Ohio State Board of Pharmacy; 77 South High Street, 17th Floor; Columbus, Ohio 43266-0320
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Minutes Of The Meeting
Ohio State Board of Pharmacy
Cambridge, Ohio
August 6, 7, 8, 9, 1996

TUESDAY, AUGUST 6, 1996

8:15 a.m. ROLL CALL

The State Board of Pharmacy convened in the "Truce" and "Shackleford" Rooms of Salt Fork State Park Lodge, Cambridge, Ohio with the following members present:

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.; Ruth Plant, R.Ph.; and Nicholas Repke, Public Member.

Also present were Assistant Attorney General Mary Hollern; William Winsley, Assistant Executive Director; Nancy Little, Licensing Administrator; Tim Benedict, Compliance Administrator; David Rowland, Legal Affairs Administrator; and Robert Cole, Compliance Supervisor.

RES. 97-003 President Neuber administered the following Oath of Office to new Board member Diane Cohen Adelman:

I, *Diane Cohen Adelman*, as a Member of the Ohio Board of Pharmacy do solemnly swear to uphold the Constitution of the United States and the state of Ohio; to impartially enforce the laws governing the profession of pharmacy and the legal distribution of drugs in the state of Ohio; and carry out the responsibilities of the Board as mandated by the laws of the state of Ohio without bias or prejudice, so help me God.

RES. 97-004 President Neuber then announced that the following appointments were made regarding Board member responsibilities:

Adelman——— Exams/Internship/Reciprocity
Cavendish —— Legislation/Rules
Hanna ——— Continuing Education
Lamping ——— Consumer Affairs/Public Relations
Littlejohn ——— Personnel
Maslak ——— Licensure/Registration
Neuber ——— Compliance/Enforcement
Plant ——— Administration/Probationary Reports
Repke ——— Budget/Finance

RES. 97-005 Mr. Winsley presented the Board with the names of the candidates for licensure by reciprocity who appeared in Columbus for the jurisprudence review on Wednesday, July 30, 1996:

Adams, Joan M.	03-3-21969	Pennsylvania
Arno, Robin M.	03-3-21972	West Virginia

Baker, James L.	03-3-21975	Pennsylvania
Baker, Sheri L.	03-3-21968	Pennsylvania
Darr, Denise E.	03-3-21973	Missouri
Garnick, James J.	03-3-21969	Texas
Harper, Karen J.	03-3-21967	North Carolina
Merse, Chad P.	03-3-21953	Kentucky
Park, Craig S.	03-3-21977	Colorado
Riggle, Philip B.	03-3-21981	Pennsylvania
Satterfield, Robyn E.	03-3-21983	West Virginia
Ten Eick, Andrew P.	03-3-21971	Iowa
Tullis, Matthew W.	03-3-21984	Texas
Usalis, Mary B.	03-3-21959	Nebraska
Webster, Timothy M.	03-3-21979	Kentucky

Mr. Lamping moved that the candidates be approved and their licenses (identification cards) to practice pharmacy in Ohio be issued by the office. The motion was seconded by Mr. Littlejohn and approved (Aye-6/Nay-0).

RES. 97-006 Mrs. Plant moved that the names of the successful candidates for licensure by examination be memorialized in these Minutes. The motion was seconded by Mr. Maslak and approved (Aye-6/Nay-0).

