner, R.Ph.

Richard M. Magliano was represented by Harry B. Plotnick. The State of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses: None

Respondent's Witnesses: Richard M. Magliano, R.Ph., Respondent
James F. Liebetrau, R.Ph.
Chad Andrew Royer, Attorney at Law

State's Exhibits:

1. Reinstatement Hearing Request letter from Harry B. Plotnick [04-03-07]
- 1A-1B. Procedurals
2. State Board of Pharmacy Order In Re Richard M. Magliano, R.Ph. [08-10-06]

Respondent's Exhibits:

- A. State Board of Pharmacy Order In Re Richard M. Magliano, R.Ph. [08-10-06]
- B. PRO Pharmacist's Recovery Contract for Rick Magliano [08-19-06]
- C. Support Group Attendance Records [05-20-06 to 10-08-07]
- D. Calendar Pages for June 2006 to October 2007
- E. FirstLab Test History Report [02-13-06 to 09-18-07]; Drug Screen Reports [06-11-06 to 09-27-07]
- F. Warren County TASC Urine Screens [04-21-06 to 09-13-07]
- G. Three Letters of Support [09-10-07 to 09-17-07]
- H. Termination Entry, State of Ohio vs Richard M. Magliano, Case No. 06CR23078, Warren County Common Pleas Court [05-15-07]; Warren County TASC Program Certificate of Completion [04-17-07]; Letter from Janice L. Bending, Ph.D. to Kristy Summers [04-13-07]
- (I) No Exhibit
- J. Two hundred eighty-one Continuing Pharmaceutical Education Credits and Certificates [12-22-05 to 09-10-07]

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 that Richard M. Magliano has complied with the terms set forth in the Order of the State Board of Pharmacy, Docket No. D-051118-048, effective August 10, 2006.

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. 03-2-17865, held by Richard M. Magliano to practice pharmacy in Ohio and places Richard M. Magliano on probation for five years beginning on the effective date of this Order, with the following conditions:

- (A) Richard M. Magliano 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 signed contract to the Board office. 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 urine screen or a diluted urine 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) The intervener/sponsor shall submit to the Board reports, in a format acceptable to the Board, indicating drug screens and their results in a timely fashion. Actual copies of drug screens shall be made available to the Board upon request.
 - (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) Richard M. Magliano 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 Richard M. Magliano's progress towards recovery and what Richard M. Magliano 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 Richard M. Magliano'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) Richard M. Magliano may not serve as a responsible pharmacist.
 - (3) Richard M. Magliano may not destroy, assist in, or witness the destruction of controlled substances.
 - (4) Richard M. Magliano must abide by the contract with his treatment provider and must immediately report any violation of the contract to the Board.

- (5) Richard M. Magliano must not violate the drug laws of Ohio, any other state, or the federal government.
 - (6) Richard M. Magliano must abide by the rules of the State Board of Pharmacy.
 - (7) Richard M. Magliano must comply with the terms of this Order.
 - (8) Richard M. Magliano 's license is deemed not in good standing until successful completion of the probationary period.
- (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.

Richard M. Magliano 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.

The motion was seconded by Ms. Pasquale and approved by the Board: *Aye* – 6.

3:33 p.m. The Board recessed for the day.

Wednesday, October 10, 2007

8:45 A.M. The Ohio State Board of Pharmacy convened in room East B, 31st Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, with the following members present:

Gregory Braylock, R.Ph., *President*; Nathan S. Lipsyc, R.Ph., *Vice-President*; Elizabeth I. Gregg, R.Ph.; Richard F. Kolezynski, R.Ph.; Kevin J. Mitchell, R.Ph.; Heather L. Pasquale, R.Ph.; Dorothy S. Teater, Public Member; James E. Turner, R.Ph.; and Jerome J. Wiesenbahn, R.Ph.

8:48 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 Ohio Revised Code. The motion was seconded by Mrs. Teater and a roll-call vote was conducted by President Braylock as follows: Gregg – *yes*; Kolezynski – *yes*; Lipsyc – *yes*; Mitchell – *yes*; Pasquale – *yes*; Turner – *yes*; Teater – *yes* and Wiesenbahn – *yes*.

9:00 a.m. The Executive Session ended and the meeting was opened to the public.

9:10 a.m. The Board was joined by Assistant Attorney General Sally Ann Steuk to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matters of **Jae-Seung Lee**, R.Ph. (03-3-22050); **Caringwell Pharmacy** (TDDD Number 02-1428000); and **R.Ph. Care, Inc.** (TDDD Applicant)

11:13 a.m. The hearing was recessed until 1:30 p.m.

11:15 a.m. The Board meeting continued in Room South B and C, of the Vern Riffe Center where **Paul Witkowski** and **David Wagner** from **Alliance Community Hospital** (02-0035152) Alliance, Ohio, addressed the Board regarding its proposed cart-fill process.

11:45 a.m. The meeting with the representatives from Alliance Community Hospital ended and the Board recessed for lunch.

