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

Ohio State Board of Pharmacy 77 South High Street, Room 1702 Columbus, Ohio 43215-6126
telephone: 614-466-4143 fax: 614-752-4836 email: exec@bop.state.oh.us

Minutes of the September 11-13, 2006 Meeting of the Ohio State Board of Pharmacy

MONDAY, SEPTEMBER 11, 2006

10:00 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:

James E. Turner, R.Ph., *President*; Suzanne R. Eastman, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; and Dorothy Teater, Public Member.

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

R-2007-035 Mr. Winsley announced that the following Settlement Agreement with **Elizabeth Ann Baishnab**, R.Ph., Strongsville, Ohio has been signed by all parties and is now effective.

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY
Docket Number D-060112-055

in the matter of:

ELIZABETH ANN BAISHNAB, R.PH.
21701 Scenic Pointe
Strongsville, Ohio 44149

R.Ph. Number 03-1-20941

This Settlement Agreement is entered into by and between Elizabeth Ann Baishnab 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.

Elizabeth Ann Baishnab 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. Elizabeth Ann Baishnab 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, Elizabeth Ann Baishnab is licensed to practice pharmacy in the State of Ohio.

Whereas, on or about January 12, 2006, pursuant to Chapter 119. of the Ohio Revised Code, Elizabeth Ann Baishnab 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. Elizabeth Ann Baishnab requested a hearing; it was scheduled. The January 12, 2006**,** Notice of Opportunity for Hearing contains the following allegations or charges:

(1) Records of the State Board of Pharmacy indicate that Elizabeth Ann Baishnab was originally licensed by the State of Ohio as a pharmacist on February 22, 1995, pursuant to examination, and is currently licensed to practice pharmacy in the State of Ohio.

(2) Elizabeth Ann Baishnab did, on or about January 26, 2005, prior to the dispensing of Rx #90526746, fail to review the patient profile in order to conduct prospective drug utilization review, to wit: Elizabeth Ann Baishnab failed to review the patient profile for over-utilization, incorrect drug dosage and duration of drug treatment, and misuse. Elizabeth Ann Baishnab received a prescription for metolazone 2.5 mg, to be taken one tablet daily, quantity 60 with 5 refills, Elizabeth Ann Baishnab processed the prescription and it was subsequently dispensed with methotrexate 2.5 mg, which had not been specifically prescribed by the physician. The patient subsequently experienced severe harm. Such conduct is in violation of Rule 4729-5-20 of the Ohio Administrative Code.

Elizabeth Ann Baishnab neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated January 12, 2006; 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, Elizabeth Ann Baishnab knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

(A) Elizabeth Ann Baishnab 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) Elizabeth Ann Baishnab must obtain, within sixty days from the effective date of this Agreement, two hours of continuing pharmacy education (0.2 CEUs) on preventing medication errors, which may not also be used for license renewal.

Elizabeth Ann Baishnab 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.

Elizabeth Ann Baishnab 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. Elizabeth Ann Baishnab 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/	/d/ 09/12/06
Elizabeth Ann Baishnab, R.Ph., Respondent	Date Signed
/s/	/d/ 09/12/06
John T. Bulloch, Attorney for Respondent	Date Signed
/s/	/d/ 09/12/06
James E. Turner, President, Ohio State Board of Pharmacy	Date Signed
/s/	/d/ 09/12/06
Sally Ann Steuk, Ohio Assistant Attorney General	Date Signed

R-2007-036 Mr. Winsley announced that the following Settlement Agreement with **Alan Ray Wolford**, R.Ph., Barnesville, Ohio has been signed by all parties and is now effective.

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY

Docket Number D-060112-058

in the matter of:

ALAN RAY WOLFORD, R.PH.
114 East Pike Street
Barnesville, Ohio 43713

R.Ph. Number 03-2-08847

This Settlement Agreement is entered into by and between Alan Ray Wolford 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.

Alan Ray Wolford 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. Alan Ray Wolford 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, Alan Ray Wolford is licensed to practice pharmacy in the State of Ohio.

Whereas, on or about January 12, 2006, pursuant to Chapter 119. of the Ohio Revised Code, Alan Ray Wolford 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. Alan Ray Wolford requested a hearing; it was scheduled. The January 12, 2006, Notice of Opportunity for Hearing contains the following allegations or charges:

(1) Records of the State Board of Pharmacy indicate that Alan Ray Wolford was originally licensed by the State of Ohio on August 14, 1967, pursuant to examination, and his license to practice pharmacy lapsed on September 15, 1977. Alan Ray Wolford was re-licensed by examination on March 1, 1984, and his license lapsed on September 15, 2005.

(2) Alan Ray Wolford is abusing drugs and/or impaired physically or mentally to such a degree as to render him unfit to practice pharmacy, to wit: Alan Ray Wolford has admittedly stolen Viagra from eight different pharmacies on ten different occasions in an ongoing attempt to commit suicide. Alan Ray Wolford indicated to a Board agent that he intended to ingest large quantities of the drug over a period of time so as to cause a heart attack or stroke. Alan Ray Wolford has further indicated that he has suffered from depression for several years. Such conduct indicates that Alan Ray Wolford is within the ambit of Section 4729.16(A)(3) of the Ohio Revised Code.

(3) Alan Ray Wolford did, on or about the following dates, with purpose to deprive, knowingly obtain or exert control over dangerous drugs, the property of CVS, beyond the express or implied consent of the owner, to wit: Alan Ray Wolford has admittedly stolen the following:

Date of Theft	Drug	Quantity	Pharmacy
April, 2005	Viagra 100 mg	60 tablets	CVS #2735
May 10, 2005	Viagra 100 mg	60 tablets	CVS #3992
April, 2005	Viagra 100 mg	60 tablets	CVS #3410
May 07, 2005	Viagra 100 mg	60 tablets	CVS #6946
May 08, 2005	Viagra 100 mg	60 tablets	CVS #6946
May 06, 2005	Viagra 100 mg	60 tablets	CVS #3405
May 12, 2005	Viagra 100 mg	30 tablets	CVS #6159
May 13, 2005	Viagra 100 mg	30 tablets	CVS #6159
May 04, 2005	Viagra 100 mg	60 tablets	CVS #5717
May 11, 2005	Viagra 100 mg	60 tablets	CVS #3484

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

Alan Ray Wolford neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated January 12, 2006; 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, Alan Ray Wolford knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

The Board of Pharmacy hereby suspends indefinitely the pharmacist identification card, No. 03-2-08847, held by Alan Ray Wolford. Pursuant to Rule 4729-9-01(F) of the Ohio Administrative Code, Alan Ray Wolford may not be employed by or work in a facility licensed by the Board to possess or distribute dangerous drugs during such period of suspension. Division (B) of Section 4729.16 of the Revised Code provides that: “Any individual whose identification card is revoked, suspended, or refused, shall return his identification card and certificate of registration to the offices of the state board of pharmacy within ten days after receipt of the notice of such action.” The certificate and identification card should be forwarded by certified mail, return receipt requested. Further, Alan Ray Wolford must petition the Board, pursuant to a Revised Code Chapter 119. hearing, for reinstatement of his license to practice pharmacy in Ohio.

Alan Ray Wolford 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.

Alan Ray Wolford 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. Alan Ray Wolford 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/	/d/ 09/12/06
Alan Ray Wolford, R.Ph., Respondent	Date Signed
/s/	/d/ 09/12/06
Umberto A. DeBeneditto Attorney for Respondent	Date Signed
/s/	/d/ 09/12/06
James E. Turner, President, Ohio State Board of Pharmacy	Date Signed
/s/	/d/ 09/12/06
Sally Ann Steuk, Ohio Assistant Attorney General	Date Signed

10:03 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 Mr. Lipsyc and a roll-call vote was conducted by President Turner as follows: Eastman – *yes;* Gregg – *yes*; Lipsyc – *yes*; Mitchell – *yes*; and Teater – *yes*.

10:50 a.m. Board Member Gregory Braylock, R.Ph., arrived and joined the meeting in progress.

10:53 a.m. The Executive Session ended and the meeting was opened to the public.

R-2007-037 Ms. Eastman moved that the settlement offer received in the matter of **Thomas Hinderer**, R.Ph., Dellroy, Ohio, be accepted. The motion was seconded by Mrs. Teater and approved by the Board: *Aye* – 5/*Nay* – 0/*Abstain* – 1 (Braylock).

R-2007-038 Mrs. Gregg moved that the proposed Cease and Desist order drafted by Board staff be issued in the matter of **Park and Clay Pharmacy**, Baltimore, Maryland. Mr. Lipsyc seconded the motion and it was approved by the Board: *Aye* – 5/*Nay* – 0/*Abstain* – 1 (Braylock).

R-2007-039 Mrs. Gregg moved that the settlement offer received in the matter of **Michael Esber**, R.Ph., Louisville, Ohio be denied. Ms. Eastman seconded the motion and it was approved by the Board: *Aye* – 5/*Nay* – 0/*Abstain* – 1 (Braylock).

11:00 a.m.
R-2007-040 President Turner announced that he had appointed Mrs. Gregg to serve as the Board's representative at the Accreditation Council for Pharmacy Education's visit to Northeast Ohio University's College of Pharmacy.

Mr. Braylock volunteered to attend the University of Cincinnati White Coat Ceremony on the Board's behalf.

Copies of two recent Federal Register notices from DEA were distributed and discussed. One dealt with the DEA's policy on pain treatment and the other was a proposed rule on the issuance of multiple CII prescriptions on the same day. No official action was taken by the Board on either notice.

R-2007-041 The Board considered a request for an exemption from OAC Rule 4729-5-10 (Prescription pick-up station) received from:

NCS Healthcare Pharmacy/ Eastlake **(**02-0908000)
Aspen Community Living/ Lakewood (TDDD pending)

After discussion, Mrs. Gregg moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Ms. Eastman and approved by the Board: *Aye* – 6.

R-2007-042 The Board considered a request for an exemption from OAC Rule 4729-5-10 (Prescription pick-up station) received from:

Apria Healthcare/ Columbus (02-0857850).
Two physician offices on the letter of request

After discussion, Mrs. Gregg moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Mr. Lipsyc and approved by the Board: *Aye* – 6.

R-2007-043 The Board considered a request for an exemption to OAC Rule 4729-5-10 (Prescription pick-up station) received for the following sites:

Teregen Laboratories (00-1235150)
Various Physician Offices listed on the letter of request

After discussion, Mrs. Gregg moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Mr. Braylock and approved by the Board: *Aye* – 6.

R-2007-044 The Board considered a request for an exemption to OAC Rule 4729-5-11 (Responsible person) requesting that **Gary D. Adams**, R.Ph., be permitted to be the responsible person for the following sites:

Rays Pharmacy & Wellness Center (TDDD License Pending)
Rays Clock Tower Pharmacy (02-1228900)

After discussion, Mrs. Gregg moved that the Board approve the request for 90 days. The motion was seconded by Ms. Eastman and approved by the Board: *Aye* – 6.

R-2007-045 The Board considered a request for an exemption to OAC Rule 4729-5-11 (Responsible person) requesting that **Joseph Jerkins**, R.Ph., be permitted to be the responsible person for the following sites:

Maple Leaf Community Pharmacy (02-1286350)
Maple Leaf Pharmacy (TDDD License Pending)

After discussion, Mrs. Gregg moved that the Board approve the request for 1 year. The motion was seconded by Ms. Eastman and approved by the Board: *Aye* – 6.

R-2007-046 The Board considered a request for an exemption to OAC Rule 4729-5-11 (Responsible person) requesting that **Kimberly Johnson**, R.Ph., be permitted to be the responsible person for the following sites:

Bassett Market Pharmacy/Perrysburg (02-1544200)
Bassett Market Pharmacy/Sylvania (02-1544250)

After discussion, Ms. Eastman moved that the Board approve the request for 60 days. The motion was seconded by Mrs. Gregg and approved by the Board: *Aye* – 6.

Mr. Benedict discussed a request from **Anthem** that it be permitted to destroy the originals of its scanned prescriptions after 30 days and maintain those records only in the scanned form. Mrs. Gregg moved that the Board find the request approvable pending inspection of the final system to be used. The motion was seconded by Mr. Lipsyc and approved by the Board: *Aye* – 5/*Nay* – 1.

The Board discussed the November 8-10, 2006 NABP/AACP meeting and the election of the District IV Executive Committee.

Mrs. Droz updated the Board on the progress of the Prescription Drug Monitoring Program.

11:51 a.m. The Board recessed for lunch.

1:00 p.m. The Board reconvened in Room East B, 31st Floor, of the Vern Riffe Center for Government and the Arts, with the following members present:

James E. Turner, R.Ph., *President*; Gregory Braylock, R.Ph.; Suzanne R. Eastman, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; and Dorothy S. Teater, Public Member.

Mr. Keeley discussed the proposed new, amended and rescinded Rules as determined by the Ad Hoc Committee on Rules Review.

2:00 p.m. Board member Dorothy Teater, Public Member, left the meeting for personal reasons.

2:11 p.m.
R-2007-047 After discussion, Mr. Braylock moved that the following rules be approved for filing as amended. The motion was seconded by Mrs. Gregg and approved by the Board: *Aye* – 5.

Ohio State Board of Pharmacy; 77 S. High Street, Room.1702; Columbus, OH 43215-6126 ~ *PH* 614/466-4143; *EM* exec@bop.state.oh.us

FULL TEXT SHOWING PROPOSED CHANGES

UNDERLINED = Add New Language LINED THROUGH = ~~Remove~~ Old Language

(R/R) = Rules up for Review in 2006

4729-1-01 Public notice of hearing to consider proposed rule changes. **NO CHANGE (R/R)**

(A) Reasonable public notice, as required by section 119.03 of the Revised Code, shall be given at least thirty days prior to the date set for the public hearing as follows:

(1) By placing such notice in the register of Ohio. The board may also advertise such notice, one time, in at least one newspaper of general circulation in the state of Ohio.

(2) By mailing, e-mailing, or faxing such notice, one time, to all subscribers on the board's sunshine notice mailing list.

(3) By mailing, e-mailing, or faxing such notice, one time, to all persons who have requested the board to provide notification of any proposed rule changes.

(4) By placing such notice on the board's world wide web home page and remaining there until the public hearing record is closed.

(B) The board shall furnish the full text of the proposed rules as follows:

(1) By mailing to any person who requests such in writing and who pays the cost of copying and mailing.

(2) By e-mailing to any person upon request.

(3) By posting on the board's world wide web home page and remaining there until the public hearing record is closed.

4729-1-02 Notice of meetings. **PROPOSED CHANGE (R/R)**

Any person may ~~determine~~ 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 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.

4729-1-03 Public records. **PROPOSED CHANGE (R/R)**

(A) Public records, as defined in section 149.43 of the Revised Code, maintained by the state board of pharmacy, are available for inspection at the board office between the hours of eight a.m. and four-thirty p.m., Monday through Friday of each week, state holidays excluded.

(B) Copies of public records will be made available at cost pursuant to the following conditions:

(1) A written request shall be submitted to the board of pharmacy specifying which records are to be copied, the number of copies, and the date that such copies are needed.

(2) Upon receipt of the written request, the board shall determine the cost and the amount of time necessary to provide such copies. The copies will be ~~furnished~~ prepared and provided only ~~upon remittance of~~ when the board has been reimbursed for the cost.

(C) The names and addresses of persons licensed or registered with the board will be provided at cost pursuant to the following conditions.