Laura Ann Adcock; Toledo, OH	03-3-21729
Sofia Ahmad; Toledo, OH	03-3-21817
Tamalisa Leot Al-Sultan; Ada, OH	03-3-21523
Richard Lee Alexander; Paulding, OH	03-3-21621
Troy Thomas Allan; Bloomingdale, OH	03-3-21716
Theresa Mary Amshoff; West Chester, OH	03-3-21811
Georgann Anetakis; Broadview Heights, OH	03-3-21669
Leila A. Ariss-Chehab; Toledo, OH	03-3-21816
Rita Austalosh; Campbell, OH	03-3-21800
Michael Dennis Bahmer; West Lafayette, OH	03-3-21660
Rupina K. Bains; Bethel Park, PA	03-3-21915
Stacey Anne Baltas; Northfield, OH	03-3-21914
Michelle Ann Barhite; Toledo, OH	03-3-21698
Christine Ann Basilone; Kettering, OH	03-3-21828
Beth Renee Beachy; Plain City, OH	03-3-21759
Philip Irving Begany; Fairview Park, OH	03-3-21785
William Thomas Berkey; Toledo, OH	03-3-21932
Jeremy Dean Best; Arlington, OH	03-3-21919
Eric Damian Bizjak; Twinsburg, OH	03-3-21833
Thomas E. Board; Gahanna, OH	03-3-21922
Timothy Robert Bodle; Westerville, OH	03-3-21685
Craig Matthew Bogner; Toledo, OH	03-3-21745
Joseph S. Bradac; Masury, OH	03-3-21612
Woodrow A. Brooks; Akron, OH	03-3-21899
Briana Gail Brown; Middletown, OH	03-3-21872
Dea Lynn Brueggemeyer; Cincinnati, OH	03-3-21916
Mark Edward Bumpus; Mentor, OH	03-3-21771
Cheryl Lynn Burke; Columbus, OH	03-3-21659
Kelly Anne Burke; Broadview Heights, OH	03-3-21706
Thomas Alan Burke; Columbus, OH	03-3-21658
Bradley David Buroker; Springfield, OH	03-3-21754
Dixie Ann Butz; Sylvania, OH	03-3-21938
Elizabeth Joanne Cahill; Mansfield, OH	03-3-21721
Stacy L. Calkins; East Sparta, OH	03-3-21726
Erica Lynne Campbell; Columbus, OH	03-3-21895
Melissa Lynn Capper; Canton, OH	03-3-21804
Craig Andrew Carafa; Columbus, OH	03-3-21894
Gregory A. Carroll; Lakewood, OH	03-3-21920
Joseph V. Carter; Maumee, OH	03-3-21857
Lynelle L. Chan; Toledo, OH	03-3-21700
Adel Chehab; Toledo, OH	03-3-21815

Ingrid Chung; Westerville, OH	03-3-21717
Melissa M. Collins; Toledo, OH	03-3-21911
Statia Elizabeth Cordle; Carroll, OH	03-3-21610
Ryan Matthew Cox; Gahanna, OH	03-3-21926
Jeffrey Paul Czuba; Fairview Park, OH	03-3-21768
Julie C. Dadey; Pittsburgh, PA	03-3-21877
Candace Marie Daubner; Youngstown, OH	03-3-21856
Melanie Ann Davidson; Hillsboro, OH	03-3-21837
Marcie Lynne Day; Poland, OH	03-3-21667
Nicole Ann Dean; North Canton, OH	03-3-21640
Staci Rae Dermer; Warren, OH	03-3-21773
Cynthia Kay Derrow; Delphos, OH	03-3-21907
Karen Lynn Dewey; Euclid, OH	03-3-21784
Jennifer Ann Dieringer; Delphos, OH	03-3-21839
Donald Anthony Dietrich; Jefferson, OH	03-3-21750
Gina Marie Diorio; Mingo Junction, OH	03-3-21613
Mark Edward Doerr; Austintown, OH	03-3-21880
Marsha Neil Dorusha; Huber Heights, OH	03-3-21695
William Milan Dragojevic; Warren, OH	03-3-21720
Lara A. Drenning; Fostoria, OH	03-3-21661
Brian Douglas Drescher; Cortland, OH	03-3-21787
Jennifer Lee Earnest; Youngstown, OH	03-3-21674
Nedra Nichelle Ellis; Cincinnati, OH	03-3-21780
Susan Enyedy; Ridgway, PA	03-3-21808
Mary Genevieve Evers; Reading, OH	03-3-21736
Regina Sue Fairchild; Blissfield, MI	03-3-21876
Lucie Feghali; Youngstown, OH	03-3-21865
Tricia Ann Fenner; New London, OH	03-3-21861
Lisa D. Fillwock; Cortland, OH	03-3-21709
Christopher L. Frederick; Franklin, OH	03-3-21834
Julie Lynn Freed; Columbus, OH	03-3-21933
Maria Ann Friedt; Wadsworth, OH	03-3-21778
Kelly Lynne Fudge; Granville, OH	03-3-21859
John Christopher Fueston; Mansfield, OH	03-3-21775
Ethan Bernard Gallery; Kirkville, NY	03-3-21918
Jennifer Lynn Garrison; Waterville, OH	03-3-21793
Matthew Michael Gastaldo; Gahanna, OH	03-3-21925
Kikelola S. Gbadamosi; Columbus, OH	03-3-21921
Stephen Michael Geltch; Boardman, OH	03-3-21686
Lorie Ann Gentile; Sagamore Hills, OH	03-3-21620
Brian Frank George; Lexington, OH	03-3-21735
Anthony Thomas Gerlach; Columbus, OH	03-3-21821
Shannon S. Gettings; Belmont, WV	03-3-21614
David Ghazarian; Akron, OH	03-3-21652
Tad Andrew Gomez; Columbus, OH	03-3-21681
William Charles Gregory; Waterville, OH	03-3-21744
Jill Renee Kay Hafner Griffith; Minerva, OH	03-3-21796
Matthew Steven Grisik; Hudson, OH	03-3-21664
Theresa Michele Gue; Fairview Park, OH	03-3-21840
Charles R. Haas; Chillicothe, OH	03-3-21656
Travis Scott Hall; Cincinnati, OH	03-3-21854
Robin Melissa Hallas; Youngstown, OH	03-3-21643
Denise Irene Haney; Canton, OH	03-3-21863
Kevin Mark Haney; Canton, OH	03-3-21825
Jennifer L. Hanratty; Ada, OH	03-3-21649
Christine R. Harmon; Berlin Center, OH	03-3-21799
Michelle Lynn Hartman; Sunman, IN	03-3-21657
Sandra Kaye Hays; Stow, OH	03-3-21819
Bradley Edward Hein; Milford, OH	03-3-21790
Erik Charles Heinrich; Parma Heights, OH	03-3-21803
Christina Linn Helwagen; Circleville, OH	03-3-21678
Sean Christopher Higbee; Lucasville, OH	03-3-21619
Todd Michael Hill; Massillon, OH	03-3-21733
Jane Marie Hnatiuk; Parma, OH	03-3-21680