1:04 p.m. The hearing in the matter of **Jae-Seung Lee**, R.Ph. (03-3-22050); **Caringwell Pharmacy** (TDDD Number 02-1428000); and **R.Ph. Care, Inc.** resumed.

1:30 p.m. The hearing ended and the record was closed.

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 Ohio Revised Code. The motion was seconded by Mr. Wiesenhahn and a roll-call vote was conducted by President Braylock as follows: Gregg – *yes*; Kolezynski – *yes*; Lipsyc – *yes*; Mitchell – *yes*; Pasquale – *yes*; Turner – *yes*; Teater – *yes* and Wiesenhahn – *yes*.

2:26 p.m. The Executive Session ended and the meeting was opened to the public.

R-2008-065 Mr. Turner moved that the Board adopt the following order in the matter of **Jae-Seung Lee**, R.Ph. (03-3-22050) Dublin, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY

Docket Number D-070412-041

in the matter of:

JAE-SEUNG LEE, R.Ph.

7679 Windsor Drive
Dublin, Ohio 43016

R.Ph. Number 03-3-22050

INTRODUCTION

The matter of Jae-Seung Lee came for hearing on October 10, 2007, before the following members of the Board: Gregory Braylock, R.Ph. (*presiding*); Elizabeth I. Gregg, R.Ph.; Richard F. Kolezynski, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; Heather L. Pasquale, R.Ph.; Dorothy S. Teater, Public Member; James E. Turner, R.Ph.; and Jerome J. Wiesenhahn, R.Ph.

Jae-Seung Lee was represented by Edward S. Kim. The State of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness: Robert Amiet, Jr., R.Ph.
Ohio State Board of Pharmacy

Respondent's Witness: Jae-Seung Lee, R.Ph., Respondent

State's Exhibits:

1L. Summary Suspension Order/Notice of Opportunity For Hearing letter [04-12-07]

1C,1L-A. Hearing Request letter from Jae-Seung Lee [04-23-07]

1C,1L-B. Hearing Schedule letter [04-24-07]

1C,1L,1RPH-C. Hearing Continuance Request letter from Edward S. Kim [09-10-07]

1L-D. Hearing Continuance letter [09-13-07]

1L-E. Hearing Schedule letter [09-28-07]

1L-F. Pharmacist computer record of Jae-Seung Lee [10-03-07]

2. Caringwell Pharmacy and Jae Lee's Rx Data for November 2006

3. Three Graphs of Caringwell Pharmacy's Average Number of Rxs Per Day, Out-of-State Sales, Percentage of Controlled Substances [November 2006 to March 2007]
4. Two Colored Maps of the United States showing Legitimate Prescription Prescribers for Caringwell Pharmacy and Jae Lee, R.Ph. [not dated]
5. Two Colored Maps of the United States showing Internet Prescription Prescribers for Caringwell Pharmacy and Jae Lee, R.Ph. [not dated]
6. List of Prescribers that Caringwell Pharmacy and Jae Lee, R.Ph. dispensed prescriptions for from December 2006 to March 2007; List of Number of Prescriptions Dispensed by State from December 2006 to March 2007
7. Internet Prescription Orders #443074, #443071 and #443076 from Jeffrey White, M.D. of Florida [11-25-06]
8. Internet Rx #6466 [12-26-06], Rx #6455 [12-26-06] and Rx #13805 [03-27-07] from Nancy E. Tice, D.O. of New York
9. Internet Rx #6495 [12-26-06], Rx #6471 [12-26-06] and Rx #6475 [12-26-06] from Shelly A. Hope
- 9A. Internet Rx #13908 [03-28-07], Rx #13909 [03-28-07] and Rx #13903 [03-28-07] from Michael Feinberg of Florida
10. List of Caringwell and Jae Lee, R.Ph. Dispensing Date [11-29-06 to 03-29-07]
11. Seven color photographs of Caringwell Pharmacy [not dated]
12. Two Dangerous Drug Distributor Inspection Reports of Caringwell Pharmacy [03-27-07 and 03-29-07]
- 13-14. Two notarized statements of Jae-Sung (sic) Lee [03-29-07]
15. Application for Registration As A Terminal Distributor of Dangerous Drugs for RPh Care, Inc. [02-14-07]

Respondent's Exhibits: None

FINDINGS OF FACT

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

- (1) Records of the Board of Pharmacy indicate that Jae-Seung Lee was originally licensed by the State of Ohio as a pharmacist on October 16, 1996, pursuant to examination, and that his license was summarily suspended on April 12, 2007. Records further reflect during the relevant time periods stated herein, Jae-Seung Lee was the Responsible Pharmacist at Caringwell Pharmacy, 5695 Avery Road, Dublin, Ohio, pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-5-11 of the Ohio Administrative Code.
- (2) Jae-Seung Lee did, from November 29, 2006, through March 29, 2007, a period of 120 days, knowingly sell controlled substances when the conduct was not in accordance with Chapters 3719., 4729., and 4731. of the Ohio Revised Code, to wit: Jae-Seung Lee dispensed the following Controlled Substances without valid prescriptions. Practically all the following prescriptions were generated from Internet websites by out-of-state physicians for patients that reside in other states:

