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

Minutes Of The Meeting

Ohio State Board of Pharmacy
Columbus, Ohio

October 21, 22, 23, 24, 25, 1996

MONDAY, OCTOBER 21, 1996

10:16 a.m. ROLL CALL

The State Board of Pharmacy convened in Room 1914, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

Suzanne L. Neuber, R.Ph. (President); Diane Adelman, R.Ph.; John Hanna, R.Ph.; Paul Lamping, R.Ph.; and Nicholas Repke, Public Member.

Mr. Winsley and Mr. Benedict joined the meeting for the purpose of presenting reports regarding the September 1996 Licensure Examinations and Compliance and Enforcement.

Due to the fact that a quorum was not present, the Board continued their review of administrative matters, correspondence, and reports not requiring official action.

11:11 a.m.

Mr. Hanna left for personal reasons and the remaining Board members recessed until 1:00 p.m. when a quorum would be present and official Board business could be conducted.

1:09 p.m.

The following Board members convened in Room 1914, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio:

Suzanne L. Neuber, R.Ph. (President); Amonte B. Littlejohn, R.Ph.; (Vice-President); Diane Adelman, R.Ph.; Paul Lamping, R.Ph.; Joseph Maslak, R.Ph.; and Nicholas Repke, Public Member.

The Board was joined by Assistant Attorney General Mary Hollern for the purpose of conducting a disciplinary hearing pursuant to Ohio Revised Code Chapters 119. and 4729. in the matter of David Baker, R.Ph., Dayton, Ohio.

3:06 p.m.

The hearing was concluded and Mr. Maslak moved that the Board go into Executive Session for the purpose of deliberating on the evidence and testimony presented during the hearing and for the purpose of conferring with the Assistant Attorney General regarding pending and imminent court matters. The motion was seconded by Mr. Littlejohn and a roll call vote was conducted by President Neuber as follows: Adelman-Yes, Lamping-Yes, Littlejohn-Yes, Maslak-Yes, and Repke-Yes.

3:50 p.m.

RES. 97-054 The Executive Session was concluded and the meeting opened to the public. Mr. Repke moved that the Board adopt the following Order:

ORDER OF THE STATE BOARD OF PHARMACY
(Docket No. D-960227-041)

In The Matter Of:

DAVID W. BAKER, R.Ph.
3109 Benchwood Road
Dayton, Ohio 45414
(R.Ph. No. 03-3-14143)
INTRODUCTION

THE MATTER OF DAVID W. BAKER CAME TO HEARING ON OCTOBER 21, 1996, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: SUZANNE L. NEUBER, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; PAUL F. LAMPING, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; JOSEPH J. MASLAK, R.Ph.; AND NICHOLAS R. REPKE, PUBLIC MEMBER.

DAVID W. BAKER WAS NOT REPRESENTED BY COUNSEL, AND THE STATE OF OHIO WAS REPRESENTED BY MARY L. HOLLERN, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) None

Respondent's Witnesses:

- (1) David W. Baker, Respondent
(2) Nick A. Kallis, Pharmacists Rehabilitation Organization, Inc.
(3) Richard A. Kryc, Pharmacists Rehabilitation Organization, Inc.

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Ohio State Board of Pharmacy Journal, Entry No. J-940815-030, Order of the State Board of Pharmacy, Docket No. D-930621-094, in the matter of David W. Baker dated August 15, 1994.
(2) Exhibit 1A--Hearing Request letter dated February 22, 1996.
(3) Exhibit 1B--Two-page Hearing Schedule letter dated February 27, 1996.

Respondent's Exhibits:

- (1) Exhibit A--All documents are copies. Section 1: PRO and RMS Contracts: Pharmacists Rehabilitation Organization, Inc. Recovering Pharmacist's Contract of David W. Baker dated June 21, 1994; Revised two-page copy of Pharmacists Rehabilitation Organization, Inc. Recovering Pharmacist's Contract of David W. Baker dated June 21, 1994; letter from Kevin Kramer dated June 28, 1994; Shepherd Hill Hospital Recovery Monitoring Services Agreement of David Baker dated October 12, 1994; letter from Fred N. Karaffa dated October 6, 1994; Turning Point Continuing Care Contract of David Baker dated October 27, 1994; and letter from Stephen J. Cahill dated October 5, 1995. Section 2: Urine Drug Screens: Licking Memorial Hospital Certification of Debbie Znosko dated September 16, 1996; forty-one urine drug screen reports of David Baker dated as follows: August 15, 1996; July 29, 1996; two-page report dated July 24, 1996; June 22, 1996; June 15, 1996; 2 reports dated May 22, 1996; April 25, 1996; two-page report dated April 5, 1996; two-page report dated March 27, 1996; 2 two-page reports dated March 1, 1996; two-page report dated February 8, 1996; two-page report dated February 1, 1996; 2 two-page reports dated December 30, 1995; November 28, 1995;

November 20, 1995; October 30, 1995; October 27, 1995; October 4, 1995; October 3, 1995; August 31, 1995; August 18, 1995; July 28, 1995; July 6, 1995; June 21, 1995; June 5, 1995; May 27, 1995; 2 reports dated May 1, 1995; March 24, 1995; March 21, 1995; February 21, 1995; January 31, 1995; January 5, 1995; December 19, 1994; December 7, 1994; November 24, 1994; November 7, 1994; and October 24, 1994. Section 3: AA Attendance: AA Attendance Log sheet dated from June 25th to July 26th; copy of flyer for and name-badge of Dave B. for the 38th Annual Ohio State Conference dated July 29, 30, 31, 1994; and twenty pages of AA Attendance Log Sheets of David Baker dated from July 27, 1994, through October 19, 1996. Section 4: Letters of Recommendation: two-page letter from Mary Spain dated October 2, 1996; letter from Nick A. Kallis dated September 26, 1996; letter from Rick Kryc dated September 26, 1996; two-page letter from Gordon F. Smith dated September 29, 1996; letter from Rodney E. Stone dated September 23, 1996; letter from James H. McCreary dated September 25, 1996; letter from Keith M. Wire dated September 26, 1996; letter from Julia Lucente dated September 29, 1996; letter from Susan M. Fesus dated September 25, 1996; letter from William D. Miles dated September 25, 1996; letter from James W. Smetana dated September 25, 1996; letter from Dettleff E. Olson dated September 24, 1996; letter from Michael R. Haley, not dated; letter from Jack M. McDonald dated September 27, 1996; and letter from Margaret C. Baker dated September 25, 1996. Section 5: Continuing Education: Certificate dated June 23, 1995, and Certificate of Participation dated July 18, 1995, for participation in "The University of Utah School on Alcoholism and Other Drug Dependencies", Program No. 679-068-95-023, of David Baker; Certification of Participation for "Quality of Care and the Law - Defining Standards and Structuring Enforcement", Program No. 680-048-94-001, not dated; Certification of Participation for "Emerging Legal and Ethical Issues in a Managed Care Environment", Program No. 680-048-95-003, not dated; Certification of Participation for "Legal Implications of Telemedicine & Electronic Prescriptions", Program No. 048-000-96-024-L03, dated July 26, 1996; Certification of Participation for "Legal Implications of Telemedicine & Electronic Prescriptions", Program No. 048-000-96-005-L03, of David Baker dated July 26, 1996; Certification of Participation for "Legal Implications of Telemedicine & Electronic Prescriptions", Program No. 048-000-96-006-L03, dated July 26, 1996; Continuing Pharmaceutical Education Certificate for "Self Care Consulting Guide", Program No. 687-348-91-002, of David Baker dated August 23, 1994; Certificate of Participation for "Security in Pharmacy: What You Don't Know Can Hurt You", Program No. 686-342-91-024, of David W. Baker dated August 14, 1991; and Certificate of Participation for "Chemical Dependency and the Pharmacist", Program No. 679-105-95-13, of David W. Baker dated May 6, 1995. Section 6: LCC: sixteen letters from Jack McDonald dated as follows: June 7, 1994; June 27, 1994; August 4, 1994; September 6, 1994; October 6, 1994; November 2, 1994; December 14, 1994; February 8, 1995; March 8, 1995; June 2, 1995; July 7, 1995; September 7, 1995; October 19, 1995; November 20, 1995; March 4, 1996; and August 1, 1996. Section 7: Quarterly Letters: letter from Stephen J. Cahill dated July 25, 1994; letter from Gordon F. Smith dated July 25, 1994; letter from Stephen J. Cahill dated December 23, 1994; letter from Gordon F. Smith dated March 28, 1995; letter from Stephen J. Cahill dated April 10, 1995; letter from Nick A. Kallis dated April 12, 1995; letter from Fred N. Karaffa dated May 10, 1995; letter from Stephen J. Cahill dated June 12, 1995; letter from Gordon F. Smith dated July 2, 1995; letter from Stephen J. Cahill dated August 14, 1995; letter from Gordon dated October 1, 1995; letter from Mary Spain dated January 2, 1996; letter from Gordon Smith dated January 1, 1996; letter from Fred N. Karaffa dated April 3, 1996; letter from Gordon F. Smith dated April 1, 1996; letter from Mary Spain dated July 2, 1996; and letter from Gordon F. Smith dated July 4, 1996. Section 8: Legal: page five of the Order of the Board for David W. Baker; two-page hearing schedule letter dated February 27, 1996; two-page Decision and Entry in the Common Pleas Court of Montgomery County, Ohio, General Division, Case No. 92-CR-3492, of David W. Baker dated August 19, 1996; and letter from Terry L. Lewis dated August 22, 1996.

FINDING OF FACT

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

- (1) David W. Baker is in compliance with the Order of the State Board of Pharmacy, Docket No. D-930621-094, dated August 15, 1994.

ACTION OF THE BOARD

The State Board of Pharmacy hereby approves the reinstatement of the pharmacist identification card of David W. Baker to practice pharmacy in the state of Ohio and places him on probation for five years from the date his identification card is issued, with the following conditions:

- (A) David W. Baker must enter into a new contract, after the effective date of this Order, with a limited treatment provider acceptable to the Board, for a period of not less than five years and submit a copy of the signed contract to the Board office with the renewal application. The contract must provide that:
 - (1) random, **observed** urine screens shall be conducted at least once a month for the entire five-year period. The urine drug screens must report testing for alcohol and must also report testing for creatinine as the dilutional standard or specific gravity;
 - (2) regular attendance, a minimum of three times per week, at an Alcoholics Anonymous, Narcotics Anonymous, and/or similar support group meeting is required during outpatient treatment and/or during aftercare;
 - (3) the intervener/sponsor shall provide copies of all urine screens to the Ohio Board of Pharmacy in a timely fashion; and
 - (4) the program shall immediately report to the Ohio Board of Pharmacy any violations of the contract and/or lack of cooperation.
- (B) David W. Baker must submit quarterly progress reports to the Board; due January 10; April 10; July 10; and October 10; of each year of probation, that include:
 - (1) The written report and documentation provided by the treatment program pursuant to the contract, and
 - (2) A written description of his progress towards recovery and what he has been doing during the previous three months.
- (C) Other terms of probation are as follows:
 - (1) Pursuant to paragraph (D)(1) of Rule 4729-3-01 of the Ohio Administrative Code, the State Board of Pharmacy hereby declares that the pharmacist identification card of David W. Baker is not in good standing and thereby denies the privilege of being a preceptor and training pharmacy interns.
 - (2) David W. Baker may not serve as a responsible pharmacist.
 - (3) David W. Baker may not destroy, or may not assist in or witness the destruction of, controlled substances.
 - (4) David W. Baker must abide by the contract from the treatment provider and any violation must be reported to the Board immediately.
 - (5) David W. Baker must not violate the drug laws of the state of Ohio, any other state, or the federal government.
 - (6) David W. Baker must abide by the rules of the Ohio State Board of Pharmacy.
 - (7) David W. Baker must comply with the terms of this Order.

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

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

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mr. Littlejohn and approved by the Board (Aye-5/Nay-0).

RES. 97-055 Tim Benedict submitted the following request for a waiver pursuant to paragraph (A) of Ohio Administrative Code Rule 4729-5-11:

Terry Tucker, R.Ph. (03-2-15290)
-- St. Ann Hospital (02-0034150)
-- St. Ann's Apothecary (02-0393600)

Following discussion, Mr Lamping moved that R.Ph. Terry Tucker (03-2-15290) be granted the waiver until January 1, 1997. The motion was seconded by Mr. Littlejohn and approved (Aye-5/Nay-0).

RES. 97-056 Mr. Lamping moved that the names of the successful September 1996 exam candidates be memorialized in these minutes:

Heather Christine Airhart; Avon, OH	03-3-22051
Deana Lynn Anderson; Piqua, OH	03-3-21650
Steven J. Auer; Key West, FL	03-3-21998
Parminder Kaur Bathla; Beavercreek, OH	03-3-22045
Virginia L. Beaty; N. Olmsted, OH	03-3-22044
Kevin Patrick Beireis; Columbus, OH	03-3-21822
Stacie Sue Bell; Ada, OH	03-3-21802
Andrew Carl Bidinotto; Dublin, OH	03-3-22013
Julia Raquel Birkemeier; Centerville, OH	03-3-21747
Michele Lee Bohizic; New Castle, PA	03-3-22012
Julie Lynn Bowe; Chagrin Falls, OH	03-3-21714
Lisa M. Brown; Indianapolis, IN	03-3-21829
Shane T. Champ; Logan, OH	03-3-21847
Shu-Ing Chang; Dublin, OH	03-3-21666
Saradadevi Cherukuri; Kenton, OH	03-3-21846
Audrey Christina Cho; Cincinnati, OH	03-3-21665
Lee Ann Cumley; Bedford, OH	03-3-21635
Susan C. Dovich; Lowellville, OH	03-3-22028
Brandon Mark Edgeron; Dublin, OH	03-3-21832
Jan Marie Edington; Wooster, OH	03-3-21842
Evette Adel Fanous; Parma, OH	03-3-21923
Elizabeth Bohoric Field; Columbus, OH	03-3-22046
Cynthia Ann Fredendall; Hilliard, OH	03-3-21624
Jennifer Alysa Fulmer; Massillon, OH	03-3-21589
Lynette Renae Glockner; Youngstown, OH	03-3-22020
Katie McKoy Graham; Cincinnati, OH	03-3-21699
Katricia Ann Green; Columbus, OH	03-3-21845
Carrie Lynn Gunnett; Columbus, OH	03-3-22042
Gregory Allen Hall; Willard, OH	03-3-22021
Kendra Lynn Henson; Chicago, IL	03-3-21756
Robert J. Hessick; Columbus, OH	03-3-21999
Rebecca Lynn Himes; Youngstown, OH	03-3-21985
Ryan Christopher Hoppert; Avon Lake, OH	03-3-21993
James David Hovanec; Cuyahoga Falls, OH	03-3-21868
Julie L. Hughes; Huber Heights, OH	03-3-21988
Gary Evan Ingle; Akron, OH	03-3-21862
Amy Louise Kaufman; Canal Fulton, OH	03-3-21751
Patricia Caroline Keil; Seven Hills, OH	03-3-21912
Terri Maree Kennedy-Cox; Cincinnati, OH	03-3-22009
Douglas John King; Cincinnati, OH	03-3-21805
Melanie Nicole Koenig; Westerville, OH	03-3-22015