Trang Vu Hoang; Cincinnati, OH	03-3-21741
Laura Noel Hoffman; Caledonia, OH	03-3-21884
Scott Joseph Hoffman; Cincinnati, OH	03-3-21886
Elaine Courtney Hollis; Toledo, OH	03-3-21874
Douglas A. Holly; Port Clinton, OH	03-3-21713
Alan Patrick Horvath; Martins Ferry, OH	03-3-21869
Janet Laurel Hubbard; Elyria, OH	03-3-21638
Linda Sue Huber; Westerville, OH	03-3-21942
Jinny Jin Huh; Gahanna, OH	03-3-21883
Ruba Husein-Jadallah; Copley, OH	03-3-21632
Glenn Thomas Huth; Barberton, OH	03-3-21634
Thach Cam Huynh; Toledo, OH	03-3-21718
Nahla Ibrahim; Shaker Heights, OH	03-3-21931
Brad J. Jewell; St. Clairsville, OH	03-3-21924
Shawn Thomas Johnson; Newton Falls, OH	03-3-21753
Christina D. Jones; Milford Center, OH	03-3-21618
Jennifer Ann Jones; Trotwood, OH	03-3-21935
Darla Julian; Weirton, WV	03-3-21830
Aaron D. Junk; Maple Heights, OH	03-3-21715
Michael Edward Kacsmar; Martins Ferry, OH	03-3-21903
Kristen Leigh Kaczmarek; Columbus, OH	03-3-21675
Tyler Jay Kaib; Zanesville, OH	03-3-21901
Thomas M. Kamlowsky; Euclid, OH	03-3-21654
Kimberly Lynn Kear; Sylvania, OH	03-3-21943
Edward Joseph Kellett; Uniontown, OH	03-3-21728
Suzanne A. Kenkel; Cincinnati, OH	03-3-21875
Matthew P. Kern; Holland, OH	03-3-21762
Gregory Allen Kingsbury; Grove City, OH	03-3-21550
Julie Ann Kishman; Vermilion, OH	03-3-21798
Roy J. Klass; Centerville, OH	03-3-21850
Blythe Marie Klepeisz; Cincinnati, OH	03-3-21789
Joanna Marie Klepzig; N. Royalton, OH	03-3-21937
Suzanne Marie Kossick; Crestline, OH	03-3-21781
Robert Dennis Kovalchik; Columbus, OH	03-3-21893
Lisa A. Krajnak; Lyndhurst, OH	03-3-21774
James J. Krosse; Painesville, OH	03-3-21633
James Scott Kuehn; Dublin, OH	03-3-21885
Richard George Laskey; Canton, OH	03-3-21603
Shelly Ann Lewis; Loveland, OH	03-3-21844
Beth Anne Libbert; West Chester, OH	03-3-21737
Christina V. Lobur; Seven Hills, OH	03-3-21742
Linda C. Lorenz; Tavernier, FL	03-3-21892
Douglas W. Lukens; Dayton, OH	03-3-21679
Shelley Louise Lynch; Centerville, OH	03-3-21616
Michael Anthony Maas; Canal Fulton, OH	03-3-21630
Kendra Carole Maggard; Franklin, OH	03-3-21910
Leigh Ann Majersky; Cortland, OH	03-3-21708
Christine Lee Maltry; Chardon, OH	03-3-21764
Michelle Lynn Martini; Cincinnati, OH	03-3-21767
Chad Everett Mathews; Columbus, OH	03-3-21866
Nichole Marie Mayer; Cincinnati, OH	03-3-21694
Cynthia Jo McClure; Columbus, OH	03-3-21841
Jennifer Jolynn McClure; Paulding, OH	03-3-21757
Deborah S. McCray; Sheffield Lake, OH	03-3-21891
JoEllen McEldowney; Cincinnati, OH	03-3-21873
Melissa Ann McElroy; Cincinnati, OH	03-3-21909
Casey Ryan McFadden; Chillicothe, OH	03-3-21611
Maureen Therese McHale; Massillon, OH	03-3-21777
Lisa Anne McIntyre; Oregon, OH	03-3-21683
Chad Eric McKenzie; Bellefontaine, OH	03-3-21684
Melissa Marie McPheron; Elida, OH	03-3-21648
Teresa Mae Medvec; Struthers, OH	03-3-21673
Ryan James Meikle; Warren, OH	03-3-21801
Janet Meister; Bellefontaine, OH	03-3-21722