Controlled Substance	Number of Rxs	Quantity of Drug
hydrocodone/APAP 10/325 mg tablets	3231	348,480
hydrocodone/APAP 10/500 mg tablets	1412	154,336
hydrocodone/APAP 7.5/500 mg tablets	109	11,010

Controlled Substance	Number of Rxs	Quantity of Drug
hydrocodone/APAP 7.5/750 mg tablets	193	19,530
hydrocodone/APAP 10/650 mg tablets	550	62,570
hydrocodone/ APAP 10/660 mg tablets	15	1,800
Total	5510	597,726
alprazolam 1 mg tablets	82	6,330
alprazolam 2 mg tablets	527	46,890
Total	609	53,220
diazepam 10 mg tablets	205	16,265

Such conduct is in violation of Section 2925.03 of the Ohio Revised Code.

- (3) Jae-Seung Lee did, on or about March 29, 2007, and dates immediately preceding, fail to ensure that only a pharmacist had access to the prescription department and stock of dangerous drugs in his pharmacy, to wit: Jae-Seung Lee permitted a technician to possess a key to the pharmacy and open the pharmacy without Jae-Seung Lee being present. When Board of Pharmacy agents arrived at Jae-Seung Lee's pharmacy, two technicians were in the pharmacy, but there was no pharmacist on site. One technician admitted that Jae-Seung Lee had given him a pharmacy key so he could open that morning. After the technician phoned Jae-Seung Lee, he arrived approximately ten minutes later. During an inspection of Jae-Seung Lee's pharmacy on the previous day, he stated that no one other than a pharmacist possessed keys to the pharmacy, and Jae-Seung Lee also signed the inspection report which included that statement. Such conduct is in violation of Rule 4729-9-11 of the Ohio Administrative Code.
- (4) On or about March 27, 2007, and on dates immediately preceding, Jae-Seung Lee directed and permitted a person other than a registered pharmacist or a pharmacy intern under the personal supervision of a pharmacist to sell dangerous drugs and/or otherwise engage in the practice of pharmacy, to wit: Jae-Seung Lee has admitted that he permitted a pharmacy technician to dispense drugs without a pharmacist being present. Further, Jae-Seung Lee stated that a pharmacy technician began working at the pharmacy in March of 2005, indicating that "I worked at Apria Healthcare and Pure Service between May 2004 and October 2006, and during that time I have allowed Richard Kim to be an acting pharmacist approximately three months or so." Such conduct is in violation of Section 4729.28 of the Ohio Revised Code.

CONCLUSIONS OF LAW

- (1) The State Board of Pharmacy concludes that paragraphs (1) through (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 (2) through (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 constitute being guilty of willfully violating, conspiring to violate,

attempting to violate, or aiding and abetting the violation of provisions of Chapters 2925. and 3719. of the Revised Code as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.

- (4) The State Board of Pharmacy concludes that paragraphs (3) and (4) of the Findings of Fact constitute being guilty of permitting anyone other than a pharmacist or pharmacy intern to practice pharmacy as provided in Division (A)(6) of 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 Jae-Seung Lee on April 12, 2007.

Pursuant to Section 4729.16 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy adjudicates the matter of Jae-Seung Lee as follows:

- (A) On the basis of the Findings of Fact and paragraph (1) of the Conclusions of Law, the State Board of Pharmacy hereby revokes permanently the pharmacist identification card, No. 03-2-19310, held by Jae-Seung Lee effective as of the date of the mailing of this Order.
- (B) On the basis of the Findings of Fact and paragraph (2) of the Conclusions of Law, the State Board of Pharmacy hereby revokes permanently the pharmacist identification card, No. 03-2-19310, held by Jae-Seung Lee effective as of the date of the mailing of this Order.
- (C) On the basis of the Findings of Fact and paragraph (3) of the Conclusions of Law, the State Board of Pharmacy hereby revokes permanently the pharmacist identification card, No. 03-2-19310, held by Jae-Seung Lee effective as of the date of the mailing of this Order.
- (D) On the basis of the Findings of Fact and paragraph (4) of the Conclusions of Law, the State Board of Pharmacy hereby revokes permanently the pharmacist identification card, No. 03-2-19310, held by Jae-Seung Lee effective as of the date of the mailing of this Order.

Jae-Seung Lee, 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.

The motion was seconded by Mr. Wiesenbahn and approved by the Board: *Aye* – 7/*Nay* – 1.

R-2008-066

Mrs. Gregg moved that the Board adopt the following order in the matter of **Caringwell Pharmacy**, (TDDD 02-1428000) Columbus, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY

Docket Number D-070412-040

CARINGWELL PHARMACY

c/o Jae-Seung Lee, R.Ph.
7679 Windsor Drive
Dublin, Ohio 43016

INTRODUCTION

The matter of Caringwell Pharmacy came for hearing on September 10, 2007, before the following members of the Board: Gregory Braylock, R.Ph. (*presiding*); Elizabeth I. Gregg, R.Ph.; Richard F. Kolezynski, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; Heather L. Pasquale, R.Ph.; Dorothy S. Teater, Public Member; James E. Turner, R.Ph.; and Jerome J. Wiesenbahn, R.Ph.