Cynthia R. Koller; Huber Heights, OH	03-3-21889
John Eric Koshan; Brookfield, OH	03-3-22016
Daniel J. Krankovich; Muncie, IN	03-3-21890
Vikas Mohan Kulkarni; Reynoldsburg, OH	03-3-22010
Charles Nathan Lally; Berea, OH	03-3-22037
Deborah Lynne Lange; Columbus, OH	03-3-21739
Jae-Seung Lee; Dublin, OH	03-3-22050
Nathan Arthur Lentner; Richfield, OH	03-3-21710
Bonnie Fay Lin; Wadsworth, OH	03-3-21727
Li-Sun Liu; Worthington, OH	03-3-21644
William J. Louney; Pickerington, OH	03-3-22027
Tamara Sue Maag; Columbus Grove, OH	03-3-21760
Dana Madiyevskaya; Cincinnati, OH	03-3-21994
Robert Bradford Madrigal; Wadsworth, OH	03-3-21743
Sepideh Mahdavi; West Chester, OH	03-3-21772
Brian Joseph Main; Toledo, OH	03-3-21878
Lauren A. Manning; Toledo, OH	03-3-21786
Michael George Martinelli; Austintown, OH	03-3-22018
Diane Louise McAllister; Pickerington, OH	03-3-22005
Denise Lorraine McCarthy; Cincinnati, OH	03-3-21637
Tamara Ann McClain; Kenton, OH	03-3-22004
Patrick Andrew Metzger; Columbus, OH	03-3-22017
Julie Carol Miller; Columbus, OH	03-3-21848
Laura Jo Miller; Grove City, OH	03-3-22061
James Floyd Mills; Canal Winchester, OH	03-3-22011
William A. Mirt; Columbus, OH	03-3-21823
Wendy Ann Morrison; Columbus, OH	03-3-22000
Ian Francis Muncy; Springfield, OH	03-3-22034
Rhonda Christine Murray; Westerville, OH	03-3-22038
Sanda Myint; Parma Hts., OH	03-3-21676
Todd John Newton; Columbus, OH	03-3-21855
Andrea Rene Ngim; Hubbard, OH	03-3-22022
Rhonda Marie Osterwalder; Mansfield, OH	03-3-22040
Amita Patel; Solon, OH	03-3-21662
Ketan Nalin Patel; Islip, NY	03-3-22026
Michelle Pankajbhai Patel; Arlington Heights, IL	03-3-22039
Sangita Kirtesh Patel; Lancaster, OH	03-3-21814
Jeff A. Pattison; Zanesville, OH	03-3-22008
Edward Charles Payne; Columbus, OH	03-3-22007
Carolyn T. Pickering; Columbus, OH	03-3-21731
Heather Valerie Price; Stow, OH	03-3-21712
Scott C. Prine; Lima, OH	03-3-21677
Jessica Ann Rader; Amanda, OH	03-3-22025
Joseph Dale Reichert; Lewistown, OH	03-3-22003
Renee A. Riel; Columbus, OH	03-3-21887
April Lynn Roth; Paris, KY	03-3-22058
Michael Nicholas Rubesich; Warren, OH	03-3-22049
Jan M. Scaglione; Dayton, OH	03-3-21934
Robert Brent Scranton; Circleville, OH	03-3-22036
Amy Christine Sinfield; Massillon, OH	03-3-22002
Tamala L. St. Clair; Bradner, OH	03-3-22057
Debra Diane Stalker; Sylvania, OH	03-3-21645
Edward C. Stemley; Dublin, OH	03-3-21831
Kelly Jo Taylor; Orient, OH	03-3-21995
John Paul Tekulve; Cincinnati, OH	03-3-21594
Minh M. Tran; Dublin, OH	03-3-22019
Kelly Van Dorn; Toledo, OH	03-3-22041
Tami Ann Vodhanel; Youngstown, OH	03-3-21688
Michael F. Whale; Westerville, OH	03-3-21980
Michelle Fern Wolford; Kettering, OH	03-3-22006
Katy Yee Wong; Columbus, OH	03-3-22001
William Lance Workman; Columbus, OH	03-3-21992
Margolyn Young; Alliance, OH	03-3-21867

The motion was seconded by Mr. Maslak and approved (Aye-5/Nay-0).

RES. 97-057 Mr. Lamping moved that the Board approve the North America Pharmacy Licensure Examination (NAPLEX) State Letter of Agreement for 1997. The motion was seconded by Mr. Littlejohn and approved (Aye-5/Nay-0).

4:20 p.m. The meeting was recessed until 1:00 p.m., Tuesday, October 22, 1996, when a quorum will be present to conduct official business.

TUESDAY OCTOBER 22, 1996

1:00 p.m. ROLL CALL

The following members of the State Board of Pharmacy reconvened in Room 1914, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio:

Suzanne L. Neuber, R.Ph. (President); Amonte B. Littlejohn, R.Ph.; (Vice-President); Diane Adelman, R.Ph.; John Hanna, R.Ph.; Paul Lamping, R.Ph.; Joseph Maslak, R.Ph.; and Nicholas Repke, Public Member.

1:00 p.m.

RES. 97-058 The Board convened in Room 1919 for the purpose of meeting with the following reciprocity candidates.

BAIRD, ANDREA L.	03-3-22073	MARYLAND
CONSTANTINER, MARIGEL	03-3-21976	PUERTO RICO
DUBANIEWICZ, MICHAEL F.	03-3-22082	PENNSYLVANIA
FOLEY, BARBARA	03-3-22023	MICHIGAN
HART, LARRY D.	03-3-22086	VIRGINIA
HUGG, AMEY C.	03-3-22070	KENTUCKY
KAIBAS, LANI JO	03-3-22081	PENNSYLVANIA
MABIS, THOMAS J.	03-3-22064	PENNSYLVANIA
NYBO, MARK R.	03-3-22085	NEBRASKA
ONDERKO, TRACY L.	03-3-22074	PENNSYLVANIA
ORTH, PAUL A.	03-3-22079	KENTUCKY
PATEL, SONALI	03-3-22077	NEW JERSEY
REYERING, JAMES W.	03-3-22076	KENTUCKY
SHAH, HETAL S.	03-3-21997	NEW JERSEY
SILDRA, DELLA M.	03-3-22072	PENNSYLVANIA
VANDENBERG, RENE L.	03-3-22071	ILLINOIS
VIDOSH ZEMPEL, LINDA M.	03-3-22084	TEXAS
VOGT, MICHAEL R.	03-3-22089	MICHIGAN
WEAVER, JENNIFER K.	03-3-22075	KENTUCKY

Mr. Hanna moved that the candidates be approved and their licenses (identification cards) to practice pharmacy in Ohio be issued except for Michael R. Vogt whose license to practice in Ohio will be issued upon receipt of the official application by the office. The motion was seconded by Mrs. Adelman and approved (Aye-6/Nay-0).

1:45 p.m.

The Board was joined by Assistant Attorney General Mary Hollern for the purpose of conducting an adjudication hearing pursuant to Ohio Revised Code Chapters 119. and 4729. in the matter of R.Ph. Gregory T. Jacobs, Covington, Kentucky.

2:50 p.m.

The hearing was concluded and the Board recessed for five minutes.

3:05 p.m.

Mr. Repke moved that the Board go into Executive Session for the purpose of deliberating on the evidence and testimony presented during the hearing; for the purpose of discussing the investigation of complaints and charges against licensees and registrants of the Board; and conferring with the Assistant Attorney General regarding matters pending in court. The motion was

seconded by Mr. Hanna and a roll call vote was conducted by President Neuber as follows: Adelman-Yes, Hanna-Yes, Lamping-Yes, Littlejohn-Yes, Maslak-Yes, and Repke-Yes.

The Board was joined by Assistant Attorney General Mary Hollern, Tim Benedict, David Rowland, and William Winsley.

3:55 p.m.

RES. 97-059 The Executive Session was concluded and the meeting opened to the public. Mr. Lamping moved that the Board reinstate the license of R.Ph. Gregory T. Jacobs (03-1-18965) with stipulations and adopt the following Order:

ORDER OF THE STATE BOARD OF PHARMACY
(Docket No. D-960327-055)

In The Matter Of:

GREGORY THOMAS JACOBS, R.Ph.
100 Riverside Place, No. 504
Riverside Plaza
Covington, Kentucky 41011
(R.Ph. No. 03-1-18965)

INTRODUCTION

THE MATTER OF GREGORY THOMAS JACOBS CAME TO HEARING ON OCTOBER 22, 1996, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: SUZANNE L. NEUBER, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; JOHN L. HANNA, R.Ph.; PAUL F. LAMPING, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; JOSEPH J. MASLAK, R.Ph.; AND NICHOLAS R. REPKE, PUBLIC MEMBER.

GREGORY THOMAS JACOBS WAS REPRESENTED BY JACK C. RUBENSTEIN, AND THE STATE OF OHIO WAS REPRESENTED BY MARY L. HOLLERN, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

(1) None

Respondent's Witnesses:

- (1) Gregory Thomas Jacobs, Respondent
- (2) Alicia Aumentado, Pharmacists Rehabilitation Organization, Inc.
- (3) Charles Broussard

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Order of the State Board of Pharmacy, Docket No. D-940804-006, in the matter of Gregory Thomas Jacobs dated October 30, 1995.
- (2) Exhibit 1A--Hearing Request letter dated March 25, 1996.
- (3) Exhibit 1B--Two-page Hearing Schedule letter dated March 27, 1996.

Respondent's Exhibits:

- (1) Exhibit A--Copy of Shepherd Hill Hospital Process of Addiction, Models of Alcoholism and copy of two-page schedule letter dated March 27, 1996. Section 1: Ohio License Information: two-page letter from Mary Spain dated October 2, 1996; two-page fax copy of Shepherd Hill Hospital Recovery Monitoring Services Agreement of Greg Jacobs dated November 8, 1995; two-page fax copy of Shepherd Hill Hospital Authorization for Release of Medical Records of Greg Jacobs dated November 8, 1995; letter from Gregory Jacobs dated November 14, 1995, and envelope with handwritten notes; copy of letter

from Greg Jacobs dated May 6, 1996; copy of letter from Greg Jacobs dated May 10, 1996, and copy of business card of Earl G. Siegel; two-page copy of Pharmacists Rehabilitation Organization, Inc. Pharmacist's Recovery Contract of Gregory Thomas Jacobs dated November 1, 1995; copy of letter from Ms. Terrell Davis dated October 2, 1996. Section 2: Indiana License Information: letter from Linda O. Roark dated April 29, 1996; copy of two-page Notice of Hearing before the Indiana Board of Pharmacy, Cause No. 94 IBP 015, of Gregory Jacobs dated July 11, 1996; copy of five-page Findings of Fact and Order Before the Indiana State Board of Pharmacy, Cause No. 94 IBP 015, of Gregory Jacobs dated November 17, 1995; letter from Kenneth Brown dated October 5, 1995; copy of Indiana Pharmacists Association, Pharmacists Recovery Network Program Entry Agreement of Greg Jacobs dated October 4, 1995, and October 10, 1995; copy of Indiana Pharmacists Association, Pharmacists Recovery Network Aftercare Contract of Gregory T. Jacobs dated October 10, 1995; and copy of Indiana Pharmacists Association, Pharmacists Recovery Network Authorization Form for Release of Information of Greg Jacobs dated October 10, 1995. Section 3: Kentucky License Information: copy of two-page letter from Ralph E. Bouvette dated February 7, 1996; two-page letter from Fred N. Karaffa dated April 2, 1996; letter from Barbara M. Wofford and Denise M. Perone dated March 6, 1996; letter from Brian Fingerson dated October 3, 1996; and copy of Kentucky Pharmacists Association Pharmacists Helping Fellow Pharmacists Rehabilitation Contract of Gregory Jacobs dated October 3, 1996, and October 4, 1996. Section 4: Continuing Education Lists: copy of two-page list of continuing pharmacy education classes dated from June of 1993 through September of 1995; and two-page list of continuing pharmacy education classes dated from June of 1996 through September of 1996. Section 5: Letters of Recommendation: letter from Nick A. Kallis dated October 3, 1996; letter from Robert B. and Harriett Bradley dated October 4, 1996; two-page letter from Alicia Aumentado and Earl Siegel dated October 4, 1996; letter from

Karen Krummen dated September 30, 1996; letter from Robert J. and Joyce M. Bradley dated September 30, 1996; letter from Melissa Jacobs dated October 4, 1996; letter from Charles Norman dated October 4, 1996; two-page letter from Mrs. Loretta Jacobs dated October 3, 1996; letter from Richard A. Kryc dated October 2, 1996; fax copy of letter from Theodore M. Hunter dated October 2, 1996; letter from Garrett D. Kenney dated September 30, 1996; copy of letter from Ellen Yass-Reed dated December 6, 1995, letter from Tisha Carson dated October 3, 1996; letter from Larry D. Shaffer dated October 2, 1996; letter from Keith M. Wire dated October 2, 1996; letter from David W. Baker dated October 2, 1996; letter from Beverly L. Black dated September 16, 1996; letter from Rodney D. Moon dated September 20, 1996; two-page letter from Lorrie Klaserner dated October 3, 1996; letter from Richard Sorrell dated October 1, 1996; two-page letter from D. Christopher Hart dated October 2, 1996; letter from Chris Good dated October 1, 1996; letter from Barbara M. Wofford and D. M. Perone dated October 4, 1996; letter from Rev. Barry Windholtz dated October 18, 1996; and letter from George Perdue dated October 7, 1996. Section 6: Urine Screen Information: copy of letter from Fred N. Karaffa, not dated; copy of letter from Fred N. Karaffa dated March 6, 1996; letter from Mary Spain dated January 5, 1996; letter from Fred N. Karaffa dated April 9, 1996; letter from Mary Spain dated June 5, 1996; letter from Mary Spain dated July 9, 1996; five Pharmacists Rehabilitation Organization, Inc. Client Reporting Sheets/Client Monitoring Sheets regarding Client Case No. 90, for the periods dating from June 30, 1996, to September 30, 1996; March 31, 1996, to June 30, 1996; December 31, 1995, to March 30, 1996; October 1, 1995, to December 31, 1995; and July 2, 1995, to September 31, 1995; four Chain of Custody Requests of Greg Jacobs dated October 1, 1995; October 4, 1995; October 9, 1995; and October 28, 1995; six urine drug screen reports of Greg 90 dated as follows: October 27, 1995; October 13, 1995; October 10, 1995; October 5, 1995; September 23, 1995; September 19, 1995; and Chain of Custody Request of Greg Jacobs dated October 8, 1996; Licking Memorial Hospital Certification of Debbie Znosko dated September 27, 1996, and twenty-three copies of urine drug screen reports of Greg Jacobs dated as follows: September 12, 1996; August 20, 1996; July 24, 1996; July 1, 1996; two-page report dated June 18, 1996; June 4, 1996; May 17, 1996; May 4, 1996; April 23, 1996; April 9, 1996; two-page report dated March 28, 1996; two-page report dated March 9, 1996; two-page report dated February 29, 1996; two-page report dated February 14, 1996; two-page report dated January 27, 1996; two-page report dated January 24, 1996; two-page report dated January 6, 1996; January 5, 1996; two-page report dated December 29, 1995; December 27, 1995; two-page report dated December 12, 1995; two-page report dated December 8, 1995; and two-page report dated November 30, 1995. Section 7:

Meeting Attendance Verification: Twenty-nine pages of Record of AA Meeting Attendance of Gregory T. Jacobs dated from September 20, 1995, through October 20, 1996.

FINDING OF FACT

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

- (1) Gregory Thomas Jacobs is in compliance with the Order of the State Board of Pharmacy, Docket No. D-940804-006, dated October 30, 1995.