Karey Ann Melnik; Warren, OH	03-3-21788
Mary E. Menegay; Louisville, OH	03-3-21852
Scott Stephen Messbarger; Lewis Center, OH	03-3-21636
Nancy Jean Messer; Cincinnati, OH	03-3-21671
Connie Lynn Metheny; Westlake, OH	03-3-21711
Elie B. Mezher; Cincinnati, OH	03-3-21670
Susan Anne Middendorf; Cincinnati, OH	03-3-21779
Matthew Lee Miles; North Ridgeville, OH	03-3-21663
Robert Joseph Miller; Mayfield Heights, OH	03-3-21608
Tamara Jacqueline Miller; Cincinnati, OH	03-3-21888
Kent Matthew Moldovan; Ada, OH	03-3-21898
Mark Joseph Monteleone; Vermilion, OH	03-3-21625
Heather Lea Moore; Centerburg, OH	03-3-21871
Jennifer Renee Moore; Toledo, OH	03-3-21807
Jodi Lyn Mullins; Tallmadge, OH	03-3-21765
Amy L. Murphy; New Brighton, PA	03-3-21702
Jamie Robert Murphy; N. Ridgeville, OH	03-3-21413
Lisa Marie Newnham; Akron, OH	03-3-21849
Triet Ngoc Nguyen; Columbus, OH	03-3-21615
Laura Elise O'Neil; Cincinnati, OH	03-3-21655
Sheri Lynn Oberlander; Columbus, OH	03-3-21734
Mark Alan Oen; Wapakoneta, OH	03-3-21810
Jason Scott Opritza; Cuyahoga Falls, OH	03-3-21723
Laurie Ann Owens; Loveland, OH	03-3-21853
Allison Pabst; Dayton, OH	03-3-21783
Sarah Jane Pakulski; Toledo, OH	03-3-21835
Scott Patrick Payne; Cincinnati, OH	03-3-21752
Michelle Renee Pemberton; Cincinnati, OH	03-3-21769
Thu Minh Pham; Cincinnati, OH	03-3-21672
Mary Elizabeth Piekarski; Cincinnati, OH	03-3-21897
Scott David Podolan; North Royalton, OH	03-3-21770
Jeffrey Paul Pohler; Fairfield, OH	03-3-21813
Jeffrey Alan Post; Centerville, OH	03-3-21682
Paula Joy Potts; Broadview Hts., OH	03-3-21749
Brian J. Pratt; Perrysburg, OH	03-3-21927
Karen F. Prenger; Columbus, OH	03-3-21595
William Merle Preston; McGuffey, OH	03-3-21668
Bobbie Jean Putney; Cincinnati, OH	03-3-21766
Michael D. Quigley; Toledo, OH	03-3-20972
Lorinda Kay Rasor; Columbus, OH	03-3-21904
Julie Ann Reto; Beavercreek, OH	03-3-21824
Michael D. Rynearson; Medina, OH	03-3-21792
Julie Marie Salisbury; Ottawa, OH	03-3-21693
Denise Regina Sand; Cincinnati, OH	03-3-21794
Brian Richard Sargent; Cincinnati, OH	03-3-21820
Kelley A. Schmid; Sebring, OH	03-3-21696
Christopher Earl Schneider; Bowling Green, OH	03-3-21851
Roger B. Schultheis; Nashport, OH	03-3-21776
Kristina Secnik; Kirtland, OH	03-3-21725
Valerie Lynn Seidel; Greenwich, OH	03-3-21703
Wallace K. Sergent; Cincinnati, OH	03-3-21758
Nicole Rochelle Sharp; Beavercreek, OH	03-3-21732
Philip James Sheridan; Lancaster, OH	03-3-21843
Toby Wayne Silhavy; Winchester, OH	03-3-21879
Casey Vaughn Smith; Rittman, OH	03-3-21896
Lawrence Edward Smith; Cincinnati, OH	03-3-21707
Rachel Therese Smith; Mansfield, OH	03-3-21748
Melissa Anne Smitkowski; Amherst, OH	03-3-21818
Elizabeth Anne Snelling; Lancaster, OH	03-3-21626
Teresa Lynn St. John; Oak Harbor, OH	03-3-21809
Sarah Ann Steele; Dublin, OH	03-3-21651
Ronald H. Stevens; Zanesville, OH	03-3-21936
Craig Daniel Stiens; Cincinnati, OH	03-3-21547
Leigh Stratton Stoeber; Cincinnati, OH	03-3-21639