Caringwell Pharmacy was represented by Edward S. Kim. The State of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness: Robert Amiet, Jr., R.Ph.
Ohio State Board of Pharmacy

Respondent's Witness: Jae-Seung Lee, R.Ph., Respondent

State's Exhibits:

- 1C. Summary Suspension Order/Notice of Opportunity For Hearing letter [04-12-07]
- 1C,1L-A. Hearing Request letter from Jae-Seung Lee [04-23-07]
- 1C,1L-B. Hearing Schedule letter [04-24-07]
- 1C,1L,1RPh-C. Hearing Continuance Request letter from Edward S. Kim [09-10-07]
- 1C-D. Hearing Continuance letter [09-13-07]
- 1C-E. Hearing Schedule letter [09-28-07]
- 1C-F. Dangerous Drug Distributor computer record of Caringwell Pharmacy [10-03-07]
2. Caringwell Pharmacy and Jae Lee's Rx Data for November 2006
3. Three Graphs of Caringwell Pharmacy's Average Number of Rxs Per Day, Out-of-State Sales, Percentage of Controlled Substances [November 2006 to March 2007]
4. Two Colored Maps of the United States showing Legitimate Prescription Prescribers for Caringwell Pharmacy and Jae Lee, R.Ph. [not dated]
5. Two Colored Maps of the United States showing Internet Prescription Prescribers for Caringwell Pharmacy and Jae Lee, R.Ph. [not dated]
6. List of Prescribers that Caringwell Pharmacy and Jae Lee, R.Ph. dispensed prescriptions for from December 2006 to March 2007; List of Number of Prescriptions Dispensed by State from December 2006 to March 2007
7. Internet Prescription Orders #443074, #443071 and #443076 from Jeffrey White, M.D. of Florida [11-25-06]
8. Internet Rx #6466 [12-26-06], Rx #6455 [12-26-06] and Rx #13805 [03-27-07] from Nancy E. Tice, D.O. of New York
9. Internet Rx #6495 [12-26-06], Rx #6471 [12-26-06] and Rx #6475 [12-26-06] from Shelly A. Hope
- 9A. Internet Rx #13908 [03-28-07], Rx #13909 [03-28-07] and Rx #13903 [03-28-07] from Michael Feinberg of Florida
10. List of Caringwell and Jae Lee, R.Ph. Dispensing Date [11-29-06 to 03-29-07]
11. Seven color photographs of Caringwell Pharmacy [not dated]
12. Two Dangerous Drug Distributor Inspection Reports of Caringwell Pharmacy [03-27-07 and 03-29-07]

- 13-14. Two notarized statements of Jae-Sung (sic) Lee [03-29-07]
 15. Application for Registration As A Terminal Distributor of Dangerous Drugs for RPh Care, Inc. [02-14-07]

Respondent's Exhibits: None

FINDINGS OF FACT

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

- (1) Records of the Board of Pharmacy indicate that Caringwell Pharmacy is licensed with the State Board of Pharmacy as a Terminal Distributor of Dangerous Drugs and that Caringwell Pharmacy's license was summarily suspended on April 12, 2007. Records further reflect during the relevant time periods stated herein, Jae-Seung Lee was the Responsible Pharmacist pursuant to Rule 4729-5-11 of the Ohio Administrative Code and Sections 4729.27 and 4729.55 of the Ohio Revised Code.
- (2) Caringwell Pharmacy did, from November 29, 2006, through March 29, 2007, a period of 120 days, knowingly sell controlled substances when the conduct was not in accordance with Chapters 3719., 4729., and 4731. of the Ohio Revised Code, to wit: Caringwell Pharmacy dispensed the following Controlled Substances without valid prescriptions. Practically all the following prescriptions were generated from Internet websites by out-of-state physicians for patients that reside in other states:

Controlled Substance	Number of Rxs	Quantity of Drug
hydrocodone/APAP 10/325 mg tablets	3231	348,480
hydrocodone/APAP 10/500 mg tablets	1412	154,336
hydrocodone/APAP 7.5/500 mg tablets	109	11,010
hydrocodone/APAP 7.5/750 mg tablets	193	19,530
hydrocodone/APAP 10/650 mg tablets	550	62,570
hydrocodone/ APAP 10/660 mg tablets	15	1,800
Total	5510	597,726
alprazolam 1 mg tablets	82	6,330
alprazolam 2 mg tablets	527	46,890
Total	609	53,220
diazepam 10 mg tablets	205	16,265

Such conduct is in violation of Section 2925.03 of the Ohio Revised Code.