(1) A written request is submitted to the board of pharmacy specifying:

(a) The names and addresses that are to be provided;

(b) The form and format in which the records are to be provided;

(c) The date that the names and addresses are needed.

(2) Upon receipt of the written request, the board shall determine the cost and the amount of time ~~required~~ necessary to provide the names and addresses~~, as well as the cost~~. The names and addresses will be prepared and provided only when the board has been reimbursed for the cost.

4729-1-05 Advisory committees. **NO CHANGE (R/R)**

The board may appoint advisory committees to assist in obtaining information that would enable the board to carry out its responsibilities more effectively and efficiently. An appointment to an advisory committee would

be valid for a period of no longer than one year. In selecting members of an advisory committee, the board will make an effort to select (to the extent practicable), individuals or representatives who may be affected by or be a part of the subject matter being considered. Individuals and groups will be encouraged to submit the names of nominees from which the board may appoint committee members. Such committees shall meet a sufficient number of times to perform properly their functions and report their findings and recommendations to the board.

4729-3-01 Definitions. **PROPOSED CHANGE (R/R)**

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

(A) "Pharmacy internship" means the supervised practical experience required for licensure as a registered pharmacist. The purpose of the pharmacy internship program is to provide those individuals, who intend to become registered pharmacists, with the knowledge and practical experience necessary for functioning competently and effectively upon licensure.

~~(B) "Internship site" means a pharmacy licensed as a terminal distributor of dangerous drugs pursuant to Chapter 4729. of the Revised Code, except as provided in paragraph (C) or (D) of rule 4729-3-05 of the Administrative Code, and whose license is in good standing.~~

(B)~~(C)~~ "Preceptor" is the individual responsible for seeing that the intern is properly supervised and exposed to all aspects of an internship program.

(1) A "preceptor" is a pharmacist who holds a current identification card which is in good standing; or, is a person who is of good moral character and is qualified to direct the approved experience in the area approved by the director of internship pursuant to paragraph (~~D~~B) of rule 4729-3-05 of the Administrative Code.

(2) A person may serve as the preceptor for more than one intern. The number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty.

(3) A preceptor must report to the board on the progress and aptitude of an intern when requested by the director of internship.

(C)~~(D)~~ "Director of internship" has the same meaning as provided in section 4729.11 of the Revised Code.

(D)~~(E)~~ "In good standing" means that the ~~licensee or registrant~~ preceptor has not been denied the privilege of supervising interns by the board.

(E)~~(F)~~ "Statement of Preceptor" is a form provided by the state board of pharmacy that identifies the preceptor and internship site for a pharmacy intern. ~~the form provided which must be received by the board of pharmacy for each pharmacy intern within thirty days of beginning internship under a preceptor's supervision. A "Statement of Preceptor" form is not required to be submitted to the board when using an academic experience affidavit.~~

~~(1) No credit will be given for practical experience obtained prior to thirty days of the date that the "Statement of Preceptor" form is received by the board office; except, that in the event of extraordinary circumstances and when due to no fault of the intern, the board may accept a retroactive date of filing for the "Statement of Preceptor."~~

~~(2) The intern must file a "Statement of Preceptor" form whenever he/she changes internship sites and/or preceptors.~~

(F)~~(G)~~ ~~"Practical experience affidavit"~~ "Practical Experience Affidavit" is a form provided by the state board of pharmacy ~~the form which must be~~ used to submit evidence of practical experience for internship credit pursuant to rule 4729-3-06 of the Administrative Code.

~~(1) Practical experience reported on the affidavit shall be the total number of actual clock hours worked during the reported time period rounded to the nearest hour. The hours reported must be able to be documented by payroll or other records which may be examined by the board of pharmacy upon reasonable notice.~~

~~(2) Practical experience affidavits must be signed by the preceptor on file with the board of pharmacy. In the event of the unavailability of the preceptor's signature due to extraordinary circumstances and due to no fault of the intern, the board may accept an alternative method for verification of a practical experience affidavit.~~

~~(3) Practical experience affidavits for a calendar year may be filed at any time, except that they must be received in the board office or postmarked no later than the first day of March of the following year.~~

~~(H) "Academic experience affidavit" is the form that may be used to submit evidence of practical experience obtained from a board approved structured program where academic credit is awarded.~~

~~(1) The academic experience coordinator at a school of pharmacy is responsible for assuring that during the time of the experience each practice site and preceptor are currently licensed and are in good standing with the appropriate professional licensing board or have been previously approved by the board of pharmacy.~~

~~(2) The preceptor at each practice site must sign the academic experience affidavit certifying the hours of practical experience obtained by the intern.~~

~~(3) The academic experience coordinator at a school of pharmacy must submit a signed academic experience affidavit certifying that the intern obtained a passing grade and that the practice sites and the preceptors are currently licensed and in good standing with the appropriate professional licensing board or have been previously approved by the board of pharmacy.~~

~~(4) The academic experience coordinator at a school of pharmacy is responsible for maintaining records of intern experience at each practice site.~~

~~(5) Academic experience affidavits may be filed at any time, except that they must be received in the board office or postmarked no later than the first day of the July that immediately follows the successful completion of the academic course.~~

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

4729-3-02 Registration as a pharmacy intern. **PROPOSED CHANGE (R/R)**

(A) A certificate of registration as a pharmacy intern shall only be issued for the purpose of allowing those individuals who intend to become registered pharmacists the opportunity to obtain the practical experience required for examination and registration as a pharmacist.

(B) If a person is actively working towards the requirements for licensure as a pharmacist and desires to work as a pharmacy intern in Ohio, he/she must:

(1) (a) Have successfully completed at least sixty semester or ninety quarter hours of college, ~~and~~ be enrolled in a school of pharmacy, and has begun taking professional classes directly related to the practice of pharmacy; or

(b) Have obtained a first professional degree in pharmacy from a program which has been recognized and approved by the state board of pharmacy; or

(c) Have established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Commission (FPGEC) certificate, and have established proficiency in spoken English by successfully completing the Test of Spoken English (TSE) or its board approved equivalent pursuant to rule 4729-5-34 of the Administrative Code.

(2) Apply to the state board of pharmacy for registration as a pharmacy intern.

4729-3-03 Application for registration as a pharmacy intern. **PROPOSED CHANGE (R/R)**

(A) Every person desiring to register as a pharmacy intern for the purpose of obtaining the practical experience required for examination and registration as a pharmacist shall submit the following to the state board of pharmacy:

(1) A completed application form as provided by the board;

(2) A head and shoulders photograph taken within the previous six months;

(3) Fee;

(4) An original transcript certifying that the applicant has in fact successfully completed a minimum of sixty semester or ninety quarter hours of college work; and

(5) A certificate of enrollment ~~into~~ from a school of pharmacy certifying that the person is enrolled in a school of pharmacy and has begun taking professional classes directly related to the practice of pharmacy ~~is actively working towards the requirements for licensure as a pharmacist~~ ; or.

(6) All items listed in paragraphs (A)(1) to (A)(3) of this rule and:

(a) Certification of having obtained a first professional degree in pharmacy from a program that has been recognized and approved by the state board of pharmacy; or

(b) Certification of having established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and evidence of successful completion of the "Test of Spoken English (TSE)" or its board approved equivalent pursuant to rule 4729-5-34 of the Administrative Code.

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(B) The state board of pharmacy may register an applicant as a pharmacy intern as soon as the state board of pharmacy receives all the required items set forth in paragraphs (A)(1) to (A)(5) or paragraph (A)(6) of this rule.

(C) The state board of pharmacy may, pursuant to rule 4729-5-04 of the Administrative Code, deny the issuance of a certificate of registration or an identification card to practice as a pharmacy intern.

4729-3-04 Pharmacy intern identification card renewal. **PROPOSED CHANGE (R/R)**

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

(A) An intern shall be considered to be actively working towards licensure as a pharmacist if he/she has complied with all of the statutes and rules regarding internship since registration as a pharmacy intern, and:

(1) He/she is enrolled in a school of pharmacy and ~~is actively working towards the requirements for licensure as a pharmacist~~ is taking professional classes directly related to the practice of pharmacy; or

(2) He/she is a member of the armed forces and can provide evidence that he/she has been accepted for enrollment in a school of pharmacy upon his/her release from the armed forces; or

~~(3) He/she is able to provide evidence of obtaining a first professional degree in pharmacy from a school of pharmacy; or~~

~~(4) He/she is able to provide evidence of obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and can provide evidence of successful completion of the "Test of Spoken English (TSE)" or its board approved equivalent.~~

(B) An intern who has obtained a first professional degree in pharmacy from a school of pharmacy, or who has established equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, may renew his/her license only once. In the event of extraordinary circumstances and when due to no fault of the intern, the board may approve additional renewals.

4729-3-05 Internship credit. **PROPOSED CHANGE (R/R)**

(A) The pharmacy internship credit requirement for the licensure examinations shall be deemed satisfactorily completed when the intern has:

(1) Successfully graduated after December 31, 2006 with a doctor of pharmacy degree (Pharm.D.) from a school of pharmacy approved by the "Accreditation Council for Pharmacy Education (A.C.P.E.)" and the state board of pharmacy; or

(2) Obtained a total of at least one thousand five hundred hours of documented supervised practical experience accepted by the state board of pharmacy which may include any hours:

(a) Documented on a practical experience affidavit pursuant to rule 4729-3-06 of the Administrative Code; or

(b) Worked in another state where that state board of pharmacy submits officialverification of the actual practical experience contact hours worked to the Ohio board of pharmacy.

(B) No internship credit shall be granted by the board for practical experience until a foreign pharmacy graduate has established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and has established proficiency in spoken English by successfully completing the "Test of Spoken English (TSE)" or its board approved equivalent pursuant to rule 4729-5-34 of the Administrative Code.

~~(A) No internship credit shall be granted by the board for practical experience obtained before registration as an intern or during a period when the intern's registration has lapsed.~~

~~(B) Internship credit may be granted for practical experience obtained when the intern is actively working towards the requirements for licensure as a pharmacist as defined in paragraph (A) of rule 4729-3-04 of the Administrative Code, other than the structured academic program as provided for in paragraph (C) of this rule.~~

~~(C) Internship credit may be gained for practical experience obtained in a structured program for which academic credit is awarded (e.g., externship, clerkship). Such credit shall be limited to the number of hours for which the structured program has been approved by the state board of pharmacy. Internship credit shall be granted only when the intern obtains a passing grade for the course involved. The practical experience obtained may be submitted to the board on an academic experience affidavit.~~

~~(D)~~(C) Practical experience obtained pursuant to paragraph (A)(2)(a) of this rule may include up ~~Up~~ to five hundred hours of internship credit ~~may be obtained~~ at a site other than a pharmacy licensed as a terminal distributor of dangerous drugs (e.g., manufacturing, research, consulting, drug information, and drug utilization review). To receive credit for such experience, a formal request must be submitted to the director of internship for approval prior to beginning the experience in these areas. The request shall include a detailed description of the contemplated internship with respect to time, place, duties, responsibilities, professional supervision, and the person supervising the experience. The request must be signed by both the intern and the person supervising the experience and returned with a completed statement of preceptor form. If approved by the board, the hours must be documented using a practical experience affidavit pursuant to rule 4729-3-06.

~~(E)~~(D) Internship credit may be denied for the practical experience accumulated when an intern is found to be guilty of violation(s) pursuant to section 4729.16 of the Revised Code.

(F) The pharmacy internship requirement for the licensure examination shall be deemed satisfactorily completed when the intern has filed affidavits certifying that he/she has obtained a total of one thousand five hundred hours of supervised practical experience and such affidavits have been accepted by the board of pharmacy.

4729-3-06 Statement of Preceptor and Practical Experience Affidavit. **PROPOSED NEW RULE**

(A) At the beginning of internship, or if there is a change in preceptor or employment site, the intern must submit a completed statement of preceptor form within thirty days of the occurrence to the state board of pharmacy. The filing of a statement of preceptor form is not required for a change of preceptor or internship site related to a school of pharmacy academic program.

(B) If an intern has graduated after December 31, 2006 without obtaining a doctor of pharmacy degree (Pharm.D.) from a school of pharmacy approved by the "Accreditation Council for Pharmacy Education (A.C.P.E.)" and the state board of pharmacy, the intern must obtain one thousand five hundred hours of supervised practical experience, pursuant to paragraphs (A)(2), (B), and (C) of rule 4729-3-05 of the Administrative Code, to satisfy the requirement to take the examinations. The intern is responsible for submitting the following required forms to certify the hours and supervision:

(1) A statement of preceptor form must be received by the state board of pharmacy for each pharmacy intern within thirty days of beginning internship under a preceptor's supervision.

(a) No credit will be given for practical experience obtained prior to thirty days of the date that the statement of preceptor form is received by the board office; except, in the event of extraordinary circumstances and when due to no fault of the intern, the board may accept a retroactive date of filing for the "Statement of Preceptor."

(b) The intern must file a statement of preceptor form whenever he/she changes internship sites and/or preceptors.

(2) A practical experience affidavit form must be used to submit evidence of practical experience for internship credit.

(a) Practical experience reported on the affidavit shall be the total number of actual clock hours worked during the reported time period rounded to the nearest hour. The hours reported must be able to be documented by payroll or other records which may be examined by the state board of pharmacy upon reasonable notice.

(b) Practical experience affidavits must be signed by the preceptor and submitted to the state board of pharmacy. In the event of the unavailability of the preceptor's signature due to extraordinary circumstances and due to no fault of the intern, the board may accept an alternative method for verification of a practical experience affidavit.

(c) Practical experience affidavits for a calendar year may be submitted at any time, except that they must be received in the board office or postmarked no later than the first day of March of the following year.

(d) No internship credit shall be granted by the board for practical experience obtained before registration as an intern or during a period when the intern's registration has lapsed.

(C) Statement of preceptor and practical experience affidavit forms may also be used to document any additional hours desired by the intern.

4729-3-09 Expiration of pharmacy intern certificate. **NO CHANGE(R/R)**
When a candidate receives his/her first identification card to practice as a pharmacist, his/her registration as a pharmacy intern terminates.

4729-5-02 Identification card and signature. **NO CHANGE(R/R)**

Each pharmacist and pharmacy intern, to whom an identification card or renewal identification card has been issued, shall immediately sign such identification card.

4729-5-03 Renewal of registration. **NO CHANGE (R/R)**

An applicant for renewal of his/her pharmacist or pharmacy intern identification card shall complete the questionnaire which is part of the application provided for this purpose. Questions for the annual inventory data shall be limited to professional demographic information.

4729-5-05 Change of name of registrant. **NO CHANGE (R/R)**

(A) A pharmacist or pharmacy intern, who has a legal change of name, shall report the change to the board of pharmacy within sixty days from the effective date of such change. Such notification of a name change shall be accompanied by one of the following:

(1) A notarized affidavit;

(2) A certified copy of a court record;

(3) A certified copy of a marriage certificate.

(B) Requests for duplicate certificate of registration and/or an identification card, to be issued in the new name, shall be accompanied by the following:

(1) The certificate of registration and/or identification card issued in the original name; and

(2) The required fee.

Upon receipt of the required documents, the board will forward the duplicate certificate of registration and/or identification card issued in the new name.