Edward Jay Stoepfel; Fostoria, OH	03-3-21642
Amy Jo Strauss; Bedford, OH	03-3-21738
Daniel Scott Streetman; Huntington, WV	03-3-21826
Steve Suhay; Columbus, OH	03-3-21622
Kelly Jean Swensgard; Massillon, OH	03-3-21690
Raymond Sykola; New Concord, OH	03-3-21930
Elizabeth Talis; Lyndhurst, OH	03-3-21953
Deborah Lynn Thatcher; Oregon, OH	03-3-21740
Pamela A. Therriault; Tiffin, OH	03-3-21836
Jamy Gale Thompson; Marietta, OH	03-3-21692
Jeanine A. Thompson; Dayton, OH	03-3-21697
Cindy Thuy Tran; Columbus, OH	03-3-21838
Amy Renee Treon; Englewood, OH	03-3-21870
James P. Tsikouris; Cambell, OH	03-3-21900
Tuan B. Tu; Sheffield, OH	03-3-21527
Celeste Marie Urbanski; Maple Heights, OH	03-3-21806
Charles Thomas Valenti; W. Pittston, PA	03-3-21940
Katrina Marie Vaske; Springfield, OH	03-3-21719
Timothy James Vaughn; Columbus, OH	03-3-21864
Mary Frances Veliconia; South Euclid, OH	03-3-21812
Jane Marie Wainscott; Avon Lake, OH	03-3-21755
Ariane Danielle Walker; Vienna, OH	03-3-21860
Christina Jane Weer; Columbus, OH	03-3-21913
Bradley Paul White; North Canton, OH	03-3-21701
Helen Mary Wickham; Columbus, OH	03-3-21827
Andrew James Wilhelm; St. Leon, IN	03-3-21908
Shannon Marie Williams; Mason, OH	03-3-21905
Carmen Sue Wilson; Cincinnati, OH	03-3-21617
Sara Jo Wilson; Cincinnati, OH	03-3-21902
Tracy M. Wingate; Toledo, OH	03-3-21791
Heidi Marie Woebkenberg; Jackson, OH	03-3-21602
Kimberly Rhea Wong; Cincinnati, OH	03-3-21724
Paula Diane Wood; Canton, OH	03-3-21687
Chad R. Worz; Cincinnati, OH	03-3-21782
Albert Leroy Wright; Conneaut, OH	03-3-21646
Jeanette Louise Yingling; West Carrollton, OH	03-3-21906