- (3) Caringwell Pharmacy did, on or about March 29, 2007, and dates immediately preceding, fail to ensure that only a pharmacist had access to the prescription department and stock of dangerous drugs in the pharmacy, to wit: Caringwell Pharmacy permitted a technician to possess a key to the pharmacy and open the pharmacy without a pharmacist being present. When Board of Pharmacy agents arrived at Caringwell Pharmacy, two technicians were in the pharmacy, but there was no pharmacist on site. The technicians admitted that one had been given a pharmacy key so he could open that morning. After the technician phoned the responsible pharmacist, he arrived approximately ten minutes later. During an inspection of Caringwell Pharmacy on the previous day, the responsible

pharmacist stated that no one other than a pharmacist possessed keys to the pharmacy, and he also signed the inspection report which included that statement. Such conduct is in violation of Rule 4729-9-11 of the Ohio Administrative Code.

- (4) Caringwell Pharmacy did, on or about March 27, 2007, and on dates immediately preceding, permit a person other than a registered pharmacist or a pharmacy intern under the personal supervision of a pharmacist to sell dangerous drugs and/or otherwise engage in the practice of pharmacy, to wit: the pharmacy admittedly permitted a pharmacy technician to dispense drugs without a pharmacist being present. Further, a pharmacy technician began working at the pharmacy in March of 2005, while the responsible pharmacist worked at Apria Healthcare and Pure Service between May 2004 and October 2006, and during that time had allowed Richard Kim to be an acting pharmacist approximately three months or so. Such conduct is in violation of Section 4729.28 of the Ohio Revised Code.

CONCLUSIONS OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (3) of the Findings of Fact constitute violating rules of the Board as provided in Division (A)(2) of Section 4729.57 of the Ohio Revised Code.
- (2) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (4) of the Findings of Fact constitute violating any provision of this chapter as provided in Division (A)(3) of Section 4729.57 of the Ohio Revised Code.
- (3) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (2) and of the Findings of Fact constitute violating provisions of the federal drug abuse control laws and Chapter 3719. of the Revised Code as provided in Division (A)(5) of Section 4729.57 of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy adjudicates the matter of Caringwell Pharmacy as follows:

- (A) On the basis of the Findings of Fact and paragraph (1) of the Conclusions of Law, the State Board of Pharmacy hereby revokes permanently the terminal distributor license, No. 02-1428000, held by Caringwell Pharmacy effective as of the date of the mailing of this Order.
- (B) On the basis of the Findings of Fact and paragraph (2) of the Conclusions of Law, the State Board of Pharmacy hereby revokes permanently the terminal distributor license, No. 02-1428000, held by Caringwell Pharmacy effective as of the date of the mailing of this Order.
- (C) On the basis of the Findings of Fact and paragraph (3) of the Conclusions of Law, the State Board of Pharmacy hereby revokes permanently the terminal distributor license, No. 02-1428000, held by Caringwell Pharmacy effective as of the date of the mailing of this Order.

Caringwell Pharmacy, pursuant to Section 4729.57(C)(1) of the Ohio Revised Code, must return the license to the office of the State Board of Pharmacy immediately after receipt of this Order. The license should be sent by certified mail, return receipt requested.

The motion was seconded by Mr. Lipsyc and approved by the Board: *Aye* – 8.

R-2008-067

Mrs. Gregg moved that the Board adopt the following order in the matter of **R.Ph. Care, Inc.**, Dublin, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY

Docket Number D-070418-042

in the matter of:

RPh CARE, INC.

c/o Jae-Seung Lee, R.Ph.
7679 Windsor Drive
Dublin, Ohio 43017
T.D.D.D. Applicant

INTRODUCTION

The matter of RPh Care, Inc. came for hearing on September 10, 2007, before the following members of the Board: Gregory Braylock, R.Ph. (*presiding*); Elizabeth I. Gregg, R.Ph.; Richard F. Kolezynski, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; Heather L. Pasquale, R.Ph.; Dorothy S. Teater, Public Member; James E. Turner, R.Ph.; and Jerome J. Wiesenbahn, R.Ph.

RPh Care, Inc. was represented by Edward S. Kim. The State of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness: Robert Amiet, Jr., R.Ph., Ohio State Board of Pharmacy

Respondent's Witness: Jae-Seung Lee, R.Ph., Respondent

State's Exhibits:

- 1RPh. Proposal to Deny/Notice of Opportunity For Hearing letter [04-18-07]
- 1RPh-A. Hearing Request letter from Jae-Seung Lee [05-17-07]
- 1RPh-B. Hearing Schedule letter [05-21-07]
- 1C,1L,1RPH-C. Hearing Continuance Request letter from Edward S. Kim [09-10-07]
- 1RPh-D. Hearing Continuance letter [09-13-07]
- 1RPh-E. Hearing Schedule letter [09-28-07]
- 2. Caringwell Pharmacy and Jae Lee's Rx Data for November 2006
- 3. Three Graphs of Caringwell Pharmacy's Average Number of Rxs Per Day, Out-of-State Sales, Percentage of Controlled Substances [November 2006 to March 2007]
- 4. Two Colored Maps of the United States showing Legitimate Prescription Prescribers for Caringwell Pharmacy and Jae Lee, R.Ph. [not dated]
- 5. Two Colored Maps of the United States showing Internet Prescription Prescribers for Caringwell Pharmacy and Jae Lee, R.Ph. [not dated]
- 6. List of Prescribers that Caringwell Pharmacy and Jae Lee, R.Ph. dispensed prescriptions for from December 2006 to March 2007; List of