ACTION OF THE BOARD

The State Board of Pharmacy hereby approves the reinstatement of the pharmacist identification card of Gregory Thomas Jacobs to practice pharmacy in the state of Ohio and places him on probation for five years from the date his identification card is issued, with the following conditions:

- (A) Gregory Thomas Jacobs must enter into a new contract, after the effective date of this Order, with a limited treatment provider acceptable to the Board, for a period of not less than five years and submit a copy of the signed contract to the Board office with the renewal application. The contract must provide that:
 - (1) random, **observed** urine screens shall be conducted at least once every three months. The urine drug screens must report testing for alcohol and must also report testing for creatinine as the dilutional standard or specific gravity;
 - (2) regular attendance, a minimum of three times per week, at an Alcoholics Anonymous, Narcotics Anonymous, and/or similar support group meeting is required during outpatient treatment and/or during aftercare;
 - (3) the intervener/sponsor shall provide copies of all urine screens to the Ohio Board of Pharmacy in a timely fashion; and
 - (4) the program shall immediately report to the Ohio Board of Pharmacy any violations of the contract and/or lack of cooperation.
- (B) Gregory Thomas Jacobs must continue counseling with D. M. Perone, M.D., or other psychiatrist for his mood disorder. Gregory Thomas Jacobs must follow and abide by the treatment plan designed and recommended by this psychiatrist.
- (C) Gregory Thomas Jacobs must submit quarterly progress reports to the Board; due January 10; April 10; July 10; and October 10; of each year of probation, that include:
 - (1) The written report and documentation provided by PRO, Shepherd Hill Hospital, or other treatment program pursuant to the contract;
 - (2) The written report and documentation provided by D. M. Perone, M.D., or other psychiatrist regarding Mr. Jacobs mood disorder; and
 - (3) A written description of his progress towards recovery and what he has been doing during the previous three months.
- (D) Other terms of probation are as follows:
 - (1) Pursuant to paragraph (D)(1) of Rule 4729-3-01 of the Ohio Administrative Code, the State Board of Pharmacy hereby declares that the pharmacist identification card of Gregory Thomas Jacobs is not in good standing and thereby denies the privilege of being a preceptor and training pharmacy interns.

- (2) Gregory Thomas Jacobs may not serve as a responsible pharmacist.
- (3) Gregory Thomas Jacobs may not destroy, or may not assist in or witness the destruction of, controlled substances.
- (4) Gregory Thomas Jacobs must abide by the contract from the treatment provider and any violation must be reported to the Board immediately.
- (5) Gregory Thomas Jacobs must not violate the drug laws of the state of Ohio, any other state, or the federal government.
- (6) Gregory Thomas Jacobs must abide by the rules of the Ohio State Board of Pharmacy.
- (7) Gregory Thomas Jacobs must comply with the terms of this Order.

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

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

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mr. Maslak and approved by the Board (Aye-6/Nay-0).

4:00 p.m. The Board recessed until Wednesday, October 23, 1996, at 8:00 a.m.

WEDNESDAY, OCTOBER 23, 1996

8:10 a.m. ROLL CALL

The following members of the State Board of Pharmacy reconvened in Room 1914, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio:

Suzanne L. Neuber, R.Ph. (President); Amonte B. Littlejohn, R.Ph.; (Vice-President); Diane Adelman, R.Ph.; John Hanna, R.Ph.; Paul Lamping, R.Ph.; and Nicholas Repke, Public Member.

The Board continued their review of administrative matters, correspondence, and reports not requiring official action.

9:00 a.m.

The Board was joined by Assistant Attorney General Mary Hollern for the purpose of conducting an adjudication hearing pursuant to the provisions of Ohio Revised Code Chapters 119. and 4729. in the matter of R.Ph. Cheryl Hutchins, Cincinnati, Ohio.

9:08 a.m.

Mr. Maslak arrived and joined the meeting.

10:35 a.m.

The hearing was concluded and the Board recessed for 15 minutes.

11:00 a.m.

The Board reconvened and commenced a review and discussion of the proposals to revise the Pharmacy Practice Act.

12:30 p.m.

Mr. Littlejohn excused himself from the meeting for personal reasons.

RES. 97-060 The review and discussion of the proposed revisions was completed and the Board reviewed a draft of a cease and desist regarding the advertising of prescription drugs by Walgreens, Inc. Mr. Hanna moved that the following Cease and Desist Order be issued by the Board:

D R A F T

C. R. Walgreen, III
Walgreens Corporate Offices
300 Wilmot Road
Deerfield, Illinois 60015

Re: Advertisement

Dear Mr. Walgreen:

Board of Pharmacy records indicate that you are the Chairman and C.E.O. of Walgreens which owns and operates several stores throughout the state of Ohio.

It has come to the attention of the Board that advertisements issued in the Cleveland, Ohio area on Sunday, October 6, 1996, appear to be in violation Ohio's advertising laws. Specifically, Walgreens has advertised prices without indicating the generic name of the drug product. A copy of this advertisement is enclosed herein.

Please be reminded that Section 4729.36(B) of the Ohio Revised Code allows for a pharmacy or pharmacist to advertise by name or therapeutic class the availability for sale or dispensing of any dangerous drug provided such advertising includes price information as defined in division (N) of Section 4729.02 of the Ohio Revised Code. Section 4729.02(N) requires the following information to be listed with an advertisement in an easily understandable manner:

- (1) The proprietary name of the drug product;
- (2) The established (generic) name of the drug product;
- (3) The strength of the drug product if the product contains a single active ingredient or if the drug product contains more than one active ingredient and a relevant strength can be associated with the product without indicating each active ingredient. The established name and quantity of each active ingredient are required if such a relevant strength cannot be so associated with a drug product containing more than one ingredient;
- (4) The dosage form;
- (5) The price charged for a specific quantity of the drug product. The stated price shall include all charges to the consumer, including, but not limited to, the cost of the drug product, professional fees, handling fees, if any, and a statement identifying professional services routinely furnished by the pharmacy. Any mailing fees and delivery fees may be stated separately without repetition. The information shall not be false or misleading.

Any advertisement must include the entire information set forth in this statute.

YOU ARE HEREBY ADVISED that pursuant to Section 4729.25(B) of the Ohio Revised Code, the Board of Pharmacy may issue notice or warning to an alleged offender of any of the provisions of Chapter 4729. of the Ohio Revised Code; thus you are hereby notified to immediately CEASE publication of any advertisements which violate the aforementioned sections of Ohio law and DESIST from any further violations of Chapter 4729. of the Ohio Revised Code.

BY ORDER OF THE STATE BOARD OF PHARMACY

The motion was seconded by Mr. Repke and approved by the Board (Aye-5/Nay-0).

12:56 p.m.

Mr. Littlejohn returned to participate in the Board meeting.

RES. 97-061 The Board then reviewed correspondence and material regarding Epoetin Alfa. Following discussion, the Board directed staff to respond to the correspondence by reiterating Ohio law regarding generic equivalent drugs and the fact that decisions regarding whether or not products are generically equivalent are the dispensing pharmacist's. Such decisions must be made by the dispensing pharmacist based on information as to whether or not the drug products meet the legal definition of generically equivalent drug products and whether or not the federal Food and Drug Administration have listed the drugs as having proven bioequivalence problems.

1:00 p.m.

Cheryl Rooks, former Compliance Agent with the Board, joined the meeting and was presented with a plaque commemorating her fourteen years of service to Ohio's Citizens by President Neuber.

RES. 97-062 Following a review of the proposal by the Central Ohio Society of Health-System Pharmacists for documenting successful participation in continuing pharmacy education programs by their members, the Board directed staff to inform the organization that the proposal is acceptable to the Board and does not present any problems.

RES. 97-063 The Board then reviewed the United States Pharmacopeia Practitioner's Medication Errors Program material received September 19, 1996. Following discussion, Mr. Lamping moved that the Ohio Board participate in the program as soon as possible. Mr. Littlejohn seconded the motion and it was approved (Aye-5/Nay-1).

RES. 97-064 Tim Benedict submitted the following request for a waiver pursuant to paragraph (A) of Ohio Administrative Code Rule 4729-5-11:

Albert Croft, R.Ph. (03-2-11305)
-- Penn-Ohio Drugs, Inc. (02-0091750)
-- Eastern Ohio Medical Equipment Company (02-0967300)

Following discussion, Mr Lamping moved that R.Ph. Albert Croft (03-2-11305) be granted the waiver until January 31, 1997. The motion was seconded by Mr. Hanna and approved (Aye-6/Nay-0).

2:50 p.m. The Board recessed until Thursday, October 24, 1996, at 8:00 a.m.

THURSDAY, OCTOBER 24, 1996

8:25 a.m. ROLL CALL

The following members of the State Board of Pharmacy reconvened in Room 1914, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio:

Suzanne L. Neuber, R.Ph. (President); Amonte B. Littlejohn, R.Ph.; (Vice-President); Diane Adelman, R.Ph.; John Hanna, R.Ph.; Paul Lamping, R.Ph.; and Nicholas Repke, Public Member.

Mrs Adelman moved that the Minutes of the September 16, 17, 18, 19, 1996 meeting be approved as amended. The motion was seconded by Mr. Lamping and approved (Aye-5/Nay-0).

RES. 97-065 Following a report by staff on the enactment of the "Comprehensive Methamphetamine Control Act of 1996" by Congress on September 29, 1996, Mr. Lamping moved that the Board rescind Resolution 97-020 adopted by the Board during its September meeting since the Compliance Bulletin is no longer valid regarding pseudoephedrine regulations adopted by the United States Department of Justice. Mr. Hanna seconded the motion and it was approved (Aye-5/Nay-0).

8:40 a.m.

The Board was joined by Assistant Attorney General Mary Hollern for the purpose of conducting an adjudication hearing pursuant to the provisions of Ohio Revised Code Chapters 119. and 4729. in the matter of R.Ph. John Joseph Johnson, Portsmouth, Ohio.

10:45 a.m.

The hearing was concluded and the Board recessed for five minutes.

10:50 a.m.

The meeting was reconvened and Mr. Hanna moved that the Board go into Executive Session for the purpose of deliberating on the evidence and testimony received in the hearings of R.Ph. Cheryl Hutchins and R.Ph. John Joseph Johnson. The motion was seconded by Mr. Lamping and a roll call vote was conducted by President Neuber as follows: Adelman-Yes, Hanna-Yes, Lamping-Yes, Littlejohn-Yes, and Repke-Yes.

12:00 p.m.

RES. 97-066 The Executive Session was concluded and the meeting opened to the public. Mr.Repke moved that the Board adopt the following Order:

ORDER OF THE STATE BOARD OF PHARMACY
(Docket No. D-950126-034)

In The Matter Of:

JOHN JOSEPH JOHNSON, R.Ph.
3120 Richards Road
Portsmouth, Ohio 45622
(R.Ph. No. 03-2-17934)

INTRODUCTION

THE MATTER OF JOHN JOSEPH JOHNSON CAME TO HEARING ON OCTOBER 24, 1996, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: SUZANNE L. NEUBER, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; JOHN L. HANNA, R.Ph.; PAUL F. LAMPING, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; AND NICHOLAS R. REPKE, PUBLIC MEMBER.

JOHN JOSEPH JOHNSON WAS REPRESENTED BY ROGER CLARK, AND THE STATE OF OHIO WAS REPRESENTED BY MARY L. HOLLERN, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) Joseph Holliday, Ohio State Board of Pharmacy
- (2) Vince Mullenax, Rite-Aid Corporation
- (3) John Joseph Johnson, Respondent

Respondent's Witnesses:

- (1) Keith Hiles, Southern Ohio Medical Center
- (2) Michael Joseph Puccini, Kroger Company
- (3) John Joseph Johnson, Respondent

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Summary Suspension Order/Notice of Opportunity for Hearing letter dated January 26, 1995.
- (2) Exhibit 1A--Addendum Notice dated May 16, 1995.
- (3) Exhibit 1B--Hearing Request letter dated February 15, 1995.
- (4) Exhibit 1C--Hearing Schedule letter dated February 17, 1995.
- (5) Exhibit 1D--Pharmacist File Front Sheet of John Joseph Johnson showing registration date as July 27, 1989; and Renewal Application for Pharmacist License, No. 03-2-17934,

for a license to practice pharmacy in Ohio from September 15, 1994, to September 15, 1995, of John Joseph Johnson dated June 25, 1994.

- (6)
- (7) Exhibit 1F--Hearing Schedule letter dated June 27, 1995.
- (8) Exhibit 1G--Hearing Schedule letter dated June 28, 1995.
- (9) Exhibit 1H--Hearing Schedule letter dated July 11, 1995.
- (10)
- (11) Exhibit 1J--Hearing Schedule letter dated November 1, 1995.
- (12) Exhibit 1K--Hearing Schedule letter dated November 8, 1995.
- (13)
- (14) Exhibit 1M – Hearing Schedule letter dated March 19, 1996.
- (15)
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- (41)
- (42) Exhibit 10 – Letter from Jason Lovins dated February 19, 1996
- (43)
- (44)
- (45)

Respondent's Exhibits:

- (1)
- (2)
- (3)
- (4)
- (5)
- (6)
- (7)
- (8) Exhibit H – Letter from Jason Lovins dated October 2, 1996
- (9) Exhibit J – Copy of letter from Robert El Lea dated May 19, 1995.
- (10)
- (11)

FINDINGS OF FACT

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

- (1) Records of the Board indicate that John Joseph Johnson was originally licensed to practice pharmacy in the state of Ohio on July 27, 1989, pursuant to examination; and, on May 16, 1995, John Joseph Johnson's license was summarily suspended in accordance with Section 3719.121(B) of the Ohio Revised Code.
- (2)
- (3)
- (4)
- (5)

CONCLUSIONS OF LAW

- (1)
- (2)
- (3)

ACTION OF THE BOARD

Pursuant to Section 3719.121 of the Ohio Revised Code, the State Board of Pharmacy hereby removes the Summary Suspension Order issued January 26, 1995.

Pursuant to Section 4729.16 of the Ohio Revised Code, the State Board of Pharmacy takes the following actions in the matter of John Joseph Johnson:

- (A) On the basis of the Findings of Fact and paragraph (1) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes the pharmacist identification card, No. 03-2-17934, held by John Joseph Johnson effective as of the date of the mailing of this Order.
- (B) On the basis of the Findings of Fact and paragraph (2) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes the pharmacist identification card, No. 03-2-17934, held by John Joseph Johnson effective as of the date of the mailing of this Order.
- (C) On the basis of the Findings of Fact and paragraph (3) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes the pharmacist identification card, No. 03-2-17934, held by John Joseph Johnson effective as of the date of the mailing of this Order.

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

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

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mr. Littlejohn and approved by the Board (Aye-5/Nay-0).

RES. 97-067 Mr. Hanna moved that the Board adopt the following Order:

ORDER OF THE STATE BOARD OF PHARMACY
(Docket No. D-960927-017)

In The Matter Of:

CHERYL HUTCHINS, R.Ph.
4494 Colerain Avenue
Cincinnati, Ohio 45223
(R.Ph. No. 03-2-16453)

INTRODUCTION

THE MATTER OF CHERYL HUTCHINS CAME TO HEARING ON OCTOBER 23, 1996, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: SUZANNE L. NEUBER, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; JOHN L. HANNA, R.Ph.; PAUL F. LAMPING, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; AND NICHOLAS R. REPKE, PUBLIC MEMBER.