Mr. Lamping moved that the Board go into Executive Session for the purpose of conferring with the Assistant Attorney General regarding pending and imminent court matters and the investigation of complaints against licensees and registrants. The motion was seconded by Mrs. Plant and a Roll Call vote was conducted by President Neuber as follows: Adelman-Yes, Lamping-Yes, Littlejohn-Yes, Maslak-Yes, Plant-Yes, and Repke-Yes.

9:20 a.m.

RES. 97-007 The Executive Session was concluded and the meeting opened to the public. Mr. Lamping moved that the Board not approve the proposed settlement agreement in the matter of Tom Bridge, R.Ph. The motion was seconded by Mr. Repke and approved (Aye-6/Nay-0).

RES. 97-008 Tim Benedict submitted the following request for a waiver pursuant to paragraph (A) of Ohio Administrative Code Rule 4729-5-11:

Terry A. Reed, R.Ph. (03-1-09608)
Mingo Pharmacy - (02-0553500)
Steubenville Pharmacy Services - (02-0962000)

Following discussion, Mrs. Plant moved that the waiver be granted for a period not to exceed one year. The motion was seconded by Mr. Lamping and approved (Aye-6/Nay-0).

Material regarding the next biennial budget (FY 98-99) was presented to the Board members by staff and discussed in detail.

RES. 97-009 The Executive Director distributed material regarding the Schering "Medication Reminder Program" to Board members for their review and consideration. Following discussion, the Board directed staff to inform Schering that the program would violate the Board's patient confidentiality rule [paragraph (G) of OAC Rule 4729-5-17] and is misleading. The Board noted that the program is a marketing program and has nothing to do with professional pharmacy practice. The disclosure of prescription information for purposes of marketing and to persons who are not licensed health care professionals providing professional services to the patient is not in the best interest of the patient. Such disclosure will not be permitted in the state of Ohio by the Board.

RES. 97-010 Mr. Winsley reported that proposed amended refiled rules 4729-5-01 and 4729-5-30 appeared on the consent agenda of the Joint Committee on Agency Rule Review during their meeting on July 9, 1996. Mrs. Adelman moved that the following amended rules be adopted by the Board effective September 1, 1996. The motion was seconded by Mrs. Plant and approved (Aye-6/Nay-0).

Rule 4729-5-01 **Definitions**.
(Amplifies: 4729.02, 4729.26, 4729.27, 4729.28, 4729.54, 4729.66)

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 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.

Rule 4729-5-30 **Manner of issuance of prescription**.
(Amplifies: 3719.06, 3719.28, 4729.02, 4729.37, 4729.66)

(A) A prescription, to be effective, must be issued for a legitimate medical purpose by an individual practitioner or advanced practice nurse approved pursuant to section 4723.56 of the Revised Code acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law.

(B) All prescriptions shall be dated as of and signed on the day when issued, and shall bear the full name and address of the patient.

(C) All written prescriptions issued by a practitioner or advanced practice nurse approved pursuant to section 4723.56 of the Revised Code shall bear the full name and address of the prescriber and shall be manually signed by the prescriber in the same manner as he/she would sign a check or legal document.