Number of Prescriptions Dispensed by State from December 2006 to March 2007

7. Internet Prescription Orders #443074, #443071 and #443076 from Jeffrey White, M.D. of Florida [11-25-06]
8. Internet Rx #6466 [12-26-06], Rx #6455 [12-26-06] and Rx #13805 [03-27-07] from Nancy E. Tice, D.O. of New York
9. Internet Rx #6495 [12-26-06], Rx #6471 [12-26-06] and Rx #6475 [12-26-06] from Shelly A. Hope
- 9A. Internet Rx #13908 [03-28-07], Rx #13909 [03-28-07] and Rx #13903 [03-28-07] from Michael Feinberg of Florida
10. List of Caringwell and Jae Lee, R.Ph. Dispensing Date [11-29-06 to 03-29-07]
11. Seven color photographs of Caringwell Pharmacy [not dated]
12. Two Dangerous Drug Distributor Inspection Reports of Caringwell Pharmacy [03-27-07 and 03-29-07]
- 13-14. Two notarized statements of Jae-Sung (sic) Lee [03-29-07]
15. Application for Registration As A Terminal Distributor of Dangerous Drugs for RPh Care, Inc. [02-14-07]

Respondent's Exhibits: None

FINDINGS OF FACT

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

- (1) Records of the Board of Pharmacy indicate that on or about February 14, 2007, Jae-Seung Lee was the president and responsible pharmacist of RPH Care, Inc., 6631-Q Commerce Parkway, Dublin, Ohio, and that on said date, RPH Care, Inc. submitted an application for registration as a Terminal Distributor of Dangerous Drugs.
- (2) RPH Care, Inc. has not furnished satisfactory proof to the Board that it satisfies the qualifications of a terminal distributor of dangerous drugs set forth in Section 4729.55 of the Revised Code, to wit: on or about April 12, 2007, the Board suspended the license to practice pharmacy of the responsible pharmacist, Jae-Seung Lee, for the following reasons:
 - (A) Jae-Seung Lee did, from November 29, 2006, through March 29, 2007, a period of 120 days, knowingly sell controlled substances when the conduct was not in accordance with Chapters 3719., 4729., and 4731. of the Ohio Revised Code, to wit: Jae-Seung Lee dispensed the following Controlled Substances without valid prescriptions. Practically all the following prescriptions were generated from Internet websites by out-of-state physicians for patients that reside in other states:

Controlled Substance	Number of Rxs	Quantity of Drug
hydrocodone/APAP 10/325 mg tablets	3231	348,480
hydrocodone/APAP 10/500 mg tablets	1412	154,336
hydrocodone/APAP 7.5/500 mg tablets	09	11,010
hydrocodone/APAP 7.5/750 mg tablets	193	19,530
hydrocodone/APAP 10/650 mg tablets	550	62,570
hydrocodone/ APAP 10/660 mg tablets	5	1,800
Total	5510	597,726

alprazolam 1 mg tablets	82	6,330
alprazolam 2 mg tablets	527	46,890
Total	609	53,220
diazepam 10 mg tablets	205	16,265

Such conduct is in violation of Section 2925.03 of the Ohio Revised Code.

- (B) Jae-Seung Lee did, on or about March 29, 2007, and dates immediately preceding, fail to ensure that only a pharmacist had access to the prescription department and stock of dangerous drugs in his pharmacy [Caringwell Pharmacy], to wit: Jae-Seung Lee permitted a technician to possess a key to the pharmacy and open the pharmacy without a pharmacist being present. When Board of Pharmacy agents arrived at the pharmacy, two technicians were in the pharmacy, but there was no pharmacist on site. One technician admitted that Jae-Seung Lee had given him a pharmacy key so he could open that morning. After the technician phoned Jae-Seung Lee, Jae-Seung Lee arrived approximately ten minutes later. During an inspection of the pharmacy on the previous day, Jae-Seung Lee stated that no one other than a pharmacist possessed keys to the pharmacy, and Jae-Seung Lee also signed the inspection report which included that statement. Such conduct is in violation of Rule 4729-9-11 of the Ohio Administrative Code.
- (C) On or about March 27, 2007, and on dates immediately preceding, Jae-Seung Lee directed and permitted a person other than a registered pharmacist or a pharmacy intern under the personal supervision of a pharmacist to sell dangerous drugs and/or otherwise engage in the practice of pharmacy, to wit: Jae-Seung Lee has admitted that Jae-Seung Lee permitted a pharmacy technician to dispense drugs without a pharmacist being present. Further, Jae-Seung Lee stated that a pharmacy technician began working at the pharmacy in March of 2005, indicating that "I worked at Apria Healthcare and Pure Service between May 2004 and October 2006, and during that time I have allowed Richard Kim to be an acting pharmacist approximately three months or so." Such conduct is in violation of Section 4729.28 of the Ohio Revised Code.

The aforementioned indicates that RPH Care, Inc. does not satisfy the qualifications of a terminal distributor; and/or RPH Care, Inc. has not furnished adequate proof that safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs.