CHERYL HUTCHINS WAS NOT REPRESENTED BY COUNSEL, AND THE STATE OF OHIO WAS REPRESENTED BY MARY L. HOLLERN, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) Christopher K. Reed, Ohio State Board of Pharmacy
 - (2) Cheryl Hutchins, Respondent
- Respondent's Witnesses:

- (1) Cheryl Hutchins, Respondent

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Proposal to Deny/Notice of Opportunity for Hearing letter dated September 27, 1996.
- (2) Exhibit 1A--Hearing Request letter, not dated, received in the Board office on October 7, 1996.
- (3) Exhibit 1B--Hearing Schedule letter dated October 10, 1996.
- (4) Exhibit 1C--Pharmacist File Front Sheet of Cheryl Ann Cherry Hutchins showing original date of registration as August 6, 1986.
- (5) Exhibit 2--Four-page Order of the State Board of Pharmacy, Docket No. D-890920-046, in the matter of Cheryl Hutchins dated March 19, 1990.
- (6) Exhibit 3--Renewal Application for Pharmacist License, No. 03-2-16453, for a license to practice pharmacy in Ohio from September 15, 1995, to September 15, 1996, not dated; Continuing Pharmacy Education Report form of Cheryl Hutchins dated July 26, 1996; and eighteen certificates of continuing pharmaceutical education participation of Cheryl Hutchins numbered and dated as follows: 057-999-95-056-H01 dated February 5, 1996; 680-057-95-026 dated December 29, 1995; 680-057-95-039 dated February 5, 1996; 057-999-95-048-H01 dated February 5, 1996; 679702-94-018 dated June 17, 1996; 679702-94-017 dated July 4, 1996; 679-702-94-012 dated July 6, 1996; 679702-93-010 dated July 13, 1996; 057-999-96-042-H01 dated July 22, 1996; 057-999-96-029-H04 dated July 22, 1996; 057-999-96-002-H01 dated July 22, 1996; 057-999-96-028-H04 dated June 14, 1996; 057-999-96-022-H01 dated June 14, 1996; 057-999-96-003-H01 dated June 3, 1996; 057-999-96-008-H01 dated June 3, 1996; 057-999-96-007-H01 dated June 3, 1996; 057-999-96-040-H01 dated July 22, 1996; and 057-999-96-021 dated July 3, 1996.
- (7) Exhibit 4--Handwritten statement of Marilyn Cherry signed and notarized on December 27, 1990.
- (8) Exhibit 5--Two-page letter from Marilyn Cherry signed and notarized on March 14, 1991.
- (9) Exhibit 6--Copy of letter from Cheryl C. Hutchins, not dated, received April 24, 1990.

- (10) Exhibit 7--Copy of Staff Identification Card from the Central Community Health Board of Hamilton County, Inc. of Cheryl A. C. Hutchins issued May 31, 1989.
- (11) Exhibit 8--Certified copy of Report of Probation Violation in the Hamilton County Court of Common Pleas, Case No. B-871647, of Cheryl Hutchins dated April 29, 1991.
- (12) Exhibit 9--Certified copy of Judgment Entry Revoking Probation and Ordering Execution of Sentence in the Hamilton County Court of Common Pleas, Case No. B-871647, of Cheryl A. Hutchins dated May 17, 1991.
- (13) Exhibit 10--Unpaid Check No. 255 of Cheryl Hutchins dated April 13, 1993.
- (14) Exhibit 11--Inter-Office Communication from Pat Humes, Cashier Department, Treasurer of State's Office, dated April 30, 1993.
- (15) Exhibit 12--Letter from Karen E. Prather dated May 4, 1993.
- (16) Exhibit 13--Copies of twenty-four Time-Sheets of Central Community Health Board Drug Services dated as follows: March 22, 1990; March 23, 24, 25, 1990; March 23, 1990; March 26, 1990; March 27, 1990; March 28, 1990; March 29, 1990; March 30, 31, 1990, and April 1, 1990; April 2, 1990; April 3, 1990; April 4, 1990; April 5, 1990; two dated April 6, 7, 8, 1990; April 9, 1990; April 10, 1990; April 11, 1990; April 12, 1990; April 13, 14, 15, 1990; April 16, 1990; April 17, 1990; April 18, 1990; April 19, 1990; and April 20, 1990.

Respondent's Exhibits:

- (1) Exhibit A--Eight-page fax copy consisting of the following: two-page letter from Cheryl Hutchins; customer receipt No. 65270164860 of Cheryl Hutchins dated October 24, 1996; three-page Hamilton County Clerk of Court, Case Cost Statement and Docket Entries of Cheryl A. Hutchins dated from May 6, 1987, through January 31, 1995; Certificate of Parole/Release Authorization from the Adult Parole Authority, Columbus, Ohio regarding Cheryl A. Hutchins dated November 6, 1991; and Final Release from Parole Supervision of Cheryl Hutchins, effective December 30, 1992.

FINDINGS OF FACT

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

- (1) Records of the Board indicate that Cheryl Hutchins was originally licensed in the state of Ohio on August 6, 1986, pursuant to examination, and Ms. Hutchins' license to practice pharmacy in the state of Ohio was suspended by the Board on March 19, 1990, for a period of 72 months. Cheryl Hutchins applied for renewal upon termination of her suspension on or about August 5, 1996.
- (2) 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 her suspension from the practice of pharmacy, Cheryl Hutchins 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.
- (3) Cheryl Hutchins' court-ordered probation was revoked on or about April 29, 1991, and Ms. Hutchins' 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, Cheryl Hutchins was employed as a pharmacist when ordered by the court to not practice pharmacy.
- (4) 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 Ms. Hutchins 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 Cheryl Hutchins' home requesting payment went unclaimed by her.

CONCLUSIONS OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (4) of the Findings of Fact constitute not being of good moral character and habits as provided in paragraph (C) of Rule 4729-5-04 of the Ohio Administrative Code.
- (2) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (1) of the Findings of Fact constitutes having been disciplined by the Ohio State Board of Pharmacy pursuant to Section 4729.16 of the Revised Code as provided in paragraph (E) of Rule 4729-5-04 of the Ohio Administrative Code.
- (3) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) and (4) of the Findings of Fact constitute being guilty of dishonesty and unprofessional conduct in the practice of pharmacy as provided in Division (A)(2) of Section 4729.16 of the Ohio Revised Code.
- (4) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (2) 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 4729. of the Revised Code as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.

ACTION OF THE BOARD

Pursuant to Section 4729.12 of the Ohio Revised Code, and on the basis of the Findings of Fact and paragraphs (1) and (2) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby denies the issuance of an identification card to practice pharmacy in the state of Ohio and thereby denies the renewal application of Cheryl Hutchins.

Pursuant to Section 4729.16 of the Ohio Revised Code, the State Board of Pharmacy takes the following actions in the matter of Cheryl Hutchins:

- (A) On the basis of the Findings of Fact and paragraph (3) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes the pharmacist identification card, No. 03-2-16453, held by Cheryl Hutchins effective as of the date of the mailing of this Order.
- (B) On the basis of the Findings of Fact and paragraph (4) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes the pharmacist identification card, No. 03-2-16453, held by Cheryl Hutchins effective as of the date of the mailing of this Order.

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

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

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mr. Lamping and approved by the Board (Aye-5/Nay-0).

12:10 p.m.

The Board recessed for lunch.

1:25 p.m.

RES. 97-068 The Board reconvened in Room 1914 with Mr. Maslak present. Mr. Lamping moved that Board Policy 93-031 be revised as follows:

DESTRUCTION BY PHARMACIST AND NON-LICENSED EMPLOYEE
IN AN INSTITUTIONAL FACILITY SETTING

Pursuant to this policy, the Executive Director of the Board of Pharmacy may grant permission to a terminal distributor of dangerous drugs licensed as an institutional facility pharmacy the authority to destroy controlled substances which are expired, returned to the pharmacy, or unusable. This permission will allow a pharmacist and a non-licensed pharmacy employee to destroy the controlled substances. This permission will be granted only if the following conditions are met:

- (1) The responsible pharmacist for the institutional facility must submit, in writing, to the Executive Director the names and registration numbers of all the pharmacists employed at this facility who will be authorized by the responsible pharmacist to destroy drugs.
- (2) The responsible pharmacist for the institutional facility pharmacy must submit, in writing, to the Executive Director the names, dates of birth, and social security numbers of all non-licensed pharmacy employees who will be involved in the destruction of controlled substances with a licensed pharmacist.
- (3) The office staff will verify that the pharmacists are in good standing with the Board.
- (4) The responsible pharmacist will have criminal background checks completed by the Bureau of Criminal Identification and Investigation (BCI&I) on all non-licensed employees included in the initial request for authorization to destroy drugs with a licensed pharmacist.
- (5) If all employee checks are negative and in the opinion of the Executive Director the facility warrants this authorization, he may grant the approval for a pharmacist and non-licensed pharmacy employee to destroy controlled substances in each other's presence.
- (6) The Executive Director will include with the authorization letter "Controlled Substance Destruction Statement of Understanding" forms which all non-licensed pharmacy employees who are authorized to destroy controlled substances in the presence of a pharmacist must sign. The authorization shall be in effect for one year only and a criminal background check shall be done annually for those non-licensed pharmacy employees included in such request. The report regarding an employee's criminal background check shall be maintained in the pharmacy with a copy of the request letter; the signed "Controlled Substance Destruction Statement of Understanding" forms; and the letter of approval issued by the Executive Director of the Board. Initial criminal background screenings must be with BCI&I while subsequent record checks may be with local law enforcement agencies.



**CONTROLLED SUBSTANCE DESTRUCTION
STATEMENT OF UNDERSTANDING**

The Pharmacy has responsibility for the safe and appropriate use of controlled substances within this facility. This has always been a fundamental responsibility of the Pharmacy. This document is intended to ensure that each individual involved with controlled substances destruction understands his/her responsibilities associated with this activity. It does not represent any additional requirements or liability above that which is currently in place.

Ohio Revised Code Section 2925.23 states:

“No person shall knowingly make a false statement in any prescription order, report, or record required by Chapter 3719. of the Revised Code” (controlled substances chapter).

Violations of the above will be reported to the appropriate law enforcement agency.

This means that anyone found guilty of making a false statement on a prescription, report, or record dealing with a controlled substance is guilty of up to a third degree felony. The penalty for conviction of a third degree felony may include fines and/or imprisonment. In addition, pharmacists may be fined and/or have their pharmacist licenses suspended or revoked through administrative procedures by the Ohio Board of Pharmacy.

I understand the above statement with regard to my participation in controlled substances destruction and, in addition, I realize the above section applies to all controlled substance activities in the Pharmacy. I understand that, at any time, I shall contact the immediate supervisor of the area in which I work, the responsible pharmacist, or the director of pharmacy services to report any problems associated with controlled substances.

_____ <i>Signature</i>	_____ <i>Date</i>
_____ <i>Witness</i>	_____ <i>Date</i>

Mr. Repke seconded the motion and it was approved (Aye-6/Nay-0).

RES. 97-069 The Board then considered proposed amended and new rules. Mrs. Adelman moved that the Board propose to adopt amended rule 4729-5-01 as follows:

4729-5-01 Definitions.

As used in Chapter 4729. of the Revised Code:

- (A) To "practice pharmacy" is as defined in division (B) of section 4729.02 of the Revised Code.
- (B) The term "dispense" means the final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a practitioner and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug.
- (C) "Compound" means the professional judgment of a pharmacist associated with the measuring and mixing of one or more drugs, and also includes the reconstitution of a drug by the measuring and mixing of a diluent, pursuant to a prescription.
- (D) "Interpret prescriptions" means the professional judgment of a pharmacist when reviewing a prescription order of a practitioner for a patient.
- (E) "To participate in drug selection" means selecting and dispensing a drug product pursuant to sections 4729.38 and 4729.381 of the Revised Code.
- (F) "To participate with practitioners in reviews of drug utilization" means monitoring the appropriate use of drugs through communication with the practitioner(s) involved.
- (G) "Pharmacist" means an individual who holds a current pharmacist identification card pursuant to section 4729.08 or 4729.09 of the Revised Code; or, pursuant to section 4729.12 of the Revised Code and, where applicable, has met the continuing

pharmacy education requirements in accordance with Chapter 4729-7 of the Administrative Code.

- (H) "Original prescription" means the prescription issued by the practitioner in writing, ~~or~~ an oral OR ELECTRONICALLY TRANSMITTED prescription recorded in writing by the pharmacist, or a prescription transmitted by use of a facsimile machine, each of which is pursuant to rule 4729-5-30 of the Administrative Code.
- (I) "Personal supervision" means a pharmacist shall be physically present in the pharmacy and provide personal review and approval of all professional pharmaceutical activities.
- (J) "Preprinted order" is defined as a patient-specific, definitive set of drug treatment directives to be administered to an individual patient who has been examined by a practitioner and for whom the practitioner has determined that the drug therapy is appropriate and safe when used pursuant to the conditions set forth in the preprinted order. Preprinted orders may be used only for inpatients in an institutional ~~or health care~~ facility as defined in Chapter 4729-17 of the Administrative Code.
- (K) "Standing order" will mean the same as the term "protocol".
- (L) "Protocol" is defined as:
 - (1) A definitive set of treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a practitioner as defined in rule 4729-5-15 of the Administrative Code and have been approved by the board of pharmacy to be used by certified or licensed health care professionals when providing limited medical services to individuals in an emergency situation when the services of a practitioner are not immediately available; or
 - (2) A definitive set of treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a practitioner as defined in rule 4729-5-15 of the Administrative Code and have been approved by the board of pharmacy to be used by certified or licensed health care professionals when administering biologicals or vaccines to individuals for the purpose of preventing diseases.

A protocol may be used only by licensed or certified individuals acting within the scope of their license or certification who have been adequately trained in the safe administration and use of the drugs and other procedures included in the protocol.

Protocols submitted for approval by the board of pharmacy may be reviewed with the medical and/or nursing board, as appropriate, prior to any approval by the board of pharmacy.

- (M) "Prescriber" means any person authorized by the Revised Code to prescribe dangerous drugs as part of their professional practice.
- (N) "Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug. Such method may include a password access to a mechanical or automated system, but must also include a physical means of identification such as, but not limited to, the following:
 - (1) A manual signature on a hard-copy record;
 - (2) A magnetic card reader;
 - (3) A bar code reader;
 - (4) A thumbprint reader or other biometric method; or
 - (5) A daily printout of every transaction that is verified and manually signed within twenty-four hours by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for

three years and made available on request to those individuals authorized by law to review such records.

- (O) "CERTIFIED DIABETIC EDUCATOR", AS USED IN CHAPTERS 3719. AND 4729. OF THE REVISED CODE, MEANS A PERSON WHO HAS BEEN CERTIFIED TO CONDUCT DIABETES EDUCATION BY THE "NATIONAL CERTIFICATION BOARD FOR DIABETES EDUCATORS (NCBDE)".

The motion was seconded by Mr. Lamping and approved (Aye-6/Nay-0).

RES. 97-070 Mr. Lamping then moved that the Board propose to adopt the following proposed new rules setting forth the requirements for the legal distribution of peritoneal dialysis solutions:

4729-27-01 DEFINITIONS.

FOR THE PURPOSE OF CHAPTER 4729. OF THE REVISED CODE, THE TERM "PERITONEAL DIALYSIS SOLUTIONS" SHALL MEAN THE COMMERCIALY 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.

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.

(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.

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.

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.

The motion was seconded by Mr. Hanna and approved (Aye-6/Nay-0).

RES. 97-071 Mr. Littlejohn moved that all the changes the Board has approved be proposed for adoption by the Board and filed with the required agencies as follows with a public hearing date of December 3, 1996:

4729-1-02 Notice of meetings.

Any person may determine 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 ~~fifteen-dollar~~ 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.

4729-3-01 Definitions.