(D) An original signed prescription (for other than a schedule II controlled substance except as noted in rules 4729-17-09 and 4729-19-02 of the Administrative Code) may be transmitted as an "other means of communication" to a pharmacist by the use of a facsimile machine only by a practitioner, the practitioner's agent, or an advanced practice nurse approved pursuant to section 4723.56 of the Revised Code. Such a facsimile shall only be valid as a prescription if a system is in place that will allow the pharmacist to maintain the facsimile as a part of the prescription record including the positive identification of the practitioner and his/her agent or of the advanced practice nurse, as well as positive identification of the origin of the facsimile. The pharmacist must record the prescription in writing pursuant to section 4729.37 of the Revised Code or store the facsimile copy in such a manner that will allow retention of the prescription record for three years from the date of the last transaction. The original signed prescription from which the facsimile is produced shall not be issued to the patient. The original signed prescription must remain with the patient's records at the prescriber's office or the institutional facility where it was issued. A facsimile of a prescription received by a pharmacist in any manner other than transmission directly from the practitioner, the practitioner's agent, or the advanced practice nurse approved pursuant to section 4723.56 of the Revised Code shall not be considered a valid prescription, except as a copy of a prescription pursuant to rule 4729-5-24 of the Administrative Code.

(E) All prescriptions shall specify the number of times or the period of time for which the prescription may be refilled. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.

(F) Prescriptions for dangerous drugs may not be dispensed for the first time beyond six months from the date of issuance by a practitioner or an advanced practice nurse approved pursuant to section 4723.56 of the Revised Code.

(G) Prescriptions for dangerous drugs and controlled substances in schedule V may not be authorized for refill beyond one year from the date of issuance. Prescriptions for controlled substances in schedules III and IV shall be authorized for refill only as permitted by section 3719.05 of the Revised Code. Prescriptions for controlled substances in schedule II may not be refilled.

(H) A prescription may be refilled only as expressly authorized by the practitioner or the advanced practice nurse approved pursuant to section 4723.56 of the Revised Code, either in writing or orally. If no such authorization is given, the prescription may not be refilled.

(I) The drug(s) in a compounded prescription or drug product shall be identified by the product trade name or generic name.

(J) No prescription shall be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice. A "coded prescription" is one which bears letters, numbers, words or symbols, or any other device used in lieu of the name, quantity, strength and directions for its use, other than those normal letters, numbers, words, symbols, or other media recognized by the profession of pharmacy as a means of conveying information by prescription. No symbol, word, or any other device shall be used in lieu of the name of said preparation.

(K) The agent of a practitioner who transfers a facsimile of an original prescription or transmits an oral prescription or authorization of a refill for a dangerous drug must identify themselves by full name and the pharmacist shall make a record of the practitioner's agent on the original prescription and, if used, on the alternate system of recordkeeping.

(L) When forms are used that create multiple copies of a prescription issued to a patient by a practitioner or an advanced practice nurse approved pursuant to section 4723.56 of the Revised Code, the original ~~copy~~ PRESCRIPTION which ALSO bears the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.

(M) A PHARMACIST MAY ACCEPT, WITHOUT FURTHER VERIFICATION OF THE PRESCRIBER'S IDENTITY REQUIRED, A PRESCRIPTION THAT HAS BEEN TRANSMITTED BY MEANS OF A BOARD APPROVED AUTOMATED PAPERLESS SYSTEM. THE SYSTEM SHALL REQUIRE POSITIVE IDENTIFICATION OF THE PRESCRIBER AS DEFINED IN RULE 4729-5-01 OF THE ADMINISTRATIVE CODE AS WELL AS THE FULL NAME OF ANY AUTHORIZED AGENT OF THE PRESCRIBER WHO TRANSMITS THE PRESCRIPTION.

Rule 4729-5-31 **Criteria for licensure by examination**.
(Amplifies: 4729.07, 4729.08, 4729.13, 4729.26)

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

(1) THE EXAMINATION SHALL CONSIST OF THE "NATIONAL ASSOCIATION OF BOARDS OF PHARMACY LICENSURE EXAMINATION (NABPLEX)" AND A JURISPRUDENCE EXAMINATION COMPILED BY THE BOARD OR THE "NATIONAL ASSOCIATION OF BOARDS OF PHARMACY."

~~(1)~~ (2) The ~~necessary~~ MINIMUM passing grade FOR THE "NATIONAL ASSOCIATION OF BOARDS OF PHARMACY LICENSURE EXAMINATION (NABPLEX)" is ~~a score of at least~~ seventy-five. ~~on the "National Association of Boards of Pharmacy Licensure Examination (NABPLEX)."~~ Any candidate failing to attain a ~~score~~ GRADE of seventy-five on the NABPLEX examination will be required to repeat the NABPLEX examination.