CONCLUSIONS OF LAW

- (1) The State Board of Pharmacy concludes that paragraph (2) of the Findings of Fact constitute failure to meet the qualifications set forth in Division (C) of Section 4729.55 of the Ohio Revised Code.
- (2) The State Board of Pharmacy concludes that paragraph (2) of the Findings of Fact constitute not being of good moral character and habits as provided in Rule (A)(3) of Section 4729-9-19 of the Ohio Administrative Code.

DECISION OF THE BOARD

Pursuant to Section 4729.55(A) of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby

refuses to issue a license for RPh Care, Inc. and, therefore, denies the Application for Registration as a Terminal Distributor of Dangerous Drugs submitted by Jae-Seung Lee and received by the Board on February 14, 2007.

The motion was seconded by Mr. Kolezynski and approved by the Board: *Aye* – 8.

2:29 p.m. Mr. Benedict said there was no Medical Board Prescribing Committee Report this month.

The Board discussed the **Alliance Community Hospital** (TDDD 02-0035152) Alliance, Ohio, proposed cart-fill process. After consideration, Mrs. Gregg moved that the system be found approvable pending a report from a Board Specialist in six months. Mr. Turner seconded the motion and it was approved by the Board: *Aye* – 8.

Mr. Mitchell discussed the Medical Board Physician Assistant Policy Committee report with the Board.

2:55 p.m.
R-2008-068

Mr. Rowland announced that the following Settlement Agreement with **Paula Gratcl Sondergeld**, R.Ph. (03-1-10998) Sylvania, Ohio, has been signed by all parties and is now effective.

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY

Docket Number D-070508-045

in the matter of:

PAULA G. SONDERGELD, R.Ph.

6110 Cross Trails Road
Sylvania, Ohio 43560

R.Ph. Number 03-1-10998

This Settlement Agreement is entered into by and between Paula G. Sondergeld 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.

Paula G. Sondergeld voluntarily enters into this Agreement being fully informed of her 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. Paula G. Sondergeld acknowledges that by entering into this agreement she has waived her 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, Paula G. Sondergeld is licensed to practice pharmacy in the State of Ohio.

Whereas, on or about May 8, 2007, pursuant to Chapter 119. of the Ohio Revised Code, Paula G. Sondergeld was notified of the allegations or charges against her, her right to a hearing, her rights in such hearing, and her right to submit contentions in writing. Paula G. Sondergeld requested a hearing; it was

scheduled. The May 8, 2007, Notice of Opportunity for Hearing contains the following allegations or charges:

- (1) Records of the State Board of Pharmacy indicate that Paula G. Sondergeld was originally licensed in the State of Ohio on July 30, 1974, pursuant to examination, and is currently licensed to practice pharmacy in the State of Ohio.
- (2) Paula G. Sondergeld did, on or about the following dates, intentionally create false or forged prescriptions, to wit: Paula G. Sondergeld created, and filled for herself as the patient, the following prescriptions without authorization from a prescriber:

Date	RX number	N/R	Drug	Strength	Quantity
12/15/2003	6316388	N	diltiazem HCL	180 mg	90
02/03/2004	6320604	N	Lotensin HCT	10/12.5	100
02/18/2004	6321771	N	hydroxyzine HCL	25 mg	100
04/24/2004	6327294	N	ibuprofen	800 mg	100
10/23/2004	6341369	N	diltiazem HCL	180 mg	90
10/23/2004	6341370	N	Potassium CL	8 mEq	100
02/12/2005	6350581	N	Sulf/Pred	0.25% eye	10 Mls
02/16/2005	6350976	N	Lotensin HCT	10/12.5	100
03/18/2005	6353651	N	ibuprofen	800 mg	100
04/20/2005	6356400	N	EpiPen	0.3 mg	2
05/07/2005	6357952	N	Zithromax Tri Pak	500 mg	3
06/29/2005	6362227	N	hydroxyzine HCL	25 mg	100
10/11/2005	6370499	N	diltiazem HCL	180 mg	90

The following were the dates of the refills for these prescriptions:

Date	RX number	N/R	Drug	Strength	Quantity
01/12/2004	6316388	R	diltiazem HCL	180 mg	90
02/14/2004	6320604	R	Lotensin HCT	10/12.5	100
03/10/2004	6320604	R	Lotensin HCT	10/12.5	100
03/29/2004	6316388	R	diltiazem HCL	180 mg	90
04/12/2004	6320604	R	Lotensin HCT	10/12.5	100
04/12/2004	6321771	R	hydroxyzine HCL	25 mg	100
05/03/2004	6321771	R	hydroxyzine HCL	25 mg	100
05/25/2004	6320604	R	Lotensin HCT	10/12.5	100
06/21/2004	6316388	R	diltiazem HCL	180 mg	90
06/21/2004	6320604	R	Lotensin HCT	10/12.5	100
06/21/2004	6321771	R	hydroxyzine HCL	25 mg	100
08/26/2004	6327294	R	ibuprofen	800 mg	100
08/28/2004	6320604	R	Lotensin HCT	10/12.5	100
09/25/2004	6320604	R	Lotensin HCT	10/12.5	100
09/25/2004	6321771	R	hydroxyzine HCL	25 mg	100
10/23/2004	6320604	R	Lotensin HCT	10/12.5	100
12/13/2004	6320604	R	Lotensin HCT	10/12.5	100
01/10/2005	6320604	R	Lotensin HCT	10/12.5	100
01/10/2005	6341369	R	diltiazem HCL	180 mg	90
01/25/2005	6321771	R	hydroxyzine HCL	25 mg	100
01/25/2005	6341370	R	Potassium CL	8 mEq	100
03/18/2005	6341369	R	diltiazem HCL	180 mg	90
03/18/2005	6350976	R	Lotensin HCT	10/12.5	100
04/22/2005	6353651	R	ibuprofen	800 mg	100