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

- (A) "Pharmacy internship" means the supervised practical experience required for licensure as a registered pharmacist. The purpose of the pharmacy internship program is to provide those individuals, who intend to become registered pharmacists, with the knowledge and practical experience necessary for functioning competently and effectively upon licensure.
- (B) "Supervised practical experience" is the experience obtained ~~in a training~~ AT AN INTERNSHIP site and which is conducted in accordance with the "National Association of Boards of Pharmacy - American Association of Colleges of Pharmacy" publication "The Internship Experience," or a similar outline and/or manual approved by the board of pharmacy.
- (C) "~~Training~~ 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 ~~(E)~~ (C) OR (D) of rule 4729-3-05 of the Administrative Code, and whose license is in good standing.
- (D) "Preceptor" is the individual responsible for seeing that the intern is properly supervised and exposed to all aspects of the ~~training~~ INTERNSHIP program defined as the supervised practical experience.
 - (1) A "preceptor" is a pharmacist who holds a current identification card which is in good standing; or, is a person who is of good moral character and is qualified to direct the approved experience in the area approved by the director of internship pursuant to ~~paragraph (E) of~~ paragraph (E) of rule 4729-3-05 of the Administrative Code.

- (2) A PERSON MAY SERVE AS THE preceptor ~~may be responsible for the training of~~ more than one intern. The number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty.
 - (3) A preceptor must report to the board on the progress and aptitude of an intern when requested by the director of internship.
- (E) "Director of internship" has the same meaning as provided in section 4729.11 of the Revised Code.
- (F) "In good standing" means that the licensee or registrant has not been denied the privilege of ~~training~~ SUPERVISING interns by the board.
- (G) "Statement of Preceptor" is the form which must be ~~filed with~~ RECEIVED BY the board of pharmacy ~~by~~ FOR each pharmacy intern within thirty days of beginning ~~training~~ INTERNSHIP under a preceptor's supervision.
- (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 ~~training~~ INTERNSHIP sites and/or preceptors.
- (H) "Practical experience affidavit" is the form which must be used to submit practical experience for internship credit.
- (1) Practical experience must be itemized TO THE NEAREST HALF HOUR on the affidavit by the total number of hours obtained each week. 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 ~~filed~~ RECEIVED IN THE BOARD OFFICE OR POSTMARKED no later than the first day of March of the following year.

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

- (A) Every person desiring to register as a pharmacy intern shall ~~complete an application as provided by~~ SUBMIT THE FOLLOWING TO the state board of pharmacy ~~and in addition thereto shall cause to be forwarded to the state board of pharmacy the following:~~
- (1) A COMPLETED APPLICATION FORM AS PROVIDED BY THE BOARD;

- (1) ~~(2)~~ A three- by four-inch head and shoulders photograph taken within the previous six months;
- ~~(2)~~ ~~(3)~~ Fee;
- ~~(3)~~ ~~(4)~~ A transcript certifying that the applicant has in fact successfully completed a minimum of forty-eight semester or seventy-two quarter hours of college work; and
- ~~(4)~~ ~~(5)~~ A certificate of acceptance into a school or college of pharmacy or a department of pharmacy of a university recognized and approved by the state board of pharmacy.

or

- ~~(5)~~ ~~(6)~~ **Both** ALL items listed in paragraphs (A)(1) ~~and (A)(2)~~ TO ~~(A)(3)~~ of this rule and certification of having obtained a first professional degree in pharmacy from a program which has been recognized and approved by the state board of pharmacy; or 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 equivalent.
- (B) The state board of pharmacy may register an applicant as a pharmacy intern as soon as the state board of pharmacy receives a ~~completed application and~~ ALL the required items set forth in paragraphs (A)(1) to ~~(A)(4)~~ (A)(5) or paragraph ~~(A)(5)~~ (A)(6) of this rule.
- (C) The state board of pharmacy may, pursuant to rule 4729-5-04 of the Administrative Code, deny the issuance of a certificate of registration or an identification card to practice as a pharmacy intern.

4729-3-04 Pharmacy intern identification card renewal.

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

- (A) An intern shall be considered to be actively working towards licensure as a pharmacist if he/she has complied with all of the statutes and rules regarding internship since registration as a pharmacy intern, and:
 - (1) He/she is enrolled in a college of pharmacy or ~~has not been absent from the college of pharmacy for more than two consecutive semesters or three consecutive quarters and~~ is able to provide evidence that he/she has been, or will be, accepted for enrollment or re-enrollment in a college of pharmacy; or
 - (2) He/she is a member of the armed forces and can provide evidence that he/she has been, or will be, accepted for enrollment OR RE-ENROLLMENT in a college of pharmacy upon his/her release from the armed forces; or
 - (3) He/she ~~has already obtained~~ IS ABLE TO PROVIDE EVIDENCE OF OBTAINING a first professional degree in pharmacy from a school or

college of pharmacy or a department of pharmacy of a university recognized and approved by the state board of pharmacy; or

(4) He/she ~~has already obtained~~ IS ABLE TO PROVIDE EVIDENCE OF OBTAINING a Foreign Pharmacy Graduate Examination Commission (FPGEC) certificate, and ~~has provided~~ CAN PROVIDE evidence of successful completion of the Test of Spoken English (TSE) or its equivalent.

(B) An intern who has obtained a first professional degree in pharmacy from a school or college of pharmacy or a department of pharmacy of a university recognized and approved by the state board 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.

(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)~~ A maximum of fifty hours per week of internship credit may be granted for practical experience obtained at training sites and in accordance with Chapter 4729. of the Revised Code and Chapter 4729-3 of the Administrative Code.

~~(C)~~ (B) Internship credit may be granted for practical experience obtained when the intern is registered and attending classes in the academic program of a school of pharmacy, other than the structured academic program as provided for in paragraph ~~(D)~~ (C) of this rule.

~~(D)~~ (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. A school or college of pharmacy which desires to conduct such structured programs eligible for approval shall make a written request on forms provided by the board.

~~(E)~~ (D) Up to ~~three~~ 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.

~~(F)~~ (E) 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.

~~(G)~~ (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 super-

vised practical experience and such affidavits have been accepted by the board of pharmacy.

4729-5-01 Definitions.

As used in Chapter 4729. of the Revised Code:

- (A) To "practice pharmacy" is as defined in division (B) of section 4729.02 of the Revised Code.
- (B) The term "dispense" means the final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a practitioner and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug.
- (C) "Compound" means the professional judgment of a pharmacist associated with the measuring and mixing of one or more drugs, and also includes the reconstitution of a drug by the measuring and mixing of a diluent, pursuant to a prescription.
- (D) "Interpret prescriptions" means the professional judgment of a pharmacist when reviewing a prescription order of a practitioner for a patient.
- (E) "To participate in drug selection" means selecting and dispensing a drug product pursuant to sections 4729.38 and 4729.381 of the Revised Code.
- (F) "To participate with practitioners in reviews of drug utilization" means monitoring the appropriate use of drugs through communication with the practitioner(s) involved.
- (G) "Pharmacist" means an individual who holds a current pharmacist identification card pursuant to section 4729.08 or 4729.09 of the Revised Code; or, pursuant to section 4729.12 of the Revised Code and, where applicable, has met the continuing pharmacy education requirements in accordance with Chapter 4729-7 of the Administrative Code.
- (H) "Original prescription" means the prescription issued by the practitioner in writing, ~~or~~ an oral OR ELECTRONICALLY TRANSMITTED prescription recorded in writing by the pharmacist, or a prescription transmitted by use of a facsimile machine, each of which is pursuant to rule 4729-5-30 of the Administrative Code.
- (I) "Personal supervision" means a pharmacist shall be physically present in the pharmacy and provide personal review and approval of all professional pharmaceutical activities.
- (J) "Preprinted order" is defined as a patient-specific, definitive set of drug treatment directives to be administered to an individual patient who has been examined by a practitioner and for whom the practitioner has determined that the drug therapy is appropriate and safe when used pursuant to the conditions set forth in the preprinted order. Preprinted orders may be used only for inpatients in an institutional ~~or health care~~ facility as defined in Chapter 4729-17 of the Administrative Code.
- (K) "Standing order" will mean the same as the term "protocol".
- (L) "Protocol" is defined as:
 - (1) A definitive set of treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a practitioner as defined in rule 4729-5-15 of the Administrative Code and have been approved by the board of pharmacy to be used by certified or licensed health care professionals when providing limited medical services to individuals in an emergency situation when the services of a practitioner are not immediately available; or

- (2) A definitive set of treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a practitioner as defined in rule 4729-5-15 of the Administrative Code and have been approved by the board of pharmacy to be used by certified or licensed health care professionals when administering biologicals or vaccines to individuals for the purpose of preventing diseases.

A protocol may be used only by licensed or certified individuals acting within the scope of their license or certification who have been adequately trained in the safe administration and use of the drugs and other procedures included in the protocol.

Protocols submitted for approval by the board of pharmacy may be reviewed with the medical and/or nursing board, as appropriate, prior to any approval by the board of pharmacy.

- (M) "Prescriber" means any person authorized by the Revised Code to prescribe dangerous drugs as part of their professional practice.
- (N) "Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug. Such method may include a password access to a mechanical or automated system, but must also include a physical means of identification such as, but not limited to, the following:
 - (1) A manual signature on a hard-copy record;
 - (2) A magnetic card reader;
 - (3) A bar code reader;
 - (4) A thumbprint reader or other biometric method; or
 - (5) A daily printout of every transaction that is verified and manually signed within twenty-four hours by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records.
- (O) "CERTIFIED DIABETIC EDUCATOR", AS USED IN CHAPTERS 3719. AND 4729. OF THE REVISED CODE, MEANS A PERSON WHO HAS BEEN CERTIFIED TO CONDUCT DIABETES EDUCATION BY THE "NATIONAL CERTIFICATION BOARD FOR DIABETES EDUCATORS (NCBDE)".

4729-5-07 Recognized and approved colleges of pharmacy.

- (A) To be recognized and approved by the state board of pharmacy, a school or college of pharmacy or a department of pharmacy of a university 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".
- (B) For the purpose of satisfying the requirements of division (C) of section 4729.08 of the Revised Code, graduates of a school or college of pharmacy or a department of pharmacy of a university 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 a THE score of two hundred thirty or higher REQUIRED BY RULE 4729-5-34 OF THE ADMINISTRATIVE CODE on the "Test of Spoken English (TSE)".
- (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.

4729-5-17 Recordkeeping.

Rule to be rescinded. (See proposed new rules 4729-5-27, 4729-5-28, and 4729-5-29)

4729-5-19 Serial numbering of prescriptions.

All outpatient prescriptions dispensed by a pharmacy must be serially numbered.

- (A) This number must appear on the original prescription. If an alternate recordkeeping system is being used pursuant to ~~rule 4729-5-17~~ RULES 4729-5-27 AND 4729-5-28 of the Administrative Code, the serial number must also appear on the records in this alternate system.
- (B) There must be a complete and consecutive 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 practitioner to continue the medication, except:
 - (1) The prescribing practitioner may authorize additional refills of a schedule III or IV controlled substance through an oral refill authorization transmitted to a pharmacist, provided the additional refills do not exceed five refills of the original prescription nor does any refill occur beyond six months from the date of issuance of the original prescription; or
 - (2) The prescribing practitioner may authorize additional refills of a schedule V controlled substance or a non-controlled drug through an oral refill authorization transmitted to a pharmacist provided that no refill may occur beyond one year from the date of issuance of the original prescription.
 - (3) All additional refills authorized by the prescribing practitioner shall be marked on the original prescription listing authorizing agent, date, number of refills authorized, and pharmacist receiving the authorization. If an alternative recordkeeping system is used, this information must also be maintained in that system.
- (D) ~~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:~~
 - (1) ~~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.~~
 - (2) ~~The partial dispensing of a schedule II prescription can only occur at the pharmacy where the original prescription is on file.~~
 - (3) ~~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.~~
 - (4) ~~If an alternate recordkeeping system utilizing an automated data processing system is 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.~~
 - (a) ~~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.~~

- (b) ~~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.~~
- (5) ~~The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed.~~
- (6) ~~All partial dispensings of schedule II controlled substances must occur within sixty days from the date of issuance of the prescription by the practitioner.~~

4729-5-24 Prescription copy.

- (A) A pharmacist may transfer a copy of a prescription; a pharmacist may refill a copy of a prescription; such actions must be in accordance with the following:
 - (1) Copies of prescriptions shall be transferred only between pharmacists; copies of prescriptions for controlled substances pursuant to sections 3719.41, 3719.43, and 3719.44 of the Revised Code shall be communicated directly between two pharmacists and shall be transferred only one time.
 - (2) The copy transferred shall be an exact duplicate of the original prescription except that it shall also include:
 - (a) Serial prescription number assigned to the prescription;
 - (b) Name and address (and "D.E.A." number for controlled substance prescriptions) of the pharmacy transferring the copy;
 - (c) Date of issuance of the prescription;
 - (d) Date of original dispensing of the prescription;
 - (e) Original number of refills;
 - (f) Date of last refill;
 - (g) Number of valid refills remaining; and
 - (h) The name of the transferring pharmacist.
 - (3) Copies transferred for non-refillable prescriptions shall be marked on the face of the prescription or orally noted by the transferring pharmacist "For Information Purposes Only" and are not valid prescriptions for the dispensing of drugs.
 - (4) The pharmacist transferring a copy of a prescription must:
 - (a) Cancel the original prescription by writing the word "void" on the face of the prescription;
 - (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) and name of the pharmacist at the receiving pharmacy.
 - (c) Except, if an automated data processing system is being used as an alternate system of recordkeeping for prescriptions

pursuant to ~~paragraph (E)(6) of rule 4729-5-17~~ RULES 4729-5-27 AND 4729-5-28 of the Administrative Code, copies of prescriptions may be transferred by a pharmacist if the prescription record in the system is invalidated to prevent further dispensing at the original site. The prescription record in the system must contain the date of transfer, name of pharmacist making transfer, and the name and address of the pharmacy receiving the copy. Also, original written prescriptions for controlled substances must be cancelled 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 cancelling 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.

4729-5-26 PARTIAL DISPENSING OF SCHEDULE II CONTROLLED SUBSTANCES.

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 SYSTEM UTILIZING AN AUTOMATED DATA PROCESSING SYSTEM IS 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 PRACTITIONER.

4729-5-27 RECORDKEEPING.

THE FOLLOWING RECORDKEEPING REQUIREMENTS DO NOT APPLY TO DRUGS DISPENSED PURSUANT TO AN INPATIENT PRESCRIPTION AS DEFINED IN RULE 4729-17-01 OF THE ADMINISTRATIVE CODE.

(A) 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 BOARD, ENTER HIS/HER POSITIVE IDENTIFICATION INTO THE COMPUTERIZED RECORDKEEPING SYSTEM AS REQUIRED IN RULE 4729-5-28 OF THE ADMINISTRATIVE CODE. IF AN ALTERNATE RECORDKEEPING SYSTEM IS BEING USED PURSUANT TO THIS RULE, THE RECORD OF DISPENSING THE ORIGINAL PRESCRIPTION MUST ALSO BE RECORDED IN THE RECORDKEEPING SYSTEM.

(B) WHEN A PHARMACIST DISPENSES A DRUG PURSUANT TO AN AUTHORIZED REFILL OF A PRESCRIPTION, HE/SHE MUST RECORD THE DATE OF SUCH DISPENSING AND MANUALLY RECORD HIS/HER NAME OR INITIALS ON THE ORIGINAL PRESCRIPTION OR ENTER SUCH INFORMATION ON AN ALTERNATE RECORD MEETING THE REQUIREMENTS OF THIS RULE. IF AN ALTERNATE RECORDKEEPING SYSTEM IS BEING USED PURSUANT TO THIS RULE, THIS ALTERNATE RECORD MUST BE USED TO RECORD THE DISPENSING OF ALL PRESCRIPTIONS.

(C) 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.

(D) RECORDS OF DISPENSING DRUGS MUST PROVIDE ACCOUNTABILITY AND ENSURE THAT PATIENTS DO NOT RECEIVE MORE DRUGS THAN INTENDED BY THE PRESCRIBER. ALL RECORDKEEPING SYSTEMS SHALL PROVIDE RECORDS WHICH ARE READILY RETRIEVABLE AND UNIFORMLY MAINTAINED FOR A PERIOD OF THREE YEARS FROM THE DATE OF THE LAST DISPENSING.