4729-5-07 Recognized and approved colleges of pharmacy. **PROPOSED CHANGE (R/R)**

(A) To be recognized and approved by the state board of pharmacy, a school of pharmacy shall meet the requirements as set forth by the board. The board may utilize the reports, requirements, and recommendations of any recognized accrediting organization or higher education governing board in determining the requirements. The board of pharmacy shall take into consideration, but not be bound by, accreditation standards established by the ~~"American Council on Pharmaceutical Education"~~ "Accreditation Council for Pharmacy Education."

(B) For the purpose of satisfying the requirements of division (C) of section 4729.08 of the Revised Code, graduates of a school of pharmacy located outside the United States shall establish educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and by establishing proficiency in spoken English by obtaining the ~~score~~ scores required by rule 4729-5-34 of the Administrative Code on the "Test of Spoken English (TSE)" or the "Test of English as a Foreign Language, Internet-based test (TOEFL-iBT)."

(C) The term "United States," as used in paragraph (B) of this rule, shall be deemed to include all states of the United States, the District of Columbia, and all territories and any commonwealths.

4729-5-13 Prescription format. **PROPOSED CHANGE**

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 ~~name and~~ 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 issued by a medical intern, resident, or fellow as defined in paragraph (B) of rule 4729-5-15 of the Administrative Code may not be dispensed unless the prescription is issued in compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 of the Administrative Code.

(D) A prescription issued by a staff prescriber of a hospital may not be dispensed unless the prescription is issued in compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 of the Administrative Code.

(E) If a board approved 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.

4729-5-18 Patient profiles. **PROPOSED CHANGE (R/R)**

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

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

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

(a) Full name of the patient for whom the drug is intended;

(b) ~~Address~~ Residential address and telephone number of the patient;

(c) Patient's date of birth;

(d) Patient's gender;

(e) A list of current patient specific data consisting of at least the following:

(i) Known drug related allergies,

(ii) Previous drug reactions,

(iii) History of or active chronic conditions or disease states,

(iv) Other drugs and nutritional supplements, including nonprescription drugs used on a routine basis, or devices;

(f) The pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information ~~peculiar~~ unique to the specific patient or drug;

~~(g) Any information that is given to the pharmacist by the patient or caregiver to complete the patient data record shall be presumed to be accurate, unless there is reasonable cause to believe the information is inaccurate.~~

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

(a) Name and strength of the drug or device;

(b) Prescription number;

(c) Quantity dispensed;

(d) Date dispensed;

(e) Name of the prescriber;

(f) Directions for use.

(B) Any information that is given to the pharmacist by the patient or caregiver to complete the patient data record shall be presumed to be accurate, unless there is reasonable cause to believe the information is inaccurate.

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

4729-5-19 Serial numbering of prescriptions. **PROPOSED CHANGE (R/R)**

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

(A) This number must appear on the original prescription. If an alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, the serial number must also appear on the records in this alternate system.

(B) There must be a complete accounting of all numbers used in the serial numbering system.

(C) All prescriptions which are not refillable, either because of the dispensing of all refills or the length of time since issuance, shall be assigned a new serial number upon authorization by the prescriber to continue the medication, except:

(1) The prescriber may authorize additional refills of a schedule III or IV controlled substance through an oral refill authorization transmitted to a pharmacist, or authorized pharmacy intern pursuant to rule 4729-5-21 of the Administrative Code, provided the additional refills do not exceed five refills of the original prescription nor does any refill occur beyond six months from the date of issuance of the original prescription; or

(2) The prescriber may authorize additional refills of a schedule V controlled substance or a noncontrolled drug through an oral refill authorization transmitted to a pharmacist, or authorized pharmacy intern pursuant to rule 4729-5-21 of the Administrative Code, provided that no refill may occur beyond one year from the date of issuance of the original prescription.

~~(3)~~ All additional refills authorized by the prescriber shall be marked on the original prescription listing full name of the authorizing agent, date, number of refills authorized, and pharmacist receiving the authorization. If an alternative record keeping system is used, this information must also be maintained in that system.

(D) In the case of a board approved central filling operation in which the pharmacies are accessing the same real time, online database, the serial number used may be the original serial number issued at the originating pharmacy if all of the following requirements are met:

(1) The computer system maintains the appropriate records for the prescription so that it is possible to determine the identity of every person involved in the dispensing of the prescription who performs an act that would constitute the practice of pharmacy.

(2) The computer system assigns a unique internal code to the prescription so that it is possible to determine the location of the personnel involved in the dispensing as well as the location of the drug stock used in the dispensing function.

4729-5-20 Prospective drug utilization review. **PROPOSED CHANGE (R/R)**

(A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease state contraindications;

(4) Drug-drug interactions;

(5) Incorrect drug dosage;

(6) Drug-allergy interactions;

(7) Abuse/misuse;

(8) Inappropriate duration of drug treatment;

(9) ~~Documented food~~ Food-nutritional supplements-drug ~~interaction~~ interactions.

(B) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include consulting with the prescriber and/or counseling the patient.

(C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:

(1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);

(2) American hospital formulary service drug information;

(3) United States pharmacopoeia drug information;

(4) American medical association evaluations.

4729-5-21 Manner of processing a prescription. **PROPOSED CHANGE**

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) A pharmacist when dispensing a prescription must:

(1) Ensure that patient information is profiled pursuant to rule 4729-5-18 of the Administrative Code;

(2) Perform prospective drug utilization review pursuant to rule 4729-5-20 of the Administrative Code;

(3) Ensure that the drug is labeled pursuant to rule 4729-5-16 of the Administrative Code;

(4) Ensure that a patient is given an offer to counsel pursuant to rule 4729-5-22 of the Administrative Code;

(5) Ensure that a prescription is filed pursuant to rule 4729-5-09 of the Administrative Code.

(C) Prescriptions:

(1) A pharmacist may receive a signed hard copy prescription, an oral prescription, a facsimile of a signed prescription, or a prescription sent using a board approved electronic prescription transmission system.

(2) When a pharmacist dispenses a drug pursuant to an original prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or, if approved by the state board of pharmacy, enter his/her positive identification into the computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code. If an alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, the record of dispensing must also be recorded in the alternate record keeping system.

(3) When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or enter such information in an alternate record keeping system or, if approved by the state board of pharmacy, enter his/her positive identification into a computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code.

(D) Oral prescriptions:

(1) The pharmacist shall make a record of the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, on the original prescription and, if used, on the alternate system of record keeping. The pharmacist is responsible for assuring the validity of the source of the oral prescription.

(2) Upon receiving a prescription from a recording device, the pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist must document on the original prescription the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for assuring the validity of the prescription removed from the recorder.

(3) A licensed pharmacy intern may receive telephone prescriptions if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to perform this function.

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

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

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

(E) Facsimile prescriptions:

(1) A facsimile shall only be valid as a prescription if a system is in place that will allow the pharmacist to maintain the facsimile as a part of the prescription record including the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent as well as identification of the origin of the facsimile.

(2) The pharmacist must record the prescription in writing pursuant to section 4729.37 of the Revised Code or store the facsimile copy in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

(F) Electronic prescriptions:

(1) Electronic prescriptions may be received by a pharmacy if the electronic prescription transmission system has been approved by the state board of pharmacy.

(2) A pharmacy desiring to receive electronic prescriptions directly into its computer system must obtain approval from the state board of pharmacy. The original prescription information received from the prescriber must be saved and a hardcopy prescription must be printed to document the dispensing. The hardcopy prescription must be filed serially in the prescription file pursuant to rule 4729-5-09 of the Administrative Code.

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

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

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

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

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

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

(1) Also responsible for the dispensing of the drug to the patient must include on the drug order the name of the physician who originally prescribed the drug, sign the pharmacist's full name, and be in compliance with this rule in the same manner as the prescriber.

(2) Not responsible for the dispensing of the drug to the patient may transmit the order to a pharmacy by acting as an agent of the physician. Such pharmacist must personally transmit the order verbally or by facsimile to another pharmacist and be in compliance with this rule.

4729-5-22 Patient counseling. **PROPOSED CHANGE (R/R)**

(A) A pharmacist or the pharmacist's designee shall personally offer to provide the service of counseling pursuant to paragraph (B) of this rule to ~~counsel~~ the patient or caregiver whenever any prescription, new or refill, is dispensed. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel. In this situation, when counseling is refused, the pharmacist shall ensure that such refusal is documented in the presence of the patient or the patient's caregiver. If the patient or caregiver is not physically present, the offer to counsel 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.

(B) A pharmacist, or an intern under the personal supervision of a pharmacist, shall counsel the patient or caregiver. Such counseling may include, but is not limited to, the following:

(1) The name and description of the drug;

(2) The dosage form, dose, route of administration, and duration of drug therapy;

(3) The intended use of the drug and the expected action;

(4) Special directions and precautions for preparation, administration, and use by the patient;

(5) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;

(6) Techniques for self-monitoring drug therapy;

(7) Proper storage;

(8) Prescription refill information;

(9) Action to be taken in the event of a missed dose; and

(10) The pharmacist's comments relevant to the individual's drug therapy, including other necessary information ~~peculiar~~ unique to the specific patient or drug.

(C) Other forms of drug therapy information may be used when appropriate to supplement the counseling by the pharmacist. Examples of forms that may be used include, but are not limited to, drug product information leaflets, pictogram labels, and video programs.

(D) Patient counseling shall not be required for inpatients of an institutional facility as defined in rule 4729-17-01 of the Administrative Code.

~~(E) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.~~

4729-5-24 Prescription copy. **PROPOSED CHANGE (R/R)**

(A) A pharmacist may transfer a copy of a prescription; a pharmacist may refill a copy of a prescription; such actions must be in accordance with the following:

(1) Copies of prescriptions shall be transferred only between pharmacists except as provided in paragraph (G) of this rule; copies of prescriptions for controlled substances pursuant to sections 3719.41, 3719.43, and 3719.44 of the Revised Code shall be communicated directly between two pharmacists and shall be transferred only one time. However, pharmacies electronically sharing a real time, online database may transfer a controlled substance prescription up to the maximum number of refills permitted by law and the prescriber's authorization pursuant to paragraph (A)(4) of this rule.

(2) The copy transferred shall be an exact duplicate of the original prescription except that it shall also include:

(a) Serial prescription number assigned to the prescription;

(b) Name and address (and "D.E.A." number for controlled substance prescriptions) of the pharmacy transferring the copy;

(c) Date of issuance of the prescription;

(d) Date of original dispensing of the prescription;

(e) Original number of refills;

(f) Date of last refill;

(g) Number of valid refills remaining; and

(h) The full name of the transferring pharmacist.

(3) Copies transferred for nonrefillable prescriptions shall be marked on the face of the prescription or orally noted by the transferring pharmacist "For Information Purposes Only" and are not valid prescriptions for the dispensing of drugs.

(4) The pharmacist transferring a copy of a prescription must:

(a) Cancel the original prescription by writing the word "void" on the face of the prescription in such a way as to avoid destroying any of the original information contained on the prescription;

(b) Record on the reverse side of the original written prescription:

(i) Date of transfer;

(ii) His/her signature; and

(iii) When transferring an oral prescription, the name and address (and "D.E.A." number for controlled substance prescriptions) of, and full name of the pharmacist at, the receiving pharmacy.

(c) Except, if ~~an automated data processing system is being used as~~ an alternate ~~system of~~ record keeping system is being used ~~for prescriptions~~ pursuant to rule 4729-5-27 of the Administrative Code, copies of prescriptions may be transferred by a pharmacist if the prescription record in the system is invalidated to prevent further dispensing at the original site. The prescription record in the system must contain the date of transfer, name of pharmacist making transfer, and the name and address of the pharmacy receiving the copy. Also, original written prescriptions for controlled substances must be canceled as required in paragraphs (A)(4)(a) and (A)(4)(b) of this rule.

(5) The pharmacist receiving a copy of a prescription must:

(a) Exercise reasonable diligence to determine validity of the copy;

(b) Reduce an oral prescription to writing by recording all of the information transferred (must include all information required in paragraph (A)(2) of this rule) and write the word "transfer" on the face of the prescription;

(c) Record date of transfer on the face of the prescription.

(B) A prescription copy may be transferred between two pharmacies if the two pharmacies are accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner. The computerized systems must satisfy all information requirements of paragraphs (A)(2) and (A)(4)(c) of this rule. This shall include invalidation of the prescription record in the system to prevent further dispensing at the original site and, if a controlled substance prescription, the canceling of the original written prescription as required in paragraphs (A)(4)(a) and (A)(4)(b) of this rule. A system must be in place that will allow only authorized access to these computerized prescription records by a pharmacist and indicate on the prescription record when and by whom such access was made.

(C) A prescription copy may be transferred between two pharmacists by the use of a facsimile machine. This facsimile may be considered to be a copy of a prescription if all information requirements of paragraph (A) of this rule, including invalidation of the original prescription or computer records, are met. A system must be in place that will show on the facsimile positive identification of the transferring and receiving pharmacists which must become a part of the prescription record. Facsimile copies must be recorded in writing pursuant to section 4729.37 of the Revised Code, or stored in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

(D) Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient. Original copies of prescriptions shall be maintained by pharmacies for the purpose of documenting the dispensing of drugs to a particular patient.

(1) In the event that the pharmacy is not able to provide the medication when needed by the patient pursuant to an authorized refill, the pharmacist shall, upon the request of the patient, transfer the prescription information to the pharmacy designated by the patient.

(2) No pharmacy shall refuse to transfer information about a previously dispensed prescription to another pharmacy when requested by the patient. Prescription information shall be transferred in accordance with this rule as soon as possible in order to assure that the patient's drug therapy is not interrupted.

(E) Prescriptions entered into a computer system but not dispensed may be transferred to another pharmacy if all of the following conditions are met:

(1) The complete prescription information has been entered into the computer system;

(2) The information is displayed on the patient's profile;

(3) There is positive identification, either in the computer system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system;

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

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

(F) Transfer of prescription information between two pharmacies which are accessing the same real time, online database pursuant to the operation of a board approved central filling operation shall not be considered a prescription copy and, therefore, is not subject to the requirements of this rule.

(G) A licensed pharmacy intern may send or receive copies of prescriptions pursuant to the following:

(1) The pharmacist on duty who is supervising the activity of the intern will determine if the intern is competent to send or receive a prescription copy.

(2) The pharmacist on duty who is supervising the activity of the intern is responsible for the accuracy of a prescription copy that is sent or received by an intern.

(3) The supervising pharmacist must be immediately available to answer questions or discuss the prescription copy that is sent or received by an intern.

(4) The intern may not send or receive a prescription copy for a controlled substance.

(5) The pharmacist or intern receiving a prescription copy from an intern must document the full names of the sending intern and his/her supervising pharmacist. The receiving intern shall immediately reduce the prescription copy to writing and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the copy.

(6) The pharmacist or intern sending a prescription copy to an intern must document the full names of the receiving intern and his/her supervising pharmacist. There must be documented positive identification of the sending intern and his/her supervising pharmacist who authorized the transfer of the prescription copy.

(7) The approved intern and the supervising pharmacist must meet all the requirements of this rule.

4729-5-25 Dispensing ~~of drugs~~ and compounding of ~~prescriptions~~ **drugs**. **PROPOSED CHANGE (R/R)**

(A) Only a pharmacist or pharmacy intern under the personal supervision of a pharmacist is permitted to engage in dispensing and compounding.

(B) A person, not a pharmacist or intern under the personal supervision of a pharmacist, may assist a pharmacist in the compounding ~~of prescriptions~~ and dispensing of drugs in accordance with section 4729.01 of the Revised Code and according to the following requirements:

(1) May not engage in any procedure requiring professional judgment. The pharmacist is responsible for the drug dispensed.