04/25/2005	6341370	R	Potassium CL	8 mEq	100
04/25/2005	6350976	R	Lotensin HCT	10/12.5	100
05/21/2005	6350581	R	Sulf/Pred	0.25% eye	10 Mls
05/21/2005	6350976	R	Lotensin HCT	10/12.5	100
06/04/2005	6356400	R	EpiPen	0.3 mg	2
06/21/2005	6341369	R	diltiazem HCL	180 mg	90
06/21/2005	6341370	R	Potassium CL	8 mEq	100
06/21/2005	6350976	R	Lotensin HCT	10/12.5	100
08/02/2005	6350976	R	Lotensin HCT	10/12.5	100
10/11/2005	6350976	R	Lotensin HCT	10/12.5	100
10/11/2005	6353651	R	ibuprofen	800 mg	100
10/11/2005	6362227	R	hydroxyzine HCL	25 mg	100
11/30/2005	6350976	R	Lotensin HCT	10/12.5	100
11/30/2005	6370499	R	diltiazem HCL	180 mg	90
12/28/2005	6350976	R	benazepril-HCTZ	10/12.5	100
12/28/2005	6350976	R	benazepril- HCTZ	10/12.5	100
12/28/2005	6362227	R	hydroxyzine HCL	25 mg	100

Such conduct is in violation of Section 2925.23 of the Ohio Revised Code, and constitutes being guilty of a felony or gross immorality; guilty of dishonesty or unprofessional conduct in the practice of pharmacy; and/or guilty of willfully violating provisions of Chapter 2925. of the Ohio Revised.

Paula G. Sondergeld neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated May 8, 2007; however, 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, Paula G. Sondergeld knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

- (A) Paula G. Sondergeld agrees to the imposition of a monetary penalty of two thousand five hundred dollars (\$2,500.00) due and owing within thirty days from the effective date of this Agreement. Checks should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126.
- (B) Paula G. Sondergeld must obtain, within six months from the effective date of this Agreement, five hours of continuing pharmacy education (0.5 CEUs) in Jurisprudence, which may not also be used for license renewal.
- (C) Paula G. Sondergeld's license shall be limited in that she may not dispense prescriptions for herself or for any member of her family.
- (D) Paula G. Sondergeld's pharmacist identification card, No. 03-1-10998, will be placed on probation for three years from the effective date of this Settlement Agreement. The terms of probation are as follows:
 - (1) The State Board of pharmacy hereby declares that Paula G. Sondergeld'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) Paula G. Sondergeld may not serve as a responsible pharmacist.
- (3) Paula G. Sondergeld must not violate the drug laws of the state of Ohio, any other state, or the federal government.
- (4) Paula G. Sondergeld must abide by the rules of the Ohio State Board of Pharmacy.
- (5) Paula G. Sondergeld must comply with the terms of this Agreement.

If, in the judgment of the Board, Paula G. Sondergeld 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.

Paula G. Sondergeld acknowledges that she 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.

Paula G. Sondergeld waives any and all claims or causes of action she 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. Paula G. Sondergeld 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.

/s/ Paula G. Sondergeld, R.Ph. Date Signed: 10/05/07
Respondent

/s/ Ralph E. Breitfeller Date Signed: 10/09/07
Attorney for Respondent

/s/ Gregory Braylock Date Signed: 10/09/07
President; Ohio State Board of Pharmacy

/s/ Sally Ann Steuk Date Signed: 10/12/07
Ohio Assistant Attorney General

_2:56 p.m. Mrs. Gregg moved that the Board receive Per Diem as follows:

<u>Per Diem</u>	<u>10/09</u>	<u>10/10</u>	<u>Total</u>
Braylock	1	1	2
Gregg	1	1	2
Kolezynski	1	1	2
Lipsyc	1	1	2
Mitchell	1	1	2
Pasquale	1	1	2
Teater	1	1	2

Turner	1	1	2
Wiesenhahn	1	1	2

Mr. Lipsyc seconded the motion and it was approved by the Board: *Aye* – 8.

Mr. Lipsyc moved that the meeting be adjourned. The motion was seconded by Mr. Wiesenhahn and approved by the Board: *Aye* – 8.

<p>The Ohio State Board of Pharmacy approved these Minutes November 6, 2007</p>