(E) IF AN ALTERNATE RECORDKEEPING SYSTEM IS BEING USED PURSUANT TO THIS RULE, SUCH RECORD SHALL INCLUDE AT A MINIMUM THE FOLLOWING DATA:

(1) THE SERIAL NUMBER ASSIGNED TO AND RECORDED ON THE ORIGINAL PRESCRIPTION PRESERVED ON FILE AT THE PHARMACY IN ACCORDANCE WITH SECTION 4729.37 OF THE REVISED CODE.

(2) NAME, STRENGTH, AND DOSAGE FORM OF THE DRUG DISPENSED.

(3) DATE OF DISPENSING (FILLING OR REFILLING).

- (4) QUANTITY DISPENSED. IF THE QUANTITY DISPENSED IS GREATER THAN THAT PRESCRIBED, THE PHARMACIST MUST RECORD THE DATE AND TIME THAT HE/SHE CONTACTED THE PRESCRIBER AND OBTAINED APPROVAL.
- (5) THE POSITIVE IDENTIFICATION OF THE DISPENSING PHARMACIST. IF THE PHARMACIST MERELY INITIALS AND DATES THE RECORD OF DISPENSING, HE/SHE SHALL BE DEEMED TO HAVE DISPENSED THE QUANTITY PRESCRIBED ON THE ORIGINAL PRESCRIPTION. ONLY THE PHARMACIST RESPONSIBLE FOR FILLING OR REFILLING THE PRESCRIPTION OR MEDICATION ORDER SHALL MAKE THIS RECORD.
- (F) ALL RECORDS OF DISPENSING DRUGS SHALL BE READILY AVAILABLE, AND PROMPTLY PRODUCED, UPON REQUEST FOR INSPECTION BY A BOARD OF PHARMACY OFFICER, AGENT, AND/OR INSPECTOR DURING REGULAR BUSINESS HOURS.
- (G) ALL PRESCRIPTIONS OR OTHER RECORDS OF DISPENSING, WHICH ARE REQUIRED TO BE KEPT FOR THREE YEARS ACCORDING TO SECTION 4729.37 OF THE REVISED CODE, MAY BE MICROFILMED OR PLACED ON ELECTRONIC, MAGNETIC MEDIA. THE MICROFILM OR ELECTRONIC, MAGNETIC MEDIA USED FOR THIS PURPOSE MUST COMPLY WITH THE "INTERNATIONAL STANDARDS ORGANIZATION" STANDARDS OF QUALITY APPROVED FOR PERMANENT RECORDS. SUCH RECORDS ARE SUBJECT TO ALL OTHER PARAGRAPHS OF THIS RULE.
- (H) ANY PHARMACY INTENDING TO MAINTAIN RECORDS OF DISPENSING AT A LOCATION OTHER THAN THE PLACE LICENSED WITH THE BOARD OF PHARMACY MUST FIRST SEND WRITTEN NOTIFICATION TO THE BOARD BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED. IF NOT CONTESTED WITHIN SIXTY DAYS OF RECEIPT BY THE BOARD OFFICE, SUCH REQUEST WILL STAND AS APPROVED.

4729-5-28 COMPUTERIZED RECORDKEEPING SYSTEMS.

IF A COMPUTERIZED RECORDKEEPING SYSTEM IS BEING USED AS AN ALTERNATE RECORDKEEPING SYSTEM PURSUANT TO RULE 4729-5-27 OF THE ADMINISTRATIVE CODE, THE FOLLOWING REQUIREMENTS MUST BE MET:

- (A) THE SYSTEM MUST BE CAPABLE OF PROVIDING IMMEDIATE RETRIEVAL (VIA CRT DISPLAY AND HARD-COPY PRINTOUT OR OTHER MUTUALLY AGREEABLE TRANSFER MEDIUM) OF PATIENT PROFILE INFORMATION FOR ALL PRESCRIPTIONS FILLED WITHIN THE PREVIOUS TWELVE MONTHS AND RETRIEVAL WITHIN THREE WORKING DAYS, EXCLUDING WEEKENDS AND HOLIDAYS, OF ALL PRESCRIPTIONS DISPENSED WITHIN THE PREVIOUS THIRTY-SIX MONTHS. THIS INFORMATION SHALL INCLUDE AT LEAST, BUT IS NOT LIMITED TO, THE FOLLOWING DATA:
 - (1) THE ORIGINAL PRESCRIPTION NUMBER;
 - (2) DATE OF ISSUANCE OF THE ORIGINAL PRESCRIPTION ORDER BY THE PRACTITIONER;
 - (3) DATE OF DISPENSING BY THE PHARMACIST;
 - (4) FULL NAME AND ADDRESS OF THE PATIENT;
 - (5) FULL NAME AND ADDRESS OF THE PRACTITIONER;
 - (6) DIRECTIONS FOR USE;
 - (7) THE NAME, STRENGTH, DOSAGE FORM, AND QUANTITY OF THE DRUG PRESCRIBED;
 - (8) THE QUANTITY DISPENSED IF DIFFERENT FROM THE QUANTITY PRESCRIBED;
 - (9) POSITIVE IDENTIFICATION OF THE DISPENSING PHARMACIST;
 - (10) THE TOTAL NUMBER OF REFILLS AUTHORIZED BY THE PRESCRIBER;

(1) THE REFILL HISTORY OF THE PRESCRIPTION AS DEFINED IN PARAGRAPH (B) OF THIS RULE.

(B) THE REFILL HISTORY OF THE PRESCRIPTION MUST INCLUDE, BUT IS NOT LIMITED TO:

(1) THE PRESCRIPTION NUMBER;

(2) THE NAME OF THE DRUG DISPENSED;

(3) THE DATE OF REFILL;

(4) THE QUANTITY DISPENSED;

(5) THE NAME OR INITIALS OF THE DISPENSING PHARMACIST FOR EACH REFILL;

(6) THE TOTAL NUMBER OF REFILLS DISPENSED TO DATE FOR THAT PRESCRIPTION ORDER.

(C) DOCUMENTATION OF THE FACT THAT THE PRESCRIPTION REFILL INFORMATION ENTERED INTO THE AUTOMATED DATA PROCESSING SYSTEM IS CORRECT MUST BE PROVIDED BY EACH INDIVIDUAL PHARMACIST WHO MAKES USE OF SUCH SYSTEM BY ONE OF THE FOLLOWING METHODS:

(1) POSITIVE IDENTIFICATION, AS DEFINED IN RULE 4729-5-01 OF THE ADMINISTRATIVE CODE, OF THE PHARMACIST RESPONSIBLE FOR EACH DATA ENTRY. IF THIS METHOD IS USED, THE AUTOMATED DATA PROCESSING SYSTEM MUST HAVE A DAILY BACKUP;

(2) A HARD-COPY PRINTOUT OF EACH DAY'S PRESCRIPTION REFILL DATA THAT SHALL INCLUDE, AT A MINIMUM, THE FOLLOWING DATA:

(a) DATE OF DISPENSING;

(b) PRESCRIPTION NUMBER;

(c) PATIENT NAME;

(d) NAME, STRENGTH (IF APPLICABLE), AND QUANTITY OF DRUG;

(e) IDENTIFICATION OF PHARMACY AND PHARMACIST;

(f) IDENTIFICATION OF CONTROLLED SUBSTANCES.

THIS PRINTOUT MUST BE VERIFIED, DATED, AND SIGNED BY EACH INDIVIDUAL PHARMACIST WHO DISPENSED A PRESCRIPTION THAT DAY. THE PHARMACIST MUST VERIFY THAT THE DATA ON THE PRINTOUT IS COMPLETE AND CORRECT AND SIGN A STATEMENT TO THAT EFFECT ON THE DOCUMENT AS HE/SHE WOULD SIGN A CHECK OR LEGAL DOCUMENT (E.G., J. H. SMITH OR JANE H. SMITH). THESE DOCUMENTS MUST BE MAINTAINED IN CHRONOLOGICAL ORDER IN A SEPARATE FILE AT THE LICENSED LOCATION WHERE THE DRUG WAS DISPENSED FOR A PERIOD OF THREE YEARS FROM THE DATE OF DISPENSING. IF THE PRINTOUT IS PREPARED AT A LOCATION OTHER THAN THAT WHERE THE DRUG WAS DISPENSED, THE PRINTOUT MUST BE PROVIDED TO THE LICENSED LOCATION WITHIN THREE WORKING DAYS, EXCLUDING HOLIDAYS AND WEEKENDS, OF THE DATE ON WHICH THE DRUGS WERE DISPENSED. SUCH PRINTOUTS MUST BE VERIFIED AND SIGNED BY EACH PHARMACIST WHO DISPENSED DRUGS WITHIN TWENTY-FOUR HOURS OF THE DATE THE PRINTOUT IS RECEIVED;

(3) A TAMPER-EVIDENT LOG BOOK IN WHICH SHALL BE ENTERED, AT A MINIMUM, THE DATE OF DISPENSING AND PRESCRIPTION NUMBER. THE DISPENSING PHARMACIST MUST MANUALLY RECORD HIS/HER NAME OR

INITIALS ON EACH LOG BOOK ENTRY AT THE TIME OF DISPENSING EACH REFILL; OR

(4) EACH INDIVIDUAL PHARMACIST INVOLVED IN DISPENSING DRUGS MUST ENTER INTO A TAMPER-EVIDENT LOG BOOK, AT A MINIMUM, THE FOLLOWING DATA FOR EACH PRESCRIPTION REFILLED:

- (a) DATE OF DISPENSING;
- (b) PRESCRIPTION NUMBER;
- (c) PATIENT NAME;
- (d) NAME, STRENGTH (IF APPLICABLE), AND QUANTITY OF DRUG;
- (e) IDENTIFICATION OF PHARMACY AND PHARMACIST;
- (f) IDENTIFICATION OF CONTROLLED SUBSTANCES.

EACH INDIVIDUAL PHARMACIST INVOLVED IN DISPENSING DRUGS MUST REVIEW THIS INFORMATION AT THE END OF EACH DAY AND THEN MUST SIGN A STATEMENT IN THE LOG BOOK ATTESTING TO THE FACT THAT THE PRESCRIPTION INFORMATION ENTERED INTO THE COMPUTER THAT DAY AND RECORDED IN THE LOG BOOK HAS BEEN REVIEWED BY HIM/HER AND IS CORRECT AS SHOWN.

(D) ANY SUCH COMPUTERIZED RECORDKEEPING SYSTEM MUST HAVE THE CAPABILITY OF PRODUCING A PRINTOUT OF ANY PRESCRIPTION DATA WHICH THE USER PHARMACY IS RESPONSIBLE FOR MAINTAINING PURSUANT TO FEDERAL AND STATE LAWS AND THEIR IMPLEMENTING REGULATIONS AND RULES WITHIN THREE WORKING DAYS OF A REQUEST BEING SUBMITTED BY AN INDIVIDUAL AUTHORIZED BY LAW TO ACCESS SUCH RECORDS.

(E) IN THE EVENT THAT THE COMPUTERIZED RECORDKEEPING SYSTEM EXPERIENCES DOWN-TIME, A RECORD OF ALL REFILLS DISPENSED DURING SUCH TIME MUST BE RECORDED ON THE BACK OF THE ORIGINAL PRESCRIPTION. THE REFILL INFORMATION MUST BE ENTERED INTO THE COMPUTERIZED RECORDKEEPING SYSTEM AS SOON AS IT IS AVAILABLE FOR USE. DURING THE TIME THE COMPUTERIZED RECORDKEEPING SYSTEM IS NOT AVAILABLE, PRESCRIPTIONS MAY BE REFILLED ONLY IF, IN THE PROFESSIONAL JUDGMENT OF THE PHARMACIST, THE NUMBER OF REFILLS AUTHORIZED BY THE PRESCRIBER HAS NOT BEEN EXCEEDED.

(F) A PHARMACY PURGING A COMPUTERIZED RECORDKEEPING SYSTEM OF PRESCRIPTION RECORDS MUST DEVELOP A METHOD OF RECORDKEEPING CAPABLE OF PROVIDING RETRIEVAL (VIA CRT DISPLAY, HARD-COPY PRINTOUT, OR OTHER MUTUALLY AGREEABLE TRANSFER MEDIUM) WITHIN THREE WORKING DAYS, EXCLUDING HOLIDAYS AND WEEKENDS, OF PRESCRIPTION ORDER INFORMATION FOR ALL PRESCRIPTIONS FILLED OR REFILLED WITHIN THE PREVIOUS THREE YEARS. THIS INFORMATION SHALL INCLUDE, AT A MINIMUM, THE FOLLOWING DATA:

- (1) PHARMACY NAME AND ADDRESS;
- (2) ORIGINAL PRESCRIPTION NUMBER;
- (3) DATE OF ISSUANCE OF THE ORIGINAL PRESCRIPTION ORDER BY THE PRACTITIONER;
- (4) DATE OF ORIGINAL DISPENSING BY THE PHARMACIST;
- (5) FULL NAME AND ADDRESS OF THE PATIENT;
- (6) FULL NAME AND ADDRESS OF THE PRACTITIONER;
- (7) DIRECTIONS FOR USE;

- (8) NAME, STRENGTH, DOSAGE FORM, AND QUANTITY OF THE DRUG PRESCRIBED;
- (9) QUANTITY DISPENSED IF DIFFERENT FROM THE QUANTITY PRESCRIBED;
- (10) TOTAL NUMBER OF REFILLS AUTHORIZED BY THE PRESCRIBING PRACTITIONER;
- (11) TOTAL NUMBER OF REFILLS DISPENSED TO DATE FOR THAT PRESCRIPTION ORDER;
- (12) DATE OF EACH REFILL;
- (13) NAME OR INITIALS OF THE DISPENSING PHARMACIST.

SUCH DATA MUST BE ACCESSIBLE BY PATIENT PROFILE, ALPHABETICALLY, OR SERIALLY BY PRESCRIPTION NUMBER.

(G) A LOG MUST BE MAINTAINED OF ALL CHANGES MADE TO A PRESCRIPTION RECORD AFTER THE PRESCRIPTION HAS BEEN DISPENSED. SUCH LOG MAY BE ACCESSIBLE TO THE PHARMACIST FOR REVIEW, BUT SHALL BE PROTECTED FROM BEING ALTERED IN ANY WAY. THE LOG MUST CONTAIN AT LEAST, BUT IS NOT LIMITED TO, THE FOLLOWING:

- (1) DATE AND TIME OF CHANGE;
- (2) CHANGES MADE;
- (3) PHARMACIST MAKING THE CHANGE.

4729-5-29 CONFIDENTIALITY OF PATIENT RECORDS.