(2) The system of drug distribution must provide exact control and assign immediate responsibility only to a pharmacist accountable at every point in the system between receipt of the order for a drug and final delivery for administration or use by the patient.

(3) May not engage in any procedure contrary to the intent of the statutes and rules regulating the dispensing ~~of drugs~~ and compounding of ~~prescriptions~~drugs.

(4) All such persons must not have any pending charges or prior convictions of any state or federal pharmacy or drug laws, or be addicted to or abusing alcohol or drugs, or impaired physically or mentally to such a degree as to render him/her unfit.

(C) No dangerous drug, as defined in section 4729.01 of the Revised Code, shall be sold, offered for sale, or dispensed by means of any mechanical device unless such device is approved by the state board of pharmacy.

4729-5-26 Partial dispensing of schedule II controlled substances. **PROPOSED CHANGE (R/R)**

At the time of partial dispensing of a schedule II controlled substance prescription for a "terminally ill" patient or a patient residing in a "long term care facility", in accordance with section 1306.13 of the Code of Federal Regulations, the following must be observed:

(A) Prior to a partial dispensing of a schedule II controlled substance, the pharmacist must confirm that the patient is "terminally ill" or a patient residing in a "long term care facility" and note this on the prescription.

(B) The partial dispensing of a schedule II prescription can only occur at the pharmacy where the original prescription is on file.

(C) At the time of partial dispensing of a schedule II controlled substance, the following must be noted on the back of the original prescription: the date dispensed, quantity dispensed, remaining quantity authorized to be dispensed, prescription number of this partial dispensing if different, and the manual initials of the dispensing pharmacist.

(D) If an alternate ~~recordkeeping~~ record keeping system ~~utilizing an automated data processing system~~ is being used and the ~~automated data processing~~ system will not permit refills of schedule II controlled substances, a new prescription number for the partial dispensing must be assigned.

(1) A notation must also be made in the database that identifies this new prescription number as a partial dispensing and provides the serial number of the original prescription.

(2) A prescription bearing the new serial number must be placed in the schedule II file. The prescription for each partial filling must also show the serial number of the original prescription.

(E) The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed.

(F) All partial dispensings of schedule II controlled substances must occur within sixty days from the date of issuance of the prescription by the prescriber.

4729-5-29 Confidentiality of patient records. **PROPOSED CHANGE (R/R)**

(A) Records relating to the practice of pharmacy ~~or administering~~ , the administration of drugs, or any patient specific drug transaction are not a public record. A person having custody of, or access to, such records shall not divulge the contents thereof, or provide a copy thereof, to anyone except:

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

(2) The prescriber who issued the prescription or medication order.

(3) Certified/licensed health care personnel who are responsible for the care of the patient.

(4) A member, inspector, agent, or investigator of the state board of pharmacy or any federal, state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug.

(5) An agent of the state medical board when enforcing Chapter 4731. of the Revised Code.

(6) An agency of government charged with the responsibility of providing medical care for the patient upon a written request by an authorized representative of the agency requesting such information.

(7) An agent of a medical insurance company who provides prescription insurance coverage to the patient upon authorization and proof of insurance by the patient or proof of payment by the insurance company for those medications whose information is requested.

(8) An agent who contracts with the pharmacy as a "business associate" in accordance with the regulations promulgated by the secretary of the United States department of health and human services pursuant to the federal standards for privacy of individually identifiable health information.

(9) An agent of the state board of nursing when enforcing Chapter 4723. of the Revised Code.

~~(9)~~(10) Any person, other than those listed in paragraphs (A)(1) to (A)(~~8~~9) of this rule, only when the patient has given consent for such disclosure in writing, except where a patient requiring medication is unable to deliver a written consent to the necessary disclosure. Any consent must be signed by the patient and dated. Any consent for disclosure is valid until rescinded by the patient. In an emergency, the pharmacist may disclose the prescription information when, in the professional judgment of the pharmacist, it is deemed to be in the best interest of the patient. A pharmacist making an oral disclosure in an emergency situation must prepare a written memorandum showing the patient's name, the date and time the disclosure was made, the nature of the emergency, and the names of the individuals by whom and to whom the information was disclosed.

(B) Testimonial privilege is not waived for any communication between a physician, a pharmacist, and a patient pursuant to section 2317.02 of the Revised Code.

(C) Records relating to the practice of pharmacy ~~or administering~~ , the administration of drugs, or any patient specific drug transaction which may be required as evidence of a violation shall be released to a member, inspector, agent, or investigator of the state board of pharmacy or any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug upon his request. Such person shall furnish a receipt to the person having legal custody of the records. If the record is a prescription, the receipt shall list the following information:

(1) Prescription identification number; or, if an order for medication, the name of the patient;

(2) The drugs prescribed;

(3) Quantity of drugs prescribed and dispensed;

(4) Name of the prescriber;

(5) Date, name of agency, and signature of person removing the records.

(D) All such records, including consents, memoranda of emergency disclosures, and written requests pursuant to paragraph (A)(9) of this rule, shall be kept on file at the pharmacy for a period of three years in a readily retrievable manner.

4729-5-30 Manner of issuance of a prescription. **PROPOSED CHANGE**

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) All prescriptions issued by a prescriber shall:

(1) Be dated as of and on the day when issued.

(2) Contain the manually printed, typewritten, or preprinted full name and address of the prescriber.

(3) Indicate a telephone number where the prescriber can be personally contacted during normal business hours.

(4) Indicate the full name and address of the patient.

(5) Indicate the drug name and strength.

(6) Indicate the quantity to dispense.

(7) Indicate the appropriate directions for use.

(8) Specify the number of times or the period of time for which the prescription may be refilled. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.281 of the Revised Code. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.

(9) Not authorize any refills for schedule II controlled substances.

(10) Authorize refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code.

(11) Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances and for dangerous drugs that are not controlled substances.

(12) Identify the trade name or generic name of the drug(s) in a compounded prescription.

(13) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice.

(14) For prescriptions issued to a patient by a prescriber, be:

(a) Manually signed on the day issued by the prescriber in the same manner as he/she would sign a check or legal document.

(b) Issued in compliance with rule 4729-5-13 of the Administrative Code.

(15) 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)~~(15)~~ Be issued in compliance with all applicable federal and state laws, rules, and regulations.

(C) When forms are used that create multiple copies of a prescription issued to a patient by a prescriber, the original prescription that bears the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.

(D) Oral transmission by the prescriber or the prescriber's agent of original prescriptions and refills authorized by a prescriber, pursuant to the requirements of this rule, may be transmitted by telephone only to:

(1) A pharmacist.

(2) A recording device within the pharmacy if the pharmacist is unavailable. The pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist is responsible for assuring the validity of the prescription removed from the recorder.

(3) A licensed pharmacy intern if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to receive telephone prescriptions.

The prescriber's agent must provide his/her full name when transmitting an oral prescription.

(E) Original written prescriptions authorized and signed by a prescriber may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy pursuant to the following:

(1) The facsimile of the prescription must include the full name of the prescriber and if applicable the full name of the prescriber's agent transmitting the prescription to the pharmacy.

(2) The original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.

(3) Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for:

(a) A resident of a long term care facility pursuant to rule 4729-17-09 of the Administrative Code.

(b) A narcotic substance issued for a patient enrolled in a hospice. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must also meet the other requirements of this rule.

(c) A compounded sterile product prescription for a narcotic substance pursuant to rule 4729-19-02 of the Administrative Code.

(4) A facsimile of a prescription received by a pharmacy in any manner other than transmission directly from the prescriber or the prescriber's agent shall not be considered a valid prescription.

(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~~, without further verification by the pharmacist of the prescriber's identity,~~ provided that:

(1) The system ~~shall require~~ 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 ~~must be~~ is retained for a period of three years at the prescriber's office.

4729-5-31 Criteria for licensure by examination. **PROPOSED CHANGE**

(A) Pursuant to section 4729.07 of the Revised Code:

(1) The examination shall consist of the "North American Pharmacist Licensure Examination (NAPLEX)" and a jurisprudence examination compiled by the state board of pharmacy or the "National Association of Boards of Pharmacy (NABP)."

(2) (a) The minimum passing score for the NAPLEX is seventy-five. Any candidate failing to attain a score of seventy-five on the NAPLEX examination will be required to repeat the NAPLEX examination and remit the fee established by the state board of pharmacy for re-examination.

(b) Pursuant to the procedures established by the NABP, a candidate may transfer his/her NAPLEX score to Ohio only after the candidate has met all of the requirements set by the board for examination and licensure in Ohio.

(3) The minimum passing score for the jurisprudence examination is seventy-five. Any candidate who fails to receive a score of seventy-five on the jurisprudence examination will be required to repeat the jurisprudence examination and remit the fee established by the state board of pharmacy for re-examination.

(B) Pursuant to section 4729.13 of the Revised Code:

(1) The examination shall consist of the "North American Pharmacist Licensure Examination (NAPLEX)" and a jurisprudence examination compiled by the state board of pharmacy or the "National Association of Boards of Pharmacy (NABP)."

(2) The minimum passing scores for renewal of the pharmacist's identification card is a seventy-five on each exam.

(a) Any candidate for renewal of an identification card who fails to receive a score of seventy-five on the jurisprudence examination shall make application and remit the fee established by the state board of pharmacy for re-examination.

(b) Any candidate for renewal of an identification card who fails to receive a score of seventy-five on the NAPLEX examination shall make application and remit the fee established by the state board of pharmacy for re-examination.

(C) Pursuant to section 4729.08 of the Revised Code:

Applicants for examination and registration as a pharmacist who are graduates of schools or colleges of pharmacy located outside the United States and who are using an approved examination to establish equivalency of their education shall:

(1) Obtain a score no lower than seventy-five on the "Foreign Pharmacy Graduate Equivalency Examination (FPGEE)"; and

(2) Show oral proficiency in English by successful completion of the "Test of Spoken English (TSE)" or its equivalent, pursuant to rule 4729-5-34 of the Administrative Code.

(D) Any examination candidate who fails to take both of the required examinations within twelve months from the date the board receives the application materials shall submit a new application for the required examination or examinations and remit the fee established by the state board of pharmacy.

(E) The record of the passing score for an examination candidate who takes both of the required examinations, but successfully only completes one examination will:

(1) Be maintained up to three years if no more than twelve months has elapsed between attempts to successfully complete the remaining examination.

(2) Not be maintained if more than twelve months has elapsed between attempts to successfully complete the remaining examination. It will then be necessary for the examination candidate to repeat both examinations for Ohio licensure.

(F) Any candidate who has requested to transfer their NAPLEX score to Ohio must take the Ohio jurisprudence examination within twelve months from the date the candidate completed the NAPLEX examination or the score transfer will be denied.

~~**4729-5-33** Criteria for re-licensure by reciprocity.~~ **RESCIND**

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

~~(A) Submits evidence of having met the requirements of rule 4729-7-02 of the Administrative Code during the three-year period immediately preceding the date of application; or~~

~~(B) Is reciprocating from a state where continuing pharmacy education is mandatory and submits evidence of having met the continuing pharmacy education requirements of that state.~~

4729-5-33 Examination application for registration as pharmacist. **PROPOSED NEW RULE**

(A) Every person desiring to apply to take the examinations for registration as a pharmacist shall submit the required application materials and fees to the national association of boards of pharmacy and the following to the state board of pharmacy:

(1) A completed application form as provided by the board;

(2) A head and shoulders photograph taken within the previous six months;

(3) Required fee;

(4) A certificate of education completed and certified by an approved school of pharmacy documenting the successful graduation of the applicant with a doctor of pharmacy degree obtained after December 31, 2006; or

(5) All items in (A)(1) to (A)(3) of this rule, one thousand five hundred hours of supervised practical experience pursuant to paragraph (A)(2) of rule 4729-3-05 of the Administrative Code; and

(a) A certificate of education completed and certified by an approved school of pharmacy documenting the successful graduation of the applicant; or

(b) Certification of having established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and evidence of successful completion of the "Test of Spoken English (TSE)" or its board approved equivalent pursuant to rule 4729-5-34 of the Administrative Code.

(B) The state board of pharmacy may make an applicant eligible to take the examinations as soon as the board receives all the required items set forth in paragraphs (A)(1) to (A)(3) and paragraph (A)(4) or (A)(5) of this rule.

(C) The state board of pharmacy may, pursuant to rule 4729-5-04 of the Administrative Code, deny admission to the licensure examination.

4729-6-01 Definitions; impaired pharmacists. **PROPOSED CHANGE(R/R)**

As used in Chapter 4729-6 of the Administrative Code:

(A) "Substance abuse/chemical dependency" means a condition involving the use of alcohol or other drugs to a degree that it interferes in the functional life of the licensee, as manifested by physical health, family, job, legal, financial, or emotional/psychiatric problems.

(B) "Impaired pharmacist" means a pharmacist who, because of his/her use of psychoactive substances, is unable to practice pharmacy with requisite judgment, skill, competence, or safety to the public.

(C) "Approved treatment provider" means a ~~board approved and~~ designated treatment program pursuant to section 4729.18 of the Revised Code and ~~Chapter 4729-6~~ rule 4729-6-03 of the Administrative Code ~~that has been certified by the Ohio department of alcohol and drug addiction services (ODADAS) pursuant to division (A) of section 3793.06 of the Revised Code and who provides or has contractual arrangements to provide all of the following services: to identify, verify, assess the degree of impairment, detoxify, rehabilitate, and monitor the impaired pharmacist~~.

(D) "Limited approved treatment provider" means a board approved and designated treatment program pursuant to section 4729.18 of the Revised Code and ~~Chapter 4729-6~~ rule 4729-6-05 of the Administrative Code ~~who provides or has contractual arrangements to provide identification and referral services for the impaired pharmacist and may provide monitoring during rehabilitation~~.

(E) "Intervenor" means a person who participates in a process whereby a pharmacist alleged to be impaired is confronted to evaluate the presence of impairment and, if indicated, who refers the pharmacist for assessment and treatment of the problem.

(F) "Referral for assessment" means a process whereby an intervenor who has reason to believe that a pharmacist is impaired directs that individual to be examined for diagnosis and treatment.

(G) "Treatment assessor" means an individual who is licensed under Chapter 4731. of the Revised Code as a doctor of medicine or a doctor of osteopathic medicine and surgery and who is a certified addictionist or an individual who is certified by the Ohio department of alcohol and drug addiction services (ODADAS) as a certified chemical dependency counselor 3 or 2 pursuant to section 3793.07 of the Revised Code and Chapter 3793:2 of the Administrative Code and who by training and experience can make an assessment of a pharmacist's impairment.

(H) "Individualized treatment plan" is a written document which shall provide for inpatient treatment, outpatient treatment, family therapy, psychotherapy, professional support groups, twelve-step programs, aftercare including support and self-help groups, monitoring programs consisting of random, chain of evidence drug screens, and work site review. The above services and other services may be determined by an approved treatment provider.

(I) "Treatment contract" means the document which outlines the individualized treatment plan, the requirement to cease practice, the requirement for compliance by the impaired pharmacist, and the requirement for notification of the board for non-compliance or relapse pursuant to section 4729.18 of the Revised Code.

(J) "Inpatient treatment" shall consist of placing the pharmacist in an approved treatment provider facility that will provide lodging and food, as well as care and treatment for detoxification and rehabilitation as indicated by the treatment contract.