(A) RECORDS OF DISPENSING OR ADMINISTERING OF DRUGS ARE NOT A PUBLIC RECORD. A PERSON HAVING CUSTODY OF, OR ACCESS TO, SUCH RECORDS SHALL NOT DIVULGE THE CONTENTS THEREOF, OR PROVIDE A COPY THEREOF, TO ANYONE EXCEPT:

- (1) THE PATIENT FOR WHOM THE PRESCRIPTION OR MEDICATION ORDER WAS ISSUED.
- (2) THE PRACTITIONER WHO ISSUED THE PRESCRIPTION OR MEDICATION ORDER.
- (3) CERTIFIED/LICENSED HEALTH CARE PERSONNEL WHO ARE RESPONSIBLE FOR THE CARE OF THE PATIENT.
- (4) A MEMBER, INSPECTOR, AGENT, OR INVESTIGATOR OF THE BOARD OF PHARMACY OR ANY FEDERAL, STATE, COUNTY, OR MUNICIPAL OFFICER WHOSE DUTY IS TO ENFORCE THE LAWS OF THIS STATE OR THE UNITED STATES RELATING TO DRUGS AND WHO IS ENGAGED IN A SPECIFIC INVESTIGATION INVOLVING A DESIGNATED PERSON OR DRUG.
- (5) AN AGENT OF THE STATE MEDICAL BOARD WHEN ENFORCING CHAPTER 4731. OF THE REVISED CODE.
- (6) AN AGENCY OF GOVERNMENT CHARGED WITH THE RESPONSIBILITY OF PROVIDING MEDICAL CARE FOR THE PATIENT UPON A WRITTEN REQUEST BY AN AUTHORIZED REPRESENTATIVE OF THE AGENCY REQUESTING SUCH INFORMATION.
- (7) AN AGENT OF A MEDICAL INSURANCE COMPANY WHO PROVIDES PRESCRIPTION INSURANCE COVERAGE TO THE PATIENT UPON AUTHORIZATION AND PROOF OF INSURANCE BY THE PATIENT OR PROOF OF PAYMENT BY THE INSURANCE COMPANY FOR THOSE MEDICATIONS WHOSE INFORMATION IS REQUESTED.

(8) ANY PERSON, OTHER THAN THOSE LISTED IN PARAGRAPHS (A)(1) TO (A)(6) OF THIS RULE, ONLY WHEN THE PATIENT HAS GIVEN CONSENT FOR SUCH DISCLOSURE IN WRITING, EXCEPT WHERE A PATIENT REQUIRING MEDICATION IS UNABLE TO DELIVER A WRITTEN CONSENT TO THE NECESSARY DISCLOSURE. ANY CONSENT MUST BE SIGNED BY THE PATIENT AND DATED. ANY 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) RECORDS OF DISPENSING OR ADMINISTERING DRUGS WHICH MAY BE REQUIRED AS EVIDENCE OF A VIOLATION SHALL BE RELEASED TO A MEMBER, INSPECTOR, AGENT, OR INVESTIGATOR OF THE 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. THE RECEIPT SHALL LIST THE RECORDS REMOVED AND SHALL INCLUDE 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 PRESCRIBING PRACTITIONER;

(5) DATE, NAME OF AGENCY, AND SIGNATURE OF PERSON REMOVING THE RECORDS.

(C) ALL SUCH RECORDS, INCLUDING CONSENTS, MEMORANDA OF EMERGENCY DISCLOSURES, AND WRITTEN REQUESTS PURSUANT TO PARAGRAPH (A)(7) OF THIS RULE, SHALL BE KEPT ON FILE AT THE PHARMACY FOR A PERIOD OF THREE YEARS IN A READILY RETRIEVABLE MANNER.

4729-9-01 Definitions.

- (A) "Dangerous drug," as defined in division (D)(1) of section 4729.02 of the Revised Code, means any drug or drug product ~~the~~ WHOSE commercial package ~~of which~~ bears a label containing the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Licensed Veterinarian" or any similar restrictive statement.
- (B) A dangerous drug is adulterated if beyond the expiration date as stated by the manufacturer, packer, or distributor in its labeling or if it is not stored or dispensed according to the requirement of the federal act as indicated in the product labeling.
- (C) "Psychiatric outpatient facility" means a facility where psychiatric evaluation and treatment is provided on an outpatient basis.
- (D) "Registered" and "licensed", as used in Chapters 3719. and 4729. of the Revised Code, have the same meaning. "Registered" and "licensed" mean that an individual or facility has met the initial qualifications for registration and licensure with the board of pharmacy and, if they are still actively practicing pharmacy or distributing drugs, have complied with annual renewal procedures, including payment of applicable fees.

- (E) "Revoke", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against a license which renders such license void and such license may not be reissued. "Revoke" is an action which is permanent against the license and licensee except that after twelve months or such period of time as the individual board order may require, a licensee whose license has been revoked may make application to the board for issuance of a new license. A pharmacist whose license has been revoked must pass any examination required by the board prior to the issuance of any new license.
- (F) "Suspend", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against a license which renders such license without force and effect for a period of time as determined by the board of pharmacy. The board may require that an individual whose license has been suspended may not be employed by or work in a facility licensed by the board of pharmacy to possess or distribute dangerous drugs during such period of suspension.
- (G) "Place on probation", as used in Chapter 4729. of the Revised Code, means to take action against a license which suspends the sanctions imposed by the board of pharmacy during a period of good behavior for a period of time and under such conditions as determined by the board of pharmacy.
- (H) "Refuse to grant or renew", as used in Chapter 4729. of the Revised Code, means to deny original or continued licensure for a period of at least twelve months. After twelve months or such period of time as the individual board order may require, a pharmacist, a pharmacy intern, a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, a wholesaler of controlled substances, a manufacturer of controlled substances, or an individual or facility who desires to attain such status by licensure, and whose license the board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A pharmacist, or an individual who desires to attain such status by licensure, whose license the board of pharmacy has refused to grant or renew must meet any requirements established by the board or must pass any examination required by the board.

4729-9-04 Returned drugs.

No drug or drug product, which has been sold at retail and has left the physical premises of the terminal distributor of dangerous drugs, shall be dispensed again except ~~non-controlled drugs dispensed for inpatients pursuant to paragraph (C) of rule 4729-17-01 and paragraph (C) of rule 4729-17-05 of the Administrative Code or non-controlled drugs dispensed and delivered for outpatients to a psychiatric outpatient facility licensed with the board of pharmacy and provided by a government entity that are packaged in unopened, single-dose or hermetic~~ TAMPER-EVIDENT containers and whereby the drug has not been in the possession of the ultimate user. Drugs that have been dispensed or possessed; not in accordance with this rule; are considered to be adulterated.

4729-9-15 Report of theft or loss of dangerous drugs, controlled substances, and drug documents.

- (A) ~~To be in compliance with federal and state requirements, each~~ EACH practitioner; AND terminal or wholesale distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance:
 - (1) The board of pharmacy, by telephone immediately upon discovery of the theft or significant loss;
 - (2) If a controlled substance, the drug enforcement administration (DEA) pursuant to section 1301.76(b), Code of Federal Regulations;
 - (3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

- (B) Controlled substance thefts must also be reported by using the federal DEA report form whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them. A copy of the federal form regarding such theft or loss shall be filed with the board of pharmacy within thirty days following the discovery of such theft or loss.
 - (1) An exemption may be obtained upon sufficient cause if the federal form cannot be filed within thirty days.
 - (2) A request for a waiver of the thirty-day limit must be requested in writing.
- (C) Each practitioner; AND terminal or wholesale distributor of dangerous drugs immediately upon discovery of any theft or loss of:
 - (1) Uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed, shall notify the board of pharmacy and law enforcement authorities.
 - (2) Official written order form(s) as defined in division (U) of section 3719.01 of the Revised Code shall notify the board of pharmacy and law enforcement authorities, and the drug enforcement administration (DEA) pursuant to section 1305.12(b), Code of Federal Regulations.

4729-9-16 Minimum requirements for wholesalers.

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 board 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 board. 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 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 board 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 pharmacopeia/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, when required, operated to disclose orders for controlled substances and other dangerous drugs subject to abuse, as designated by the board of pharmacy. The board shall furnish wholesalers with the name and identification numbers of drug products subject to abuse at least fourteen days prior to the date that such system is required to commence or when a product is deleted from such requirements.
 - (i) The wholesaler shall inform the board 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 board 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 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 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 board of pharmacy must first send notification to the board.
- (l) 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.
- (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 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.

4729-27-01 DEFINITIONS.

FOR THE PURPOSE OF CHAPTER 4729. OF THE REVISED CODE, THE TERM "PERITONEAL DIALYSIS SOLUTIONS" SHALL MEAN THE COMMERCIALY 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.

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.

(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.

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.

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.

The motion was seconded by Mr. Lamping and approved by the Board (Aye-6/Nay-0).

RES. 97-072 Staff then presented language amending Ohio Administrative Code Rule 4729-17-14 for consideration and discussion. Mr. Maslak moved that the proposal be referred to the 1997 Ad Hoc Advisory Committee on Rule Review for consideration and recommendations in August of 1997. The motion was seconded by Mr. Lamping and approved (Aye-6/Nay-0). Staff was also directed to publish an article in the State Board Newsletter regarding the theft and loss of controlled substances. The article will discuss what needs to be reported and how it is to be reported.

2:25 p.m.

Mr. Repke excused himself from the meeting for personal business reasons.

3:10 p.m.

The Board was joined by Assistant Attorney General Mary Hollern for the purpose of conducting an adjudication hearing pursuant to the provisions of Ohio Revised Code Chapters 119. and 4729. in the matter of R.Ph. Thomas Lawrence Bridge, Olmsted Township.

6:50 p.m.

The hearing was concluded and Mr Hanna moved that the Board go into Executive Session for the purpose of deliberating on the evidence and testimony received in the hearing. The motion was seconded by Mr. Littlejohn and a roll call vote was conducted by President Neuber as follows: Adelman-Yes, Hanna-Yes, Lamping-Yes, Littlejohn-Yes, and Maslak-Yes.

7:00 p.m.

RES. 97-073 The Executive Session was concluded and the meeting opened to the public. Mr.Hanna moved that the Board adopt the following Order:

ORDER OF THE STATE BOARD OF PHARMACY
(Docket No. D-960725-069)

In The Matter Of:

THOMAS LAWRENCE BRIDGE, R.Ph.
28500 Glen Hollow Lane
Olmsted Township, Ohio 44138
(R.Ph. No. 03-3-16000)

INTRODUCTION

THE MATTER OF THOMAS LAWRENCE BRIDGE CAME TO HEARING ON OCTOBER 24, 1996, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: SUZANNE L. NEUBER, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; JOHN L. HANNA, R.Ph.; PAUL F. LAMPING, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; AND JOSEPH J. MASLAK, R.Ph.

THOMAS LAWRENCE BRIDGE WAS REPRESENTED BY MICHAEL E. MURMAN, AND THE STATE OF OHIO WAS REPRESENTED BY MARY L. HOLLERN, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) James Reye, Ohio State Board of Pharmacy
- (2) Dale Fritz, Ohio State Board of Pharmacy
- (3) Joann Predina, Ohio State Board of Pharmacy
- (4) Mark Keeley, Ohio State Board of Pharmacy
- (5) Thomas Lawrence Bridge, Respondent

Respondent's Witnesses:

- (1) Thomas Lawrence Bridge, Respondent

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Summary Suspension Order/Notice of Opportunity for Hearing letter dated July 25, 1996.
- (2) Exhibit 1A--Hearing Request letter dated July 30, 1996.
- (3) Exhibit 1B--Hearing Schedule letter dated August 5, 1996.
- (4) Exhibit 1C--Pharmacist File Front Sheet of Thomas Lawrence Bridge showing original date of registration as August 2, 1985; and Renewal Application for Pharmacist License, No. 03-3-16000, for a license to practice pharmacy in Ohio from September 15, 1995, to September 15, 1996, of Thomas L. Bridge dated July 31, 1995.
- (5) Exhibit 2--Five-page Dangerous Drug Distributor Inspection Report of All Care Pharmaceutical Services, Terminal Distributor License No. 02-517300, dated July 16, 1996.
- (6) Exhibit 2A--Copy of two-page letter from Sharon Snee dated August 12, 1996.
- (7) Exhibit 2B--Letter from Kent Marvin dated July 19, 1996.
- (8) Exhibit 3--Ohio State Board of Pharmacy Drug Audit Accountability Sheet of All Care Pharmacy for the drug Oxycodone 5mg with APAP 325mg, by computer records, dated July 17, 1996.
- (9) Exhibit 4--Ohio State Board of Pharmacy Drug Audit Accountability Sheet of All Care Pharmacy for the drug Oxycodone 5mg with APAP 325mg, by prescription records, dated July 17, 1996.

- (10) Exhibit 5--Ohio State Board of Pharmacy Drug Audit Accountability Sheet of All Care Pharmacy for the drug Oxycodone 5mg with APAP 325mg, by computer records, dated August 31, 1996.
- (11) Exhibit 6--Two-page handwritten statement of Thomas L. Bridge signed and notarized on July 16, 1996.
- (12) Exhibit 7--Copy of Toxicology report of Tom Bridge dated July 19, 1996.
- (13) Exhibit 8--All Care Pharmaceutical Services Patient Prescription Summary for Tom Bridge dated July 16, 1996.
- (14) Exhibit 9--Zip-lock baggie containing unmarked amber vial containing 18 round, white tablets marked 54/543; and Receipt for All Care Pharm, Terminal Distributor License No. 02-517300, written on a Dangerous Drug Distributor Inspection Report and dated July 16, 1996.
- (15) Exhibit 10--Five-page Dangerous Drug Distributor Inspection Report of All Care Pharmaceutical Services, Inc., Terminal Distributor License No. 02-517300, dated November 2, 1992.
- (16) Exhibit 10A--Copy of five-page letter from Thomas L. Bridge dated November 19, 1992; copy of front and back of Ohio State Board of Pharmacy Pocket Identification Card, No. 03-3-16000, of Thomas L. Bridge, R.Ph., expiration date of September 15, 1993; copy of All Care Pharmaceutical Services Controlled Substance Tracking Report of L. Klein, M.D. dated November 19, 1992; copy of All Care Pharmaceutical Services Controlled Substance Tracking Report of K. Masterson, M.D. dated November 19, 1992; copy of All Care Pharmaceutical Services Controlled Drug Listing for prescriptions numbered 101407 and 101509, report dated November 19, 1992; and copy of test fax page dated November 13, 1992.
- (17) Exhibit 11--Seven-page Dangerous Drug Distributor Inspection Report of All Care Pharmaceutical Services, Inc., Terminal Distributor License No. 02-581650, dated October 28, 1992; six-page Dangerous Drug Distributor Inspection Report of All Care Pharmaceutical Services, Inc., Terminal Distributor License No. 02-581650, Nursing Services Report dated October 28, 1992; copy of four-page letter from Thomas L. Bridge dated November 14, 1992, with the following attachments: copy of three-page Controlled Medication - Ordering and Receipt; copy of Returning Medications to the Pharmacy; and copies of nine All Care Pharmaceutical Services Medication Cart Maintenance Records with service dates as follows: September 29, 1992; October 28, 1992; November 1, 1992; two for November 4, 1992; November 10, 1992; and three for November 13, 1992.
- (18) Exhibit 12--Five-page handwritten statement of Kendra Drobnak signed and notarized on August 28, 1996.
- (19) Exhibit 13--Three-page statement of Susan Kortyna signed and notarized on July 23, 1996.
- (20) Exhibit 14--Prescription Number 119771.
- (21) Exhibit 14A--Copy of All Care Pharmaceutical Services Statement of Account of Mike Callas, No. 170020, dated April 30, 1996.
- (22) Exhibit 14B--Copy of vacation schedule calendar for April 1996.
- (23) Exhibit 14C--Copy of All Care Pharmaceutical Services Prescription Log Report -- Nursing Home and Retail Rx's for April 20, 1996, through April 21, 1996, dated April 25, 1996; and All Care Pharmaceutical Services Prescription Log Summary -- Nursing Home and Retail Rx's for April 20, 1996, through April 21, 1996.
- (24) Exhibit 15--Light blue binder, approximately 15¼" x 11¾" x 2¼", containing daily computer printouts of All Care Pharmaceutical Services daily Prescription Log Reports and Prescription Log Summaries for April 1, 1996, through July 15, 1996.
- (25) Exhibit 15A--Dark blue binder, approximately 15¼" x 11¾" x 3½", containing daily computer printouts of All Care Pharmaceutical Services reports as follows: New and Refill Prescriptions Filled for dates June 21, 1995, through December 31, 1994; Controlled Drug Listing for dates May 31, 1995, through June 21, 1995; three Drug Usage Reports dated June 21, 1995, March 6, 1995, and January 31, 1995; and Pricing Error List dated January 31, 1995.
- (26) Exhibit 15A1--Section of Exhibit 15A, run continuously from April 24, 1995, through May 7, 1995.
- (27) Exhibit 15A2--Section of Exhibit 15A showing lack of daily reports from March 22, 1995, through April 22, 1995.
- (28) Exhibit 15A3--Section of Exhibit 15A showing lack of daily reports and/or misfiled daily reports from March 16, 1995, through April 20, 1995.
- (29) Exhibit 15A4--Section of Exhibit 15A showing misfiled daily reports from April 5, 1995, through April 20, 1995.

- (30) Exhibit 15B--Light blue binder, approximately 15¼" x 11¾" x 2¼", containing computer printouts of All Care Pharmaceutical Services reports of New and Refill Prescriptions Filled for dates December 30, 1994, through December 6, 1994; November 22, 1994, through October 2, 1994; and August 5, 1994, through June 27, 1994.
- (31) Exhibit 16--Five-page Repackaging List dated from June 3rd through June 13th.
- (32) Exhibit 17--Copy of All Care Pharmaceutical Services Co. Medication Return Form of Eugene Meador dated October 31, 1995.
- (33) Exhibit 17A--Copy of All Care Pharmaceutical Services Co. Medication Return Form of Neil Carothers dated June 6, 1996.
- (34) Exhibit 18--Copy of All Care Pharmaceutical Services Co. Medication Return Form of Mildred Domalgalski dated July 4, 1996, with attached copy of blank Medication Return Form for Mildred Domalgalski, copy of medication numbered Rx C120540 dated July 2, 1996, and two pages of All Care Pharmaceutical Services Evening, Bedtime, Morning, and Noon Medication regimens for patient Mildred Domalgalski, reports dated July 5, 1996.
- (35) Exhibit 19--Prescriptions numbered 120637 and 120638.
- (36) Exhibit 19A--Prescription number 120514.
- (37) Exhibit 19B--Prescription number 120528.
- (38) Exhibit 19C--Prescription number 120482.
- (39) Exhibit 19D--Prescription number 120487.
- (40) Exhibit 19E--Prescription number 120527.
- (41) Exhibit 19F--Prescription number 120529.
- (42) Exhibit 20--Faxed prescription number 119756.
- (43) Exhibit 20A--Faxed prescription number 120640.
- (44) Exhibit 21--Copy of medication numbered Rx 116820 dated August 30, 1995.
- (45) Exhibit 21A--Copy of medication numbered Rx C120323 dated June 12, 1996.
- (46) Exhibit 21B--Copy of medication numbered Rx 119911 dated May 3, 1996.
- (47) Exhibit 21C--Copy of zip-lock baggie containing medication and labeled "Dolega, Elsie, Please Credit".
- (48) Exhibit 21D--Copy of medication numbered Rx 116557, not dated, labeled "8am & 8pm".
- (49) Exhibit 21E--Copy of medication numbered Rx 116557, not dated, labeled "Use thru: 8/30 only!"
- (50) Exhibit 21F--Back side of Exhibit 21E stating in part "MTS Packaging Systems, Inc. . . . Item #300-25".
- (51) Exhibit 21G--Copy of one capsule and prescription label numbered Rx 120006 dated May 14, 1996.
- (52) Exhibit 21H--Copy of baggie containing medication with label numbered Rx 120006 dated May 14, 1996, and "Return" handwritten.
- (53) Exhibit 22--Fifteen 4" x 6" color photographs taken on premises of All Care Pharmaceutical Services.

Respondent's Exhibits:

- (1) Exhibit A--copy of letter from Dennis Farina dated October 22, 1996; copy of Glenbeigh Health Sources Progress Report of Thomas Bridge dated July 25, 1996; copy of Glenbeigh Health Sources Progress Report of Thomas Bridge dated July 28, 1996; copy of page one of Pharmacists Rehabilitation Organization, Inc. Pharmacist's Recovery Contract of Thomas L. Bridge dated August 27, 1996; copy of letter from Linda Advay dated August 1, 1996; copy of two-page Glenbeigh Hospital Discharge Summary of Thomas Bridges (sic) dated July 29, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated July 31, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated August 8, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated August 14, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated August 21, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated August 28, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated September 4, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated September 11, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated September 18, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated September 25, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated October 2, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated October 9, 1996; copy of Glenbeigh Hospital Continuing Care Progress Report of Thomas Bridge dated October 16, 1996; copy of two-page Pharmacists Rehabilitation Organization, Inc. Pharmacist's Recovery Contract of Thomas L. Bridge dated August 27, 1996; copy of urine drug screen report of Tom Bridge dated September 19, 1996; copies of four pages of AA Meetings Attended by Tom Bridge dated from July 30, 1996, through October 23, 1996; letter from Elizabeth A. Bridge dated October 22, 1996; copy of letter from Timothy J. Clancy dated October 22, 1996; copy of two letters from Jeffrey Rinda dated October 21, 1996; copy of letter from Ruth B. Bertrand dated October 22, 1996; and copies of four certificates of continuing pharmaceutical education participation of Thomas L. Bridge numbered and dated as follows: 692-424-94-027 dated October 7, 1996; 692-424-94-026 dated October 7, 1996; 424-000-95-022 dated October 7, 1996; and 692-424-94-025 dated October 7, 1996.
- (2) Exhibit B--Copy of two letters from Jeffrey Rinda dated October 21, 1996.

FINDINGS OF FACT

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

- (1) Records of the Board indicate that Thomas Lawrence Bridge was originally licensed to practice pharmacy in the state of Ohio on August 2, 1985, pursuant to examination; and, on July 25, 1996, Thomas Lawrence Bridge's license was summarily suspended in accordance with Section 3719.121(B) of the Ohio Revised Code.
- (2) Thomas Lawrence Bridge did, from July 1, 1994, through July 16, 1996, with purpose to deprive, knowingly obtain or exert control over dangerous drugs, the property of All Care Pharmaceutical Services, beyond the express or implied consent of the owner, to wit: Thomas Lawrence Bridge stole an amount in excess of 4,262 tablets of Oxycodone with APAP from his place of employment. Such conduct is in violation of Section 2913.02 of the Ohio Revised Code.
- (3) Thomas Lawrence Bridge did, on or about July 8, 1996, knowingly possess a schedule II controlled substance when the conduct was not in accordance with Chapters 3719., 4729., or 4731. of the Ohio Revised Code, the amount being less than bulk, to wit: Thomas Lawrence Bridge admittedly possessed, and surrendered to Board agents, 18 tablets of Roxicet which he had possessed without a prescription and not for a legitimate medical purpose. Such conduct is in violation of Section 2925.11 of the Ohio Revised Code.
- (4) Thomas Lawrence Bridge did, on or about July 13, 1996, and July 14, 1996, knowingly use marijuana when the conduct was not in accordance with Chapters 3719., 4729., or 4731. of the Ohio Revised Code, to wit: Thomas Lawrence Bridge admit-

tedly used marijuana, a schedule I controlled substance. Such conduct is in violation of Section 2925.11 of the Ohio Revised Code.

- (5) Thomas Lawrence Bridge is addicted to or abusing liquor or drugs or impaired physically or mentally to such a degree as to render him unfit to practice pharmacy, to wit: Thomas Lawrence Bridge has admitted drug abuse; Thomas Lawrence Bridge has admitted consuming drugs and alcohol together; and, Thomas Lawrence Bridge has admitted that his abuse of Oxycodone began with "sporadic" use in 1989 and increased to 4 to 6 tablets per day, being "Percocet-free" for periods of "several days at a time" to the present. Further, as the Responsible Pharmacist, Thomas Lawrence Bridge has been unwilling and/or unable to oversee the practice of pharmacy in his store, to wit: the store keys were available to non-registered individuals; the pharmacy was stocked with out-dated drugs; D.E.A. 222 forms were missing from the files; no accurate record of original prescription dispensings or refills could be produced when requested by Board agents; and, prescription filing was non-compliant with Board rules. Thomas Lawrence Bridge was admonished by a Board agent for improper key control, improper D.E.A. 222 recordkeeping, and possession of outdated drugs on November 2, 1992, and the activity was not corrected on the July 16, 1996, inspection by Board agents.
- (6) Thomas Lawrence Bridge did, on or about April 23, 1996, intentionally make and/or knowingly possess a false or forged prescription, to wit: after a pharmacy technician entered the pharmacy and filled the prescription on April 21, 1996, while he was away from the pharmacy on vacation, Thomas Lawrence Bridge signed and dated prescription number 119771, written for 20 units of Darvocet N-100, to make it appear as if he had been the dispensing pharmacist. Such conduct is in violation of Section 2925.23(B)(10) of the Ohio Revised Code.
- (7) Thomas Lawrence Bridge did, on or about July 16, 1996, knowing that an official investigation was in progress, make, present, or use records, knowing them to be false and with purpose to mislead a public official who was engaged in the investigation and/or to corrupt the outcome of such investigation, to wit: when requested by Board agents to produce pharmacy records, Thomas Lawrence Bridge created and signed false records indicating three months of signed, daily dispensing reports. Such conduct is in violation of Section 2921.12 of the Ohio Revised Code.
- (8) Thomas Lawrence Bridge did, on or about July 16, 1996, knowingly possess and use controlled substances when the conduct was not in accordance with Chapters 3719., 4729., or 4731. of the Ohio Revised Code, the amount being less than bulk, to wit: Thomas Lawrence Bridge admittedly possessed and used Oxycodone, a schedule II controlled substance, and Tetrahydrocannabinol, a schedule I controlled substance, without a prescription and not for a legitimate medical purpose. Such conduct is in violation of Section 2925.11 of the Ohio Revised Code.

CONCLUSIONS OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (8) of the Findings of Fact constitute being guilty of dishonesty and unprofessional conduct in the practice of pharmacy as provided in Division (A)(2) of Section 4729.16 of the Ohio Revised Code.
- (2) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (3) through (5) of the Findings of Fact constitute being addicted to or abusing liquor or drugs or impaired physically or mentally to such a degree as to render him unfit to practice pharmacy as provided in Division (A)(3) of Section 4729.16 of the Ohio Revised Code.
- (3) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (3), (4), (6), and (8) of the Findings of Fact constitute being guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of provisions of Chapter 2925. of the Revised Code as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.
- (4) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (6) of the Findings of Fact constitutes being guilty of permitting

anyone other than a pharmacist or pharmacy intern to practice pharmacy as provided in Division (A)(6) of Section 4729.16 of the Ohio Revised Code.

- (5) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (6) of the Findings of Fact constitutes being guilty of knowingly lending his name to an illegal practitioner of pharmacy or having professional connection with an illegal practitioner of pharmacy as provided in Division (A)(7) of Section 4729.16 of the Ohio Revised Code.

ACTION OF THE BOARD

Pursuant to Section 3719.121 of the Ohio Revised Code, the State Board of Pharmacy hereby removes the Summary Suspension Order issued July 25, 1996.

Pursuant to Section 4729.16 of the Ohio Revised Code, the State Board of Pharmacy takes the following actions in the matter of Thomas Lawrence Bridge:

- (A) On the basis of the Findings of Fact and Conclusions of Law set forth above, the State Board of Pharmacy hereby suspends the pharmacist identification card, No. 03-3-16000, held by Thomas Lawrence Bridge indefinitely and such suspension is effective as of the date of the mailing of this Order. Pursuant to Rule 4729-9-01(F) of the Ohio Administrative Code, Thomas Lawrence Bridge may not be employed by or work in a facility licensed by the Board of Pharmacy to possess or distribute dangerous drugs during such period of suspension.
- (B) Five years after the date of the mailing of this Order, the Board will consider any petition filed by Thomas Lawrence Bridge for a hearing, pursuant to Revised Code Chapter 119., upon the question of the reinstatement of his license to practice pharmacy in Ohio. The Board will consider the reinstatement of the license only if the following conditions have been met:
- (1) Thomas Lawrence Bridge must take and successfully complete the NAPLEX examination offered by the Board within the six-month period immediately preceding the hearing for reinstatement.
 - (2) Thomas Lawrence Bridge must enter into a new contract, from the effective date of this Order, with a limited treatment provider acceptable to the Board, for a period of not less than five years and, upon signing, submit a copy of the contract to the Board office. The contract must provide that:
 - (a) random, **observed** urine drug screens shall be conducted at least every three months. The urine drug screens must report testing for alcohol and must also report testing for creatinine or specific gravity of the sample as the dilutional standard;
 - (b) regular attendance, at least three times per week, at an Alcoholics Anonymous, Narcotics Anonymous, and/or similar support group meetings, and at meetings of a professional support group, is required during outpatient treatment and/or during aftercare; and
 - (c) the program shall immediately report to the Board of Pharmacy any positive urine screens and/or other violations of the contract.

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

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

MOTION CARRIED.

SO ORDERED.

The motion was seconded by Mr. Maslak and approved by the Board (Aye-5/Nay-0).

7:05 p.m. The Board recessed until Friday, October 25, 1996, at 9:00 a.m.

FRIDAY, OCTOBER 25, 1996

9:15 a.m. ROLL CALL

The following members of the State Board of Pharmacy reconvened in Room 1914, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio:

Suzanne L. Neuber, R.Ph. (President); Amonte B. Littlejohn, R.Ph.; (Vice-President); Diane Adelman, R.Ph.; Paul Lamping, R.Ph.; Joseph Maslak, R.Ph.; and Nicholas Repke, Public Member.

The Board was joined by John Cassady, Dean of The Ohio State University College of Pharmacy; Ken Hale, R.Ph.; Dr. Metta Lou Henderson, Assistant Dean of Ohio Northern University College of Pharmacy; Tom Gossell, Dean of Ohio Northern University College of Pharmacy; Vic Warner, Dean of the University of Cincinnati College of Pharmacy; and Dr. Alan Escovitz, Executive Director of the Council of Ohio Colleges of Pharmacy. Also present were Pharmacy Board staff - William T. Winsley and Timothy J. Benedict.

The following topics were discussed and information shared between the Colleges and the Board:

1. The NAPLEX exam
2. Non-traditional Doctor of Pharmacy degree programs
3. Proposed Amended and New Rules that will be considered at the December 1997 public rules hearing.
4. Proposed revision of the Pharmacy Practice Act

11:00 a.m.

The meeting with the representatives of Ohio's Colleges of Pharmacy was concluded and Mr. Repke moved that the Board receive Per Diem as follows:

PER DIEM	<u>10/3</u>	<u>10/21</u>	<u>10/22</u>	<u>10/23</u>	<u>10/24</u>	<u>10/25</u>	<u>Total</u>
Adelman	-	1	1	1	1	1	5
Cavendish	-	-	-	-	-	-	0
Hanna	-	1	1	1	1	-	4
Lamping	-	1	1	1	1	1	5
Littlejohn	-	1	1	1	1	1	5
Maslak	-	1	1	1	1	1	5
Neuber	-	1	1	1	1	1	5
Plant	-	-	-	-	-	-	0
Repke	1	1	1	1	1	1	6

The motion was seconded by Mr. Lamping and approved by the Board (Aye-5/Nay-0).

11:22 a.m. Mr. Repke moved that the business meeting be adjourned. The motion was seconded by Mrs. Adelman and approved (Aye-5/Nay-0).

Suzanne L. Neuber, President

Date

Franklin Z. Wickham, Executive Director