(K) "Outpatient treatment" shall consist of the pharmacist not residing in an inpatient treatment facility but who is participating in aftercare, twelve-step programs, professional support group (if available), and monitoring programs consisting of random, chain of evidence drug screens and work site review, to establish compliance ~~for a minimum of two years~~.

(L) "Responsible person" for an approved treatment provider or limited approved treatment provider is an individual who shall be in full and actual charge of the treatment program; including but not limited to, ~~having a current license as an approved treatment provider or limited approved treatment provider,~~ assuring the provider has the necessary facilities and personnel to provide services, maintaining records, and notification of the board when required.

(M) "Twelve-step program" is a self-help program such as Alcoholics Anonymous or Narcotics Anonymous which the individual shall be required to personally attend. The minimum attendance required shall not be less than three documented meetings each week ~~during the first two years in recovery~~.

(N) "Aftercare" is a counselor-facilitated group meeting which directly responds to problems relating to the ongoing treatment and monitoring of the pharmacist's sobriety, and should extend for a minimum of six months.

(O) "Professional support group" is a group of peers meeting to discuss the problems ~~peculiar~~ specific to recovery and re-entry to practice of the licensed professional.

(P) "Relapse" means a positive drug screen or a return to a pattern of impairment activities which affects the pharmacist's ability to practice.

4729-6-02 Applicability. **NO CHANGE (R/R)**

(A) No person, except a licensed approved treatment provider, shall purport to be or operate as a treatment facility for the purpose of administering care in the detoxification and rehabilitation of an impaired pharmacist.

(B) The rules in Chapter 4729-6 of the Administrative Code are applicable to all licensed pharmacists, pharmacy interns, and any other board licensees. For the purposes of this chapter only, the word "pharmacist" shall include pharmacy interns and other individuals licensed by the board.

(C) Should the board have reason to believe that a pharmacist suffers from impairment because of conduct or behavior committed or displayed by the pharmacist, the board may compel the individual to be examined by an approved treatment provider. If the pharmacist fails to submit to an assessment as ordered by the board, or if the assessment discloses impairment, or if there is an admission of impairment, or if the board has other reliable, substantial, and probative evidence demonstrating impairment, the board may:

(1) Refer the licensee for treatment;

(2) Initiate action against the licensee pursuant to Chapter 119. of the Revised Code;

(3) Summarily suspend the license of a pharmacist pursuant to rule 4729-6-10 of the Administrative Code if the licensee's continued practice poses a danger of immediate and serious harm to others.

(D) Before being eligible to apply for reinstatement of a license suspended because of impairment, the pharmacist must demonstrate to the board that he/she possesses the requisite judgment, skill, and competence to ensure public safety in the practice of pharmacy. Such demonstration shall include but not be limited to the following:

(1) Certification from an approved treatment provider that the pharmacist:

(a) Has signed a treatment contract and is participating in and complying with an individualized treatment plan;

(b) Has successfully completed the required inpatient treatment;

(c) Is actively participating in an outpatient treatment program;

(d) Has been shown to be alcohol and drug free by random, chain of evidence drug screens for a period of time as determined by the board at the time of the suspension;

(e) Has been evaluated by an approved treatment provider who has made a clear determination, documented in a written statement, that the pharmacist is capable of practicing.

(2) Certification that the pharmacist has met all requirements of the board order and satisfactory evidence has been submitted to the board, including but not limited to:

(a) A copy of the signed and agreed to treatment contract;

(b) Written reports and documentation from the approved treatment program;

(c) Written reports from the pharmacist describing progress towards recovery.

4729-6-03 Requirements for approved treatment providers. **NEW RULE**

(A) An approved treatment provider, as defined in rule 4729-6-01 of the Administrative Code, shall meet or exceed the following requirements:

(1) Certification by the Ohio department of alcohol and drug addiction services (ODADAS) pursuant to Chapter 3793. of the Revised Code;
(2) Accreditation by the appropriate accrediting agency(s); and
(3) Have certified personnel including but not limited to intervenor, treatment assessor, and responsible person as defined in rule 4729-6-01 of the Administrative Code.

(B) An intervenor associated with an approved treatment provider shall:

(1) Respond to information from concerned individuals;

(2) Ascertain validity of the information received;

(3) Assess the situation and, if the pharmacist is showing evidence of impairment, the intervenor shall refer the individual for evaluation;

(4) If the pharmacist fails to comply within one week to a referral for evaluation, the intervenor must report the name of the pharmacist to the board of pharmacy within one working day.

(C) A treatment assessor associated with an approved treatment provider shall evaluate a pharmacist referred to the approved treatment provider to determine if the pharmacist has a substance abuse/chemical dependency related impairment.

(D) If such an impairment exists, the approved treatment program shall formulate the pharmacist's individualized treatment plan as defined in rule 4729-6-01 of the Administrative Code. The specific requirements shall be determined by an assessment of psychological, physical, developmental, family, social, environmental, recreational, and professional needs. The individualized treatment plan shall be part of a treatment contract which the impaired pharmacist must sign. If the impaired pharmacist fails to sign the treatment contract and enter treatment within forty-eight hours of the determination that the pharmacist needs treatment, the approved treatment provider must report the name of the pharmacist to the board of pharmacy within one working day.

(E) The responsible person for the approved treatment provider shall:

(1) Establish a system of records that will provide for complete information about an impaired pharmacist from intervention through the rehabilitation stage;

(2) Establish treatment contracts meeting the requirements of this chapter and a system of follow up to determine compliance by the impaired pharmacist with the treatment contract;

(3) Assure confidentiality of the impaired pharmacist, except:

(a) If the pharmacist fails to comply within one week to a referral for evaluation;

(b) If the impaired pharmacist fails to sign the contract and enter treatment within forty-eight hours of the determination that the pharmacist needs treatment;

(c) If the impaired pharmacist does not suspend practice on entering treatment;

(d) If the impaired pharmacist does not comply with the terms of the treatment contract;

(e) If the impaired pharmacist resumes practice before the approved treatment provider has made a clear determination that the pharmacist is capable of practicing;

(f) If the impaired pharmacist suffers a relapse at any time during or following rehabilitation.

(4) Notify the state board of pharmacy within one working day if the pharmacist violates any portion of this rule.

4729-6-04 ~~Approval of treatment providers.~~ **RESCIND (R/R)**

~~(A) Any individual, institution, organization, association, corporation, or agency located in Ohio desiring to become an approved treatment provider for impaired pharmacists shall make an application, containing such information as the board of pharmacy may require, on forms provided by the board and submit a fee as determined by the board. The application for such a program shall be subject to review by the board of pharmacy and upon issuance shall be effective for a period of twelve months from the first day of April of each year. The approval of a treatment provider may be denied, suspended, or revoked by action of the board pursuant to Chapter 119. of the Revised Code.~~

~~(B) Prior to the end of the approval period a renewal application, requesting such information as the board of pharmacy may require, will be sent to the address of record to the attention of the responsible person. Such renewal application form shall be completed and returned with the applicable fee on or before the established deadline. A properly completed application and fee not received in the board office by the first day of May shall be subject to a late fee to be determined by the board of pharmacy.~~

~~(C) The approval of a treatment provider shall become invalid upon the transfer of ownership, a change in the location of the provider, or any substantial change in the program, and shall require a new application and fee.~~

~~(D) If the executive director and board president determine there is clear and convincing evidence that an approved treatment provider has violated section 4729.18 of the Revised Code or Chapter 4729-6 of the Administrative Code and that continuing the approval of their treatment provider status presents a danger of immediate and serious harm to the public, they may recommend that the board suspend the approval without a prior hearing. Written allegations shall be prepared for consideration by the board. The board, upon review of the written allegations and by a majority vote of its members, excluding the president, may suspend approval of a treatment provider without a prior hearing. Telephone calls may be utilized for reviewing the allegations and taking such a vote. The board shall issue a written order of the suspension by certified mail or in person in accordance with section 119.07 of the Revised Code. If the approved treatment provider requests an adjudication hearing by the board, the date set for such hearing shall be within fifteen days, but not earlier than seven days, unless otherwise agreed to by both the approved treatment provider and the board so that it may effectively conduct its business. Any such summary suspension imposed under this rule shall remain in effect until a final adjudication order issued by the board pursuant to Chapter 119. of the Revised Code becomes effective. The board shall issue its final adjudication order within ninety days after completion of its hearing. A failure to issue the order within ninety days shall result in dissolution of the summary suspension order, but shall not invalidate any subsequent, final adjudication order.~~

4729-6-05 Requirements for limited approved treatment providers. **NEW RULE**

(A) A limited approved treatment provider, as defined in rule 4729-6-01 of the Administrative Code, must be approved by the state board of pharmacy and shall meet or exceed the following requirements:

(1) Have board approved policies and procedures which shall include but not be limited to the following:

(a) The program's standards and procedures for care;
(b) The program's standards and training/approval process for personnel.

(2) Have personnel including but not limited to an intervenor and a responsible person as defined in rule 4729-6-01 of the Administrative Code.

(B) An intervenor associated with a limited approved treatment provider shall:

(1) Respond to information from concerned individuals;

(2) Ascertain validity of the information received;

(3) Assess the situation and, if the pharmacist is showing evidence of impairment, the intervenor shall refer the individual for evaluation;

(4) If the pharmacist fails to comply within one week to a referral for evaluation, the intervenor must report the name of the pharmacist to the board of pharmacy within one working day.

(C) The responsible person for the limited approved treatment provider shall:

(1) Assure confidentiality of the impaired pharmacist, except:

(a) If the pharmacist fails to comply within one week to a referral for evaluation; or

(b) If the impaired pharmacist suffers a relapse at any time during or following rehabilitation.

(2) Notify the state board of pharmacy within one working day if the pharmacist violates any portion of this rule.

4729-6-06 ~~Qualifications of approved treatment providers.~~ **RESCIND(R/R)**

~~Entities who desire to become approved treatment providers or limited approved treatment providers must furnish satisfactory proof to the board of pharmacy that:~~

~~(A) The applicant has agreed that he/she will, on behalf of himself/herself, his/her agents and employees, submit to the jurisdiction of the board of pharmacy and the laws and rules of this state for the purposes of enforcement of section 4729.18 of the Revised Code and Chapter 4729-6 of the Administrative Code.~~

~~(B) The applicant has on staff or under contract a treatment assessor(s) who shall be qualified to make an initial assessment of any pharmacist showing evidence of impairment and who shall determine the type of treatment required; except, the applicant wishing to become a limited approved treatment provider shall have on staff or under contract an intervenor who shall be qualified to determine if a pharmacist is showing evidence of impairment and who shall refer the individual for assessment.~~

~~(C) There is a responsible person, pursuant to paragraph (K) of rule 4729-6-01 of the Administrative Code, charged with the administration of the program for the approved treatment provider and the liaison with the board. Notification in writing shall be made to the board within thirty days after the change of such responsible person.~~

~~(D) The applicant is equipped as to land, buildings, equipment, and personnel to properly carry on the treatment of impaired pharmacists.~~

~~(1) The approved treatment provider applicant shall meet or exceed the following requirements:~~

~~(a) Certification by the Ohio department of alcohol and drug addiction services (ODADAS) pursuant to Chapter 3793. of the Revised Code;~~

~~(b) Accreditation by the appropriate accrediting agency(s);~~

~~(c) Certified personnel including but not limited to intervenor, treatment assessor, and responsible person as defined in rule 4729-6-01 of the Administrative Code.~~

~~(2) The limited approved treatment provider applicant, as defined in rule 4729-6-01 of the Administrative Code, shall meet or exceed the following requirements:~~

(a) Board-approved policies and procedures which shall include but not be limited to the following:

(i) The program's standards and procedures for care;

(ii) The program's standards and training/approval process for personnel.

(b) Personnel, including but not limited to intervenor and responsible person as defined in rule 4729-6-01 of the Administrative Code.

4729-6-08 Requirements for approved treatment providers and limited approved treatment providers. **RESCIND (R/R)**

(A) An intervenor associated with either an approved treatment provider or a limited approved treatment provider shall:

(1) Respond to information from concerned individuals;

(2) Ascertain validity of the information received;

(3) Assess the situation and, if the pharmacist is showing evidence of impairment, the intervenor shall refer the individual for examination evaluation;

(4) If the pharmacist fails to comply within one week to a referral for examination evaluation, the intervenor must report the name of the pharmacist to the board of pharmacy within one working day.

(B) A treatment assessor associated with an approved treatment provider shall examine evaluate a pharmacist referred to the approved treatment provider to determine if the pharmacist has a substance abuse/chemical dependency related impairment.

(C) If such an impairment exists, the approved treatment program shall formulate the pharmacist's individualized treatment plan as defined in rule 4729-6-01 of the Administrative Code. The specific requirements shall be determined by an assessment of psychological, physical, developmental, family, social, environmental, recreational, and professional needs. The individualized treatment plan shall be part of a treatment contract which the impaired pharmacist must sign. If the impaired pharmacist fails to sign the treatment contract and enter treatment within forty-eight hours of the determination that the pharmacist needs treatment, the approved treatment provider must report the name of the pharmacist to the board of pharmacy within one working day.

(D) The responsible person for the approved treatment provider shall:

(1) Establish a system of records that will provide for complete information about an impaired pharmacist from intervention through the rehabilitation stage;

(2) Establish treatment contracts meeting the requirements of this chapter and a system of follow up to determine compliance by the impaired pharmacist with the treatment contract;

(3) Assure confidentiality of the impaired pharmacist, except:

(a) If the pharmacist fails to comply within one week to a referral for examination evaluation,

(b) If the impaired pharmacist fails to sign the contract and enter treatment within forty-eight hours of the determination that the pharmacist needs treatment,

(c) If the impaired pharmacist does not suspend practice on entering treatment,

~~(d) If the impaired pharmacist does not comply with the terms of the treatment contract,~~

~~(e) If the impaired pharmacist resumes practice before the approved treatment provider has made a clear determination that the pharmacist is capable of practicing,~~

~~(f) If the impaired pharmacist suffers a relapse at any time during or following rehabilitation.~~

~~(4) Notify the board of pharmacy within one working day if the pharmacist violates any portion of this rule.~~

~~(E) The responsible person for the limited approved treatment provider shall:~~

~~(1) Assure confidentiality of the impaired pharmacist, except:~~

~~(a) If the pharmacist fails to comply within one week to a referral for examination~~ evaluation ~~or,~~

~~(b) If the impaired pharmacist suffers a relapse at any time during or following rehabilitation.~~

~~(2) Notify the board of pharmacy within one working day if the pharmacist violates any portion of this rule.~~

4729-6-10 Summary suspension, license of impaired pharmacist. **NO CHANGE (R/R)**

(A) The license of the pharmacist may be summarily suspended without a prior hearing pursuant to section 3719.121 of the Revised Code if, in the opinion of the board, an impaired pharmacist poses a danger of immediate and serious harm to others by:

(1) Refusing to seek evaluation, treatment, and rehabilitation for a substance abuse/chemical dependency related impairment;

(2) Not signing and/or complying with the treatment contract from an approved treatment provider;

(3) Resuming practice before the approved treatment provider has made a determination that the pharmacist is capable of practicing;

(4) A relapse, as defined in rule 4729-6-01 of the Administrative Code, of substance abuse/chemical dependency at any time.

(B) The license of the pharmacist may be summarily suspended without a prior hearing pursuant to section 3719.121 of the Revised Code if a pharmacist is guilty of a felony drug abuse offense as defined in section 2925.01 of the Revised Code.

4729-7-01 Definitions. **PROPOSED CHANGE**

As used in Chapter 4729-7 of the Administrative Code:

(A) "Continuing pharmacy education", as required in section 4729.12 of the Revised Code, is defined as post-registration pharmacy education of approved quality undertaken to maintain professional competency to practice pharmacy, improve professional skills, and preserve uniform qualifications for continuing the practice of the profession for the purpose of protecting public health and welfare.

(B) "Continuing education unit (C.E.U.)" is defined as ten contact hours of participation in an organized continuing pharmacy education experience presented by an approved provider.

(C) "Approved continuing education" is defined as participation in an organized and structured continuing pharmacy education experience which has been presented by an approved provider or the state board of pharmacy and which presents information directly related to the practice of pharmacy.

(D) "Approved provider" is defined as an individual, institution, organization, association, corporation, or agency that has been approved by the state board of pharmacy and/or the ~~"Accreditation Council on Pharmaceutical Education"~~ "Accreditation Council for Pharmacy Education" (A.C.P.E.).

(E) "Evidence of approved C.E.U.s" is defined as a certificate or other document certifying that the pharmacist has satisfactorily participated in an organized and structured continuing pharmacy education experience which was presented by an approved provider.

(F) "Pharmacy jurisprudence" related continuing education shall include Ohio state board of pharmacy approved continuing pharmacy education experiences that deal with current laws, rules, and regulations dealing with the practice of pharmacy and the recent changes that have occurred to those laws, rules, and regulations.

4729-7-02 Requirements for renewal of a pharmacist identification card. **PROPOSED CHANGE**

(A) Except as provided in rule 4729-7-08 of the Administrative Code, evidence of six C.E.U.s of approved continuing education shall be submitted every three years by the date indicated on the continuing pharmacy education report form ~~not to exceed three years~~. At least 0.3 C.E.U.s of the total required C.E.U.s must be obtained from Ohio state board of pharmacy approved programs in jurisprudence.

(B) Documentation of the required C.E.U.s shall be submitted on forms provided by the state board of pharmacy.

(C) The C.E.U.s must be obtained on or after March first of the year that is three years prior to May fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal. A pharmacist shall be subject to further action of the board if ~~If~~ the continuing pharmacy education report forms are not filed ~~in a timely manner, the C.E.U.s must have been obtained during the three-year period immediately preceding the date that the continuing pharmacy education report form is filed~~ by the date indicated on the continuing pharmacy education report form, or if the hours submitted are incomplete. If reporting continuing education is required after a pharmacist's license has lapsed or where the license is being renewed after board action, continuing education must be obtained during the three year period immediately preceding the date the renewal application is filed with the board office.

(D) C.E.U.s obtained in excess of the required C.E.U.s at the time the continuing education is required for identification card renewal, may not be transferred and applied to future requirements.

(E) A pharmacist whose identification card has lapsed or has been suspended may renew his/her identification card, if he/she qualifies for renewal pursuant to section 4729.12 or section 4729.13 of the revised Code, by paying the required fee, completing the application for renewal, and, if he/she would have been required to report continuing pharmacy education during the period of lapse or suspension, by providing evidence of having obtained the number of C.E.U.s required at the time of renewal by submitting the certificates of participation obtained during the three-year period immediately preceding the date of applying for renewal.

(F) Ohio-registered pharmacists who hold a current license in states where continuing education is mandatory, have met the continuing pharmacy education requirements of that state, and who do not practice pharmacy in Ohio, may renew their identification card by paying the required fee, completing the application for renewal, and submitting the following signed statement on their continuing pharmacy education report form:

"I declare under penalties of falsification that I hold a current and valid pharmacist license, number (insert license number), in the state of (insert name of state), that I have met the continuing pharmacy education requirements of this state and I do not presently practice pharmacy in the state of Ohio. I hereby agree to immediately notify the Ohio state board of pharmacy if I return and commence the practice of pharmacy in the state of Ohio."

4729-7-05 Procedure for approval as a provider of continuing pharmacy education. **PROPOSED CHANGE**

(A) An individual, institution, organization, association, corporation or agency located in the state of Ohio desiring to be an in-state provider of continuing pharmacy education shall submit an application containing such information as the board of pharmacy may require on forms provided by the board.

(B) An individual, institution, organization, association, corporation or agency located outside the state of Ohio desiring to be an approved out-of-state provider of continuing pharmacy education shall meet the requirements of and be approved by the ~~"Accreditation Council on Pharmaceutical Education."~~ Accreditation Council for Pharmacy Education."

(C) Approval of in-state providers shall be valid for a period of three years at which time reapplication is necessary.

4729-7-09 Jurisprudence continuing education programs. **(NEW RULE)**

A) Jurisprudence continuing education programs must:

1) Be approved by the state board of pharmacy;
2) Contain information from current laws, rules, and regulations pursuant to paragraph (F) of rule 4729-7-01 of the Administrative Code;
3) Contain accurate information;
4) Consist of information relevant to the practice of pharmacy in Ohio;
5) Be presented in an unbiased manner; and
6) Not be utilized for more than two years from the date the program was approved by the state board of pharmacy.

B) If an initial jurisprudence program submission is denied by the state board of pharmacy, the approved continuing education provider may resubmit that program one time to address the problem areas outlined by the board during the review process. If the resubmitted program is not approved by the board, the provider shall not submit a program covering the same topic for a period of one year from the date of the denial.

C) Failure to meet all of the requirements listed in paragraph (A) of this rule shall result in the state board of pharmacy's denial to approve a submitted jurisprudence program. Repeated denials of programs or violations of rule 4729-7-06 of the Administrative Code may result in the suspension or revocation of the board approval of a continuing education provider.

4729-9-04 Returned drugs. **NO CHANGE (R/R)**

(A) No drug that has been dispensed pursuant to a prescription and has left the physical premises of the terminal distributor of dangerous drugs shall be dispensed again except:

(1) Drugs dispensed for inpatients pursuant to paragraph (C) of rule 4729-17-01 of the Administrative Code provided that:

(a) The drugs are packaged in unopened, single-dose or tamper-evident containers and

(b) The drugs have not been in the possession of the ultimate user.

(2) Non-controlled drugs dispensed by a government entity and delivered for outpatients to a psychiatric outpatient facility licensed with the state board of pharmacy provided that:

(a) The drugs are packaged in unopened, single-dose or tamper-evident containers and

(b) The drugs have not been in the possession of the ultimate user.

(B) Drugs that have not been dispensed or possessed in accordance with this rule are considered to be adulterated.

4729-9-05 Security requirements. **NO CHANGE (R/R)**

(A) All registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion.

(B) Substantial compliance with the standards set forth in rule 4729-9-11 of the Administrative Code may be deemed sufficient by the state board of pharmacy after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the state board of pharmacy may consider any of the following factors, as they deem relevant, for strict compliance with security requirements:

(1) The type of activity conducted;

(2) Type and form of dangerous drugs handled;

(3) Quantity of dangerous drugs handled;

(4) Location of the premises and the relationship such location bears on security needs;

(5) Type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) Type of vaults, safes, and secure enclosures or other storage system (e.g.-automatic storage and retrieval system) used;

(7) Type of closures on vaults, safes, and secure enclosures;

(8) Adequacy of key control systems and/or combination lock control systems;

(9) Adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;

(10) Extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) Adequacy of supervision over employees having access to areas containing dangerous drugs;

(12) Procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;

(13) Availability of local police protection or of the registrant's or applicant's security personnel, and;

(14) Adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of dangerous drugs in its operation.

(C) When physical security controls become inadequate as a result of a significant increase in the quantity of dangerous drugs in the possession of the registrant during normal business operation, the physical security controls shall be expanded and extended accordingly.

(D) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in rule 4729-9-11 of the Administrative Code may submit any plans, blueprints, sketches, or other materials regarding the proposed security system to the state board of pharmacy.

(E) The state board of pharmacy shall be notified of any new facilities, work or storage areas to be constructed or utilized for dangerous drugs or of any changes in operation of the registrant before being used or implemented.

4729-9-06 Disposal of dangerous drugs which are controlled substances. **PROPOSED CHANGE(R/R)**

(A) Any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances may dispose of such drugs by the following procedure:

(1) If the person is a registrant or prescriber required to keep records pursuant to Chapters 3719. and 4729. of the Revised Code, the responsible pharmacist or prescriber shall send the state board of pharmacy a list of the dangerous drugs which are controlled substances containing the name, strength, dosage form, and quantity to be disposed of.

(2) If the person is not a registrant or prescriber, he shall submit to the state board of pharmacy a letter stating:

(a) The full name and address of the person possessing the dangerous drugs which are controlled substances to be disposed of;

(b) The name, strength, dosage form, and quantity of each controlled substance;

(c) How the applicant obtained the controlled substances; and

(d) The full name, address, and registration number of the person who possessed the controlled substances prior to the applicant, if known.

(B) The executive director shall authorize and instruct the applicant to dispose of the dangerous drugs which are controlled substances in one of the following manners:

(1) By transfer to persons registered under Chapters 3719. and 4729. of the Revised Code, and authorized to possess the controlled substances;

(2) By destruction in the presence of a state board of pharmacy officer, agent, or inspector or other authorized person; or

(3) By such other means as the state board of pharmacy may determine to assure that the controlled substances do not become available to unauthorized persons.

(C) In the event that a registrant is required regularly to dispose of dangerous drugs which are controlled substances, the executive director may authorize the registrant to dispose of such controlled substances, in accordance with paragraph (B)(1) of this rule, without prior approval of the state board of pharmacy in each instance on the condition that the registrant keep records of such disposals and file periodic reports with the state board of pharmacy summarizing the disposals made by the registrant. In granting such authority, the executive director may place conditions on the disposal of dangerous drugs which are controlled substances including, but not limited to, the method of disposal and the frequency and detail of reports.

4729-9-09 Security of prescription blanks and D.E.A. controlled substance order forms. **NO CHANGE (R/R)**

For the purpose of aiding compliance with section 2925.23 of the Revised Code, a prescriber, responsible pharmacist, or responsible person shall provide security and control for their prescription blanks and D.E.A. controlled substance order forms by limiting their availability only to authorized persons.

4729-9-10 Occasional sale. **NO CHANGE (R/R)**

The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale of a drug by a pharmacist who is a terminal distributor of dangerous drugs or is employed by a terminal distributor of

dangerous drugs and the buyer shall be a wholesale distributor of dangerous drugs, a terminal distributor of dangerous drugs, or a prescriber as defined in section 4729.01 of the Revised Code.

The total value of all dangerous drugs distributed by the terminal distributor of dangerous drugs pursuant to this rule shall not exceed five per cent of the total value of dangerous drugs purchased by the terminal distributor of dangerous drugs during the same calendar year. In addition, the total amount of controlled substances sold pursuant to this rule shall not exceed the allowable amount as specified in section 1307.11 of the Code of Federal Regulations.

The value of the dangerous drugs shall be based on the cost of the dangerous drugs to the terminal distributor of dangerous drugs.

4729-9-13 Distributor of dangerous drug samples. **NO CHANGE (R/R)**

No manufacturer, manufacturer's representative, or wholesale dealer in pharmaceuticals may furnish a sample of a drug of abuse as defined in section 3719.011 of the Revised Code to a prescriber unless requested by the prescriber and unless the company is registered as a wholesale distributor of dangerous drugs and maintains a record of such distribution which will be available to the state board of pharmacy.

4729-9-16 Minimum requirements for wholesalers. **PROPOSED CHANGE**

The following minimum requirements shall apply to all persons distributing dangerous drugs at wholesale in Ohio.

(A) The following information shall be required on a form supplied by the state board of pharmacy from each person making application for a license as a wholesale distributor of dangerous drugs:

(1) The name, full business address (not a post office box), and telephone number;

(2) All trade or business names used by the licensee, any trade or business names under which licensee was previously or is presently licensed;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of dangerous drugs;

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, corporation, or government agency);

(5) The name(s) of the owner and/or operator of the licensee, including:

(a) If a sole proprietorship, the full name of the sole proprietor, and the name of the business entity;

(b) If a partnership, the name of each partner, and the name of the partnership;

(c) If a corporation, the name and title of each corporate officer and director, the corporate names, the name of the state of incorporation, the corporation number, and a copy of the corporation papers;

(d) If a government agency, the name of the agency, and the name of each officer and director of the agency.

(6) If the entity making application for a wholesale distributor of dangerous drugs license is located outside the boundaries of the state of Ohio, part of the licensing process shall be an inquiry to the licensing authority of the state in which that entity is located. This inquiry will determine whether the entity possesses a current and valid license to distribute dangerous drugs in that state and the experience the licensing authority has had with the entity. This information will be used as part of the consideration in licensing the entity by the Ohio state

board of pharmacy. The Ohio board will respond to inquiries of a similar nature from other states about licensees in Ohio.

(B) Prior to the end of the licensing period, a renewal application requesting such information as the state board of pharmacy may require will be sent to the address of record to the attention of the responsible person. Such renewal application form shall be completed and returned with the applicable fee on or before the established deadline.

(C) All facilities where dangerous drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored no longer than two years pursuant to rule 4729-9-17 of the Administrative Code;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(D) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lighted.

(3) Entry into areas where dangerous drugs are held shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are held shall be equipped with a state board of pharmacy approved alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(E) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs.

(3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all stored drugs.

(F) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions;

(3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all incoming and outgoing dangerous drugs.

(G) All returned, damaged, and outdated dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to their supplier.

(2) Any dangerous drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(H) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs.

(1) These records shall include but not be limited to the following information:

(a) The source of the drugs, including the name and principle address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The identity and quantity of the drugs received and distributed or disposed of.

(c) The dates of receipt and distribution of the drugs.

(d) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized by division (B) of section 4729.51 of the Revised Code.

(e) A system of procedures shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse.

(i) The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs, as described in paragraph (H)(1)(e) of this rule, when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

(ii) Reports, generated by the system as described in paragraph (H)(1)(e) of this rule, shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.

(2) Inventories and records shall be made available for inspection and photocopying by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.

(3) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.

(a) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials.

(b) Wholesalers intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must first send notification to the board.

(I) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a dangerous drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(4) A procedure to ensure that any outdated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated dangerous drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

(J) Wholesale distributors of dangerous drugs shall establish and maintain accurate and current lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications. When there is a change in the designated contact person to whom communications with the state board of pharmacy may be directed, the board shall be notified of the new contact person within thirty days on a board approved form. This notice to the board shall be sent by certified mail, return receipt requested, or by verified facsimile transmission.

(K) Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.

(L) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(1) Wholesale drug distributors shall permit properly identified and authorized state board of pharmacy designated agents, federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Any entity making a wholesale sale of a controlled substance shall be required to possess a license as a wholesale distributor of dangerous drugs and a license as a wholesaler or manufacturer of controlled substances, except that a licensed terminal distributor of dangerous drugs may make an occasional sale of a controlled substance pursuant to rule 4729-9-10 of the Administrative Code.

(M) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

4729-9-17 Storage of adulterated drugs. **NO CHANGE (R/R)**

To prevent their use, adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for dispensing and administration.

(A) Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license or two years by those holding a wholesale distributor of dangerous drugs license only.

(B) Drugs, other than controlled substances, shall be destroyed utilizing proper methods of disposal.

(C) Drugs that are controlled substances may be disposed of pursuant to rule 4729-9-06 of the Administrative Code.

(D) Methods of disposal shall prevent the possession of the drugs by unauthorized persons.

4729-15-05 Prohibitions. **PROPOSED CHANGE**

(A) No person shall receive, possess, or transfer radiopharmaceuticals except in accordance with section 4729.51 of the Revised Code.

(B) No person, other than a nuclear pharmacist, shall be personally in full and actual charge of a nuclear pharmacy.

(C) No person shall conduct a nuclear pharmacy except in accordance with section 4729.28 of the Revised Code, state board of pharmacy rules, regulations of the United States nuclear regulatory commission or the appropriate state nuclear regulatory agencies, and regulations of other appropriate state agencies.

(D) No person shall utilize reusable ~~unit-dose~~ unit dose transport containers for radioactive doses without either an effective process to decontaminate the transport container of blood or other biohazardous substances or an effective mechanism to avoid contamination of the transport container with blood or other biohazardous substances.

(E) No person shall re-use a ~~unit-dose~~ unit dose transport container that ~~has been~~ remains contaminated with blood or other biohazardous substances. Any ~~unit-dose~~ unit dose transport container that is returned with the tamper-evident seal broken and the ~~unit-dose~~ unit dose syringe included must be considered to be contaminated.

(F) This rule does not apply to:

(1) An individual prescriber who prepares radiopharmaceuticals for administration to the prescriber's patients as provided in section 4729.29 of the Revised Code.

(2) The transfer of radioactive material not intended for use as a drug to authorized persons.

(3) The occasional transfer of bulk quantities of radiopharmaceuticals to other authorized persons to meet shortages.

4729-17-01 Definitions; institutional facility. **PROPOSED CHANGE**

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

(A) "Institutional facility" means a hospital as defined in section 3727.01 of the Revised Code, or a facility licensed by the Ohio state board of pharmacy and the Ohio department of health, the Ohio department of rehabilitation and correction, or the Ohio department of mental retardation and developmental disabilities at which medical care is provided on site and a medical record documenting episodes of care, including medications ordered and administered, is maintained, including but not limited to:

(1) Convalescent homes;

(2) Developmental facilities;

(3) Long term care facilities;

(4) Nursing homes;

(5) Psychiatric facilities;

(6) Rehabilitation facilities;

(7) Mental retardation facilities.

(B) "Inpatient" means any person who receives drugs for use while within the institutional facility.

(C) "Inpatient prescription" means a written, electronic, or oral order for a drug to be dispensed for use in treating an inpatient.

(D) "Dispensing of a drug pursuant to an inpatient prescription" means the professional review by a pharmacist required to place a specific drug in final association with the name of a particular inpatient pursuant to the lawful order of a prescriber. In the case of an automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular inpatient will be deemed to have occurred when the pharmacist has given final approval to the patient specific order in the system.

(E) "Contingency drugs" are those drugs which may be required to meet the therapeutic needs of inpatients when a licensed pharmacist is not available and personally in full and actual charge of the institutional pharmacy.

(F) "Emergency drugs" are those drugs which are required to meet the immediate therapeutic needs of inpatients in order to sustain life in an emergency crisis.

(G) "Outpatient" means any person who receives drugs for use outside of the institutional facility.

(H) "Electronic drug record keeping system" means a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.

(I) "Positive identification" has the same meaning as paragraph (N) of rule 4729-5-01 of the Administrative Code except that a specific hospital having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for, but not limited to, the prescribing and administration of a drug if approved by the board of pharmacy.

(1) At a minimum, the following items will be considered during the approval process:

(a) Adequate audit controls are in place to detect and deter drug diversion;

(b) Adequate access controls are in place to assure the identity of a user and to assign accountability of the user for any drug transaction;

(c) Adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;

(d) An ongoing quality assurance program is in place to ensure that paragraphs (I)(1)(a) to (I)(1)(c) of this rule are being fulfilled and reviewed; and

(e) Appropriate policies and procedures are in place to address all of the items in paragraphs (I)(1)(a) to (I)(1)(d) of this rule.

(2) Positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code shall always be used to document the:

(a) Dispensing, compounding, or repackaging of a drug;

(b) Removal and possession of a controlled substance to administer to a patient;

(c) Waste of a controlled substance.

(J) "Password" means a private identification that is created by a user to obtain access to an electronic drug record keeping system.

(K) "Personal identifier" means a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as social security number, user identification number, or employee number.

4729-27-01 Definitions. **NO CHANGE (R/R)**

For the purpose of Chapter 4729. of the Revised Code, the term "peritoneal dialysis solutions" shall mean the commercially available, unopened, sterile solutions whose only purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis.

4729-27-02 Licensure. **NO CHANGE (R/R)**

Each person, whether located within or outside this state, who sells peritoneal dialysis solutions in original packages labeled as required by applicable federal and state laws, rules, and regulations to persons residing in this state, shall obtain a limited category II terminal distributor of dangerous drugs license from the board of

pharmacy pursuant to the provisions of sections 4729.54, 4729.55, and 4729.551 of the Revised Code. This requirement shall not apply to persons already licensed to purchase, possess, and sell unlimited category II dangerous drugs at retail.

4729-27-03 Security, storage, and sale. **NO CHANGE (R/R)**

(A) Peritoneal dialysis solutions may be sold at retail to patients only pursuant to an order from a person authorized to prescribe peritoneal dialysis solutions in the course of professional practice.

(B) Peritoneal dialysis solutions may be sold at retail and must be maintained in accordance with Chapters 3715. and 4729. of the Revised Code; rules 4729-9-04, 4729-9-05, 4729-9-11, and 4729-9-12 of the Administrative Code; and applicable federal laws and regulations.

4729-27-04 Records. **NO CHANGE (R/R)**

All retail sellers of peritoneal dialysis solutions shall maintain records of purchase of peritoneal dialysis solutions at wholesale and sale of peritoneal dialysis solutions at retail for three years at the licensed location, or an alternate site approved by the board, for inspection and copying by board of pharmacy agents. The record of sale must include, but is not limited to, the order issued by the person authorized to prescribe peritoneal dialysis solutions in the course of professional practice.

4729-27-05 Prescriber's order. **NO CHANGE (R/R)**

Before making an initial sale of peritoneal dialysis solutions to a patient, the retail seller must have an order issued by a person authorized to prescribe peritoneal dialysis solutions in the course of the prescriber's professional practice. The order must include the full name and address of the patient, the name and address of the prescriber, and the complete and accurate identification of each such product to be provided to the patient.

4729-37-03 Entities required to submit information. **PROPOSED CHANGE**

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 licensed as a terminal distributor of dangerous drugs that dispense drugs identified in rule 4729-37-02 of the Administrative Code to outpatients residing in this state.

(B) 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.

(C) 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.

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. **PROPOSED CHANGE**

(A) Pharmacies pursuant to paragraph (A) 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;

~~(2)~~(5) Patient full name;

~~(3)~~(6) Patient address;

~~(4)~~(7) Patient telephone number;

~~(5)~~(8) Patient date of birth;

(9) Patient gender;

~~(6)~~(10) Prescriber's drug enforcement administration registration number;

~~(7)~~(11) Date prescription was issued by the prescriber;

~~(8)~~(12) Date the prescription was dispensed by the pharmacy;

~~(9)~~(13) Indication of whether the prescription dispensed is new or a refill;

(14) Number of the refill being dispensed;

~~(10)~~(15) National drug code of the actual drug dispensed;

~~(11)~~(16) Quantity of drug dispensed;

~~(12)~~(17) Number of days' supply of drug dispensed;

~~(13)~~(18) Serial or prescription number assigned to the prescription order;

~~(14)~~(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) 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.

4729-37-08 Procedures for obtaining drug database information. **PROPOSED CHANGE**

Persons that are permitted pursuant to divisions (A)(1) to (A)(5) of section 4729.79 of the Revised Code to obtain information from the drug database must comply with the following procedures:

(A) A designated representative of a government entity, a prescriber, or a pharmacist must:

(1) Complete a request form giving such information as required by the board of pharmacy;

(2) Submit the completed form to the board of pharmacy in person, by mail, ~~by a verified facsimile transmission,~~ or by other board approved means.

(B) A federal, state, or local officer must:

(1) Complete a request form giving such information as required by the board of pharmacy that will include an active case number assigned by the investigating agency or department and an approval by a supervisor of that agency or department;

(2) Submit the completed form to the board of pharmacy in person, by mail, ~~by a verified facsimile transmission,~~ or by other board approved means.

(C) An individual seeking the individual's own database information must:

(1) Complete a notarized request form giving such information as required by the board of pharmacy;

(2) Submit the completed form in person or by mail;

(3) Receive the information in person at the board of pharmacy office during normal business hours and show proof of identity with a current government issued form of identification that contains a picture such as a current state issued identification card, a current state issued drivers license, or a valid passport;

(4) Pay the cost of printing the document as determined by the board of pharmacy's current per page rate.

Mr. Keeley presented the Legislative Report.

Mr. Benedict said there was no Medical Board Prescribing Committee Report this month.

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

R-2007-048 **Board Policy:**

RE: Review Process for Jurisprudence Programs

The Licensing Administrator/Director of Internship, Vice President of the Board, and a Board member appointed by the President will be responsible for reviewing submitted jurisprudence programs pursuant to the requirements in Chapter 4729-7. The initial program submissions will go to the Licensing Administrator/Director of Internship who will be responsible for distributing it to the other members of the review group. Within 60 days of receiving the submission these individuals will review the submitted program and make a decision to approve or deny the program. If a program is approved, the Licensing Administrator/Director of Internship will be responsible for sending a letter by mail to the provider indicating the approved status and posting the program on the Board's website.

If a program is denied, the three member group will indicate the section of rule 4729-7-09 where the program is deficient on a form created by the Board to the provider. The completion and mailing of the form shall be the responsibility of the Licensing Administrator/Director of Internship.

If a program is denied a second time, the Licensing Administrator/Director of Internship will notify the provider in a letter by mail that the program has been denied and the provider cannot submit a program covering the same topic for a one year period from the date of the denial. The letter shall also indicate the provider's appeal rights pursuant to paragraph (C) of section 119.06. The completion and mailing of the form shall be the responsibility of the Licensing Administrator/Director of Internship.

If deemed necessary, the three member review group may consult with the full Board regarding a jurisprudence program submission.

R-2007-049 The Board discussed the application from **Paramount Health Care/Toledo** for Continuing Education Provider approval. Ms. Eastman moved that the application be approved. The motion was seconded by Mrs. Gregg and approved by the Board: *Aye* – 5.

2:32 p.m. The Board recessed until Tuesday, September 12, 2006.

TUESDAY, SEPTEMBER 12, 2006

9:00 a.m. The Board reconvened in Room East B, 31st Floor, of the Vern Riffe Center for Government and the Arts, with the following members present:

James E. Turner, R.Ph., *President*; Gregory Braylock, R.Ph., *Vice-President*; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; and Dorothy S. Teater, Public Member.

9:13 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 matter of **Cheryl Hutchins**, Cincinnati, Ohio.

10:20 a.m. Board Member Suzanne R. Eastman, R.Ph., arrived and joined the meeting in progress, but did not participate in the hearing or subsequent vote.

10:56 a.m. The hearing ended and the record was closed. The Board recessed briefly.

11:01 a.m. Mr. Lipsyc 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. Braylock and a roll-call vote was conducted by President Turner as follows: Braylock – *yes*; Gregg – *yes*; Lipsyc – *yes*; Mitchell – *yes*; and Teater – *yes*.

11:16 a.m. The Executive Session ended and the meeting was opened to the public.

11:17 a.m.
R-2007-050 Mr. Braylock moved that the Board adopt the following order in the matter of **Cheryl Hutchins**, Cincinnati, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY
Docket Number D-060320-066

in the matter of:

CHERYL HUTCHINS
2126 St. James Avenue, Apt. 1
Cincinnati, Ohio 45206

INTRODUCTION

The matter of Cheryl Hutchins came for hearing on September 12, 2006, before the following members of the Board: James E. Turner, R.Ph. (*presiding*); Gregory Braylock, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; Kevin J. Mitchell, R.Ph.; and Dorothy S. Teater, Public Member.

Cheryl Hutchins was not represented by counsel. The State of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness: Timothy J. Benedict, R.Ph., Ohio State Board of Pharmacy

Respondent's Witness: Cheryl Hutchins, Respondent

State's Exhibits:

1. Proposal to Deny/Notice of Opportunity For Hearing letter [03-20-06]
1A-1C. Procedurals
2. State Board of Pharmacy Order In Re Cheryl Hutchins, R.Ph. [03-19-90]
2A. State Board of Pharmacy Order In Re Cheryl Hutchins, R.Ph. with United States Postal Service Certified Mail Return Receipt for Article No. P 497 578 675 [03-19-90]
3. Copy of Renewal Application for Pharmacist License for Cheryl Hutchins [08-02-89]
4. Indictment, State of Ohio vs. Cheryl A. Hutchins aka Cheryl Mundy, Case No. B871647, Hamilton County Common Pleas Court [05-06-87]; Entry Withdrawing Plea of Not Guilty and Entering Plea of Guilty [05-28-87]; Entry Ordering Probation Investigation and Report [05-28-87]; Judgment Entry: Sentence Suspended; Probation [06-25-87]
5. State Board of Pharmacy Order In Re Cheryl Hutchins, R.Ph. [12-06-96]
6. Notarized Statement of Marilyn Cherry [12-27-90]

7. Report of Probation Violation, State of Ohio vs. Cheryl Hutchins, Case No. B871647, Hamilton County Common Pleas Court [04-29-91]; Judgment Entry Revoking Probation and Ordering Execution of Sentence [05-17-91]
8. Ohio Department of Rehabilitation and Correction Offender Data [05-23-91 to 11-25-91]
9. Two-page copy of Check No. 255 made payable to Treasurer, State of Ohio, Marked "Returned Unpaid" [04-13-93]; Copy of Money Order No. 65270164860, made payable to Treasurer State of Ohio [10-24-96]
10. Application for Examination as a Pharmacist submitted by Cheryl Ann Cherry Hutchins [04- 29-86]
11. Docket Sheet, State of Ohio vs. Cheryl Mundy, Case No. 83 CRB 5674, Hamilton County Municipal Court [03-13-84]

Respondent's Exhibits:

A. Ten Letters of Support [04-21-05 to 09-11-06]

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 Cheryl Hutchins submitted an application for examination as a pharmacist on or about March 8, 2006.

(2) Records of the Board indicate that Cheryl Hutchins was originally licensed by the State of Ohio as a pharmacist on August 6, 1986; and, on March 19, 1990, her license was suspended by the Board for a period of 72 months due to the following findings:

(a) Cheryl Hutchins did, on or about August 2, 1989, knowingly make a false statement with purpose to secure the issuance by a governmental agency of a license, to wit: Cheryl Hutchins indicated on her 1989 renewal application that she had not been found guilty of a felony or drug law violations when such answer was false. Such conduct is in violation of Section 2921.13(A)(5) of the Ohio Revised Code.

(b) Cheryl Hutchins was, on or about May 28, 1987, convicted of one count of Theft of Drugs, a felony of the fourth degree in violation of Section 2925.21 of the Ohio Revised Code and two counts of Illegal Processing of Drug Documents, felonies of the fourth degree in violation of Section 2925.23 of the Ohio Revised Code. State of Ohio vs Cheryl Hutchins, Case No. B-871647, Hamilton County Common Pleas Court.

(c) Cheryl Hutchins did, on or about April 1, 1987, obtain a dangerous drug by committing or attempting to commit a theft offense, to wit: Cheryl Hutchins stole the following drugs from Kroger Pharmacy, 3829 Montgomery Road, Cincinnati, Ohio: 200 tablets of Valium 10 mg, 233 tablets of Tylenol #4, 100 tablets of Talwin, 1 pint of Hycomine Syrup, 100 tablets of Soma, and 2 bottles of 4 oz Benadryl Elixir. Such conduct is in violation of Section 2925.21 of the Ohio Revised Code.

(d) Cheryl Hutchins did, on or about March 31, 1987, with purpose to commit the commission of aggravated trafficking and/or theft of drugs, agree with another person that she would steal drugs and sell them, to wit: Cheryl Hutchins agreed with another to steal drugs from Kroger Pharmacy and sell them to that other person. Such conduct is in violation of Section 2923.01(A)(2) as it relates to Section 2925.03 of the Ohio Revised Code.

(3) Records of the Board indicate that on December 6, 1996, Cheryl Hutchins' license was revoked by the Board due to the following findings:

(a) Cheryl Hutchins did, from March 19, 1990, through May 5, 1990, while under suspension and not a registered pharmacist, compound, dispense, or sell dangerous drugs, to wit: after Cheryl Hutchins' suspension from the practice of pharmacy, she continued to practice pharmacy as a pharmacist at the Central Community Health Board of Hamilton County. Such conduct is in violation of Section 4729.28 of the Ohio Revised Code.

(b) Cheryl Hutchins' court-ordered probation was revoked on or about April 29, 1991, and her sentence of 1½ to 5 years incarceration was imposed for having committed violations of her court-ordered probation, to wit: Cheryl Hutchins tested positive on April 22, 1991, for consuming a controlled substance; and, she was employed as a pharmacist when ordered by the court not to practice pharmacy.

(c) Cheryl Hutchins did, on or about April 13, 1993, submit a personal check, No. 255, in the amount of $110.00 to the Ohio State Board of Pharmacy for the purpose of sitting for the Jurisprudence Examination on April 27, 1993. Said examination had been a condition for earlier reinstatement of her license, pursuant to the Order of the Board, Docket No. D-890920-046. However, the check was returned to the Board for reimbursement to the Treasurer due to insufficient funds. As of the date of the Proposal to Deny/Notice of Opportunity for Hearing letter dated September 27, 1996, the Board had not been compensated for the cost of allowing Cheryl Hutchins to sit for the examination. A certified letter from the Board to her home requesting payment went unclaimed by her.

On each occasion the Board concluded that Cheryl Hutchins was guilty of a felony or gross immorality and dishonesty and unprofessional conduct in the practice of pharmacy and guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of provisions of Chapter 2925. or 4729. of the Revised Code as provided in Section 4729.16 of the Ohio Revised Code. For these reasons, Cheryl Hutchins' license No. 03-2-16453, was revoked. Such conduct constitutes not being of good moral character and habits; and/or having been disciplined by the Ohio State Board of Pharmacy pursuant to Section 4729.16 of the Revised Code.

CONCLUSIONS OF LAW

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

DECISION OF THE BOARD

Pursuant to Section 4729.07 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the Application For Examination As A Pharmacist submitted by Cheryl Hutchins on March 8, 2006.

Further, the Board places Cheryl Hutchins on probation for ten years beginning on the date of the issuance of her pharmacist license. The terms of probation are as follows:

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

(3) Cheryl Hutchins may not destroy, assist in, or witness the destruction of controlled substances.

(4) Cheryl Hutchins must not violate the drug laws of Ohio, any other state, or the federal government.

(5) Cheryl Hutchins must abide by the rules of the State Board of Pharmacy.

(6) Cheryl Hutchins must comply with the terms of this Order.

(7) Cheryl Hutchins' license will not be in good standing until successful completion of the probationary period.

(8) 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.

Mrs. Teater seconded the motion and it was approved by the Board: *Aye* – 5.

11:20 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 matter of **Karen Amberg Hall**, R.Ph., Columbus, Ohio.

12:35 p.m. The hearing was recessed for lunch. Mr. Mitchell announced that he would be attending the meeting of the Medical Board's PAPC committee during the afternoon and would therefore not be participating in the rest of the hearing.

1:30 p.m. The Board reconvened in Room South A, 31st Floor of the Riffe Center for Government and the Arts with the following members present:

James E. Turner, R.Ph., *President*; Gregory Braylock, R.Ph.; Suzanne R. Eastman, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; and Dorothy Teater, Public Member.

R-2007-051 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.

SUSAN MERLE BAER-LUNA	03-1-27424	INDIANA
SETH ROBERT BAUER	03-1-27641	MINNESOTA
JULIE ANN DRAKE	03-1-27617	MASSACHUSETTS
AARON DAVID DUSH	03-1-27552	PENNSYLVANIA

LORIN MARIE DUTTON	03-1-27613	PENNSYLVANIA
THOMAS RICHARD EDWARDS	03-1-27628	NORTH CAROLINA
PATRICK JULIAN GALLEGOS	03-1-27622	TEXAS
DONALD TODD HENDRICKSON	03-1-27643	OKLAHOMA
ROSE JUNG	03-1-27619	NEW JERSEY
KRISTIN ANN LYNCH	03-1-27605	MARYLAND
ROBERT WESLEY MCGORY	03-1-27575	KENTUCKY
DEBORAH MACHELLE MCNUTT	03-1-27553	NEW MEXICO
HOLLY SUZANNE PALMER	03-1-27409	MINNESOTA
LEE HAMILTON ROSEBUSH	03-1-27633	INDIANA
LYNN DIANE STOVER	03-1-27630	IOWA

1:57 p.m. The adjudication hearing for **Karen Amberg Hall**, R.Ph., Cincinnati, Ohio, resumed in Room East B, 31st Floor of the Riffe Center.

2:28 p.m. The hearing ended and the Board recessed briefly.

2:31 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 Mr. Braylock and a roll-call vote was conducted by President Turner as follows: Eastman – *yes;* Braylock – *yes*; Gregg – *yes*; Lipsyc – *yes*; and Teater – *yes*.

2:46 p.m. The Executive Session ended and the meeting was opened to the public.

R-2007-052 Ms. Eastman moved that the Board adopt the following order in the matter of **Karen Amberg Hall**, R.Ph., Columbus, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY
Docket Number D-060310-063

in the matter of:

KAREN GAIL AMBERG HALL, R.PH.
453 Wetmore Road
Columbus, Ohio 43214

R.Ph. Number 03-3-11810

INTRODUCTION

The matter of Karen Gail Amberg Hall came for hearing on September 12, 2006, before the following members of the Board: James E. Turner, R.Ph. (*presiding*); Gregory Braylock, R.Ph.; Suzanne R. Eastman, R.Ph.; Elizabeth I. Gregg, R.Ph.; Nathan S. Lipsyc, R.Ph.; and Dorothy S. Teater, Public Member.

Karen Gail Amberg Hall was not represented by counsel. The State of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witness: Christopher K. Reed, Ohio State Board of Pharmacy

Respondent's Witness : Karen Hall, R.Ph., Respondent

State's Exhibits:

1. Notice of Opportunity For Hearing letter [03-10-06]
1A-1C. Procedurals

2. Copy of Renewal Application for Pharmacist License of Karen Gail Amberg Hall [07-22-05]
3. Columbus Airport Authority Incident Report [04-18-05]
4. Complaint, State of Ohio vs. Karen Gail Amberg Hall, Case No. 05-9125, Franklin County Municipal Court [04-19-05]; Sentence Entry and Conditions of Community Control/Probation [07-26-05]
5. Twelve-page letter from Karen Gail Amberg Hall [04-03-06]
6. Three-page facsimile letter, with attachments, from Karen Hall [05-02-06]
7. Two-page facsimile letter, with attachment, from Karen Hall [05-02-06]
8. Two-page facsimile letter from Karen Hall to the Ohio State Board of Pharmacy [09-02-06]
9. Two-page facsimile letter from Karen Hall to the Ohio State Board of Pharmacy [09-03-06]

Respondent's Exhibits:

A. Thirteen-page letter from Karen Gail Amberg Hall to State Board of Pharmacy [03-10-06]
B. Sealed Record
C. Sealed Record
D. Sealed Record
E. Sealed Record
F. Sealed Record
G. Sealed Record
H. Copy of Letter from Ed Salver [09-07-06]
I. Sealed Record
J. Letter from Social Security Administration to Karen Hall [05-08-03]
K. Sealed Record

FINDINGS OF FACT

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

(1) Records of the State Board of Pharmacy indicate that Karen Gail Amberg Hall was originally licensed by the State of Ohio as a pharmacist on August 4, 1976, pursuant to examination, and is currently licensed to practice pharmacy in the State of Ohio.

(2) Karen Gail Amberg Hall did, on or about July 22, 2005, knowingly make a false statement with purpose to secure the issuance of a license or registration, to wit: Karen Gail Amberg Hall indicated on her pharmacist license renewal application that she had not been charged with a crime when in fact Karen Gail Amberg Hall had been charged with Telecommunications Harassment in violation of Section 2917.21 of the Ohio Revised Code, a misdemeanor of the first degree. Karen Gail Amberg Hall pled guilty to the charge and was convicted just four days later, July 26, 2005. Franklin County Municipal Court, Case No. 05CRB009125. Such conduct is in violation of Section 2921.13 of the Ohio Revised Code.

(3) Karen Gail Amberg Hall is impaired physically or mentally to such a degree as to render her unfit to practice pharmacy within the meaning of Section 4729.16 (A)(3) of the Ohio Revised Code, to wit: it is reported that Karen Gail Amberg Hall has been diagnosed as paranoid schizophrenic; Karen Gail Amberg Hall was convicted of Telecommunications Harassment for having telephoned thirteen threatening phone calls within an hour to the Federal Aviation Administration's control tower at the Columbus airport, claiming to own the property where the airport is located, and threatening the lives of the personnel unless they "stopped interfering with [her] phone service."

Additionally, Karen Gail Amberg Hall told others that she is the daughter of Jim Henson (creator of "The Muppets"), and that Karen Gail Amberg Hall's brother and sister had murdered him. Karen Gail Amberg Hall told Board agents that people keep breaking into her home to "plant" syringes there. During the interview with Board agents, Karen Gail Amberg Hall was unable to keep focused on any one topic, and when questioned about her continuing education requirements, Karen Gail Amberg Hall replied by asking the agents to leave her home.

CONCLUSIONS OF LAW

(2) The State Board of Pharmacy concludes that paragraph (2) of the Findings of Fact constitutes being guilty of dishonesty 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 (3) of the Findings of Fact constitutes being impaired physically or mentally to such a degree as to render her unfit to practice pharmacy as provided in Division (A)(3) of Section 4729.16 of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Section 4729.16 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby suspends indefinitely the pharmacist identification card, No. 03-3-11810, held by Karen Gail Amberg Hall and such suspension is effective as of the date of the mailing of this Order.

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

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

Further, the Board will only consider reinstatement of the license to practice pharmacy in Ohio if the following conditions have been met:

(A) Karen Gail Amberg Hall must obtain an examination from both a psychiatrist and a neurologist, each licensed to practice in Ohio, regarding Ms. Hall's fitness to practice pharmacy.

(B) The psychiatrist and neurologist must provide the examination results directly to the Board office.

(C) Upon such time as the Board may consider reinstatement, Karen Gail Amberg Hall will be afforded a Chapter 119. hearing. At such time, the Board may consider reinstatement with or without restrictions and/or conditions as the Board deems appropriate under the circumstances.

Mrs. Gregg seconded the motion and it was approved by the Board: *Aye* – 5.

R-2007-053 Mrs. Gregg moved that the minutes of the August 17, 2006 Conference Call be accepted as written. Ms. Eastman seconded the motion and it was approved by the Board: *Aye* – 5.

R-2007-054 Mrs. Gregg moved that the minutes of the August 7-9, 2006, Board meeting be accepted as amended. Ms. Eastman seconded the motion and it was approved by the Board: *Aye* – 5.

Ms. Eastman and Mr. Benedict presented the Probation Report. No action by the Board was needed.

R-2007-055 The Board considered a request for an exemption to OAC Rule 4729-5-10 (Prescription pick-up station) received from **Medco** to allow them to ship the drug Zostavax directly to doctors' offices due to stability concerns documented in the package literature.

After discussion, Mrs. Gregg moved that the Board approve the request for **Medco** and that the Board authorize Board staff to issue a similar exemption for other licensed pharmacies that make a similar request relating to this drug. The motion was seconded by Mrs. Teater and approved by the Board: *Aye* – 5.

3:12 p.m. Mr. Braylock moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code. The motion was seconded by Mr. Lipsyc and a roll-call vote was conducted by President Turner as follows: Braylock – *yes*; Eastman – *yes*; Gregg – *yes*; Lipsyc – *yes*; and Teater – *yes*.

3:35 p.m. The Executive Session ended and the Board recessed until Wednesday, September 13, 2006.

WEDNESDAY, SEPTEMBER 13, 2006

10:00 a.m. The Ohio State Board of Pharmacy convened at the Villa Milano Restaurant, 1630 Schrock Road, Columbus, Ohio, with the following members present:

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

The Board was joined by members of the Board of Trustees of the Ohio Pharmacists Association (OPA) for a discussion of items of mutual interest.

Mr. McMillen presented a Licensing Report; Mrs. Droz discussed the Prescription Drug Monitoring Program and Mr. Keeley discussed some Legislative Issues with those present.

The two pharmacists appointed to the Medical Board's Physician Assistant (PA) Committee, Ms. Parker (OPA) and Mr. Mitchell reported on the meeting of the PA committee that had been held on Tuesday.

11:26 a.m. After concluding the discussion of further items of mutual interest, the meeting with OPA's Board of Trustees ended. There were no items requiring official Board action as a result of the discussion.

11:28 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 Ms. Eastman and a roll-call vote was conducted by President Turner as follows: Braylock – *yes;* Eastman – yes*,* Gregg – *yes*; Lipsyc – *yes*; Mitchell – *yes*; and Teater – *yes*.

11:34 a.m. The Executive Session ended and the meeting was opened to the public.

R-2007-056 Ms. Eastman moved that the Board accept the settlement offer in the matter of **Steven Meyer**, Toledo, Ohio, as amended by the Board as long as Mr. Meyer accepts the additional stipulations put on by the Board. Mrs. Gregg seconded the motion and it was approved by the Board: *Aye* – 6.

Mrs. Gregg moved that the Board receive Per Diem as follows:

PER DIEM	9/11	9/12	9/13	Total
G. Braylock	1	1	1	3
S. Eastman	1	1	1	3
R. Giacalone	-	-	-	0
E. Gregg	1	1	1	3
N. Lipsyc	1	1	1	3
K. Mitchell	1	1	1	3
H. Pasquale	-	-	-	0
D. Teater	1	1	1	3
J. Turner	1	1	1	3

Mr. Braylock seconded the motion and it was approved by the Board: *Aye* – 6.

11:35 a.m. Mr. Lipsyc moved that the meeting be adjourned. The motion was seconded by Mr. Braylock and approved by the Board: *Aye* – 6.

The Ohio State Board of Pharmacy
approved these Minutes October 11, 2006