~~(2) The minimum passing grade for the "National Association of Boards of Pharmacy Federal Drug Law Examination (FDLE)" is a score of at least seventy-five. Any candidate failing to attain a score of seventy-five on the FDLE examination will be required to repeat the FDLE examination.~~

(3) The minimum passing grade for the jurisprudence examination ~~compiled by the board~~ is seventy-five. Any candidate who fails to receive a grade of seventy-five on the jurisprudence examination will be required to repeat the jurisprudence examination.

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

(1) The examination shall consist of the "National Association of Boards of Pharmacy Licensure Examination (NABPLEX)~~", the "National Association of Boards of Pharmacy Federal Drug Law Examination (FDLE)",~~ and a jurisprudence examination compiled by the board or the "National Association of Boards of Pharmacy."

(2) The ~~necessary~~ MINIMUM PASSING grades for renewal of the pharmacist's identification card is a seventy-five on each exam.

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

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

~~(c) Any candidate for renewal of an identification card who fails to receive a grade of seventy-five on the FDLE examination shall make application and remit the fee established by the board for~~

~~re-examination.~~

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

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

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

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

RES. 97-011 Mr. Winsley then discussed the recommendations of the 1996 Ad Hoc Advisory Committee on Rule Review. The committee recommended that no changes be made regarding the rules on Administrative Procedures (OAC Chapter 4729-1), the rules on Impairment (OAC Chapter 4729-6), or Rules 4729-3-02, 4729-3-09, 4729-5-25, and 4729-9-07; that Rules 4729-3-01, 4729-3-03, 4729-3-04, 4729-3-05, 4729-5-07, 4729-5-17, 4729-5-19, 4729-5-24, 4729-9-01, 4729-9-04, and 4729-9-16 be amended and that new rules 4729-5-26, 4729-5-27, and 4729-5-28 be adopted. After a review of each recommendation made by the committee, and the Board's discussion of amending Rule 4729-1-02 to increase the fee for the Sunshine Notice, Mr. Littlejohn moved that the Board propose to amend and adopt the following rules pursuant to applicable state laws and rules:

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~~ 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 towards 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 supervised practical experience and such affidavits have been accepted by the board of pharmacy.

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

The following recordkeeping requirements do not apply to drugs dispensed pursuant to an in-patient 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 manually record his/her name or initials on the original prescription. 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 record-

keeping 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 practitioner. 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 by the practitioner, the pharmacist must record the date and time that he/she contacted the prescriber and obtained approval.

(5) The MANUAL name or MANUAL initials 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 by the practitioner. Only the pharmacist responsible for filling or refilling the prescription or medication order shall make this record.

~~(6) If the alternate system of recordkeeping utilizes an automated data processing system, it is subject to the following requirements:~~

~~(a) It must be capable of providing retrieval (via CRT display or hard-copy printout), within three working days, excluding holidays and weekends, of original prescription order information for all prescriptions filled within the previous three years. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the practitioner; full name and address of the patient; full name and address of the practitioner; directions for use; the name, strength, dosage form, quantity of the drug prescribed (and quantity dispensed if different from the quantity prescribed); and the total number of refills authorized by the prescribing practitioner.~~

~~(b) It must be capable of providing retrieval (via CRT display or hard-copy printout), within three working days, excluding holidays and weekends, of the current refill history of each prescription serially. This refill history must include, but is not limited to, the name of the drug dispensed, the date of refill, the quantity dispensed, the name or initials of the dispensing pharmacist for each refill, the total number of refills dispensed to date for that prescription order, and the location where the refill was dispensed if different.~~

(c) Documentation of the fact that the prescription refill information entered into the automated data processing system is correct must be provided by the individual pharmacist who makes use of such system. A hard-copy printout of each prescription refill data must be made and shall include, at a minimum, the following data: date of dispensing; prescription number; patient name; name, strength (if applicable), and quantity of drugs; identification of pharmacy and pharmacist; and 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. In lieu of such a printout, the pharmacy must maintain a tamper evident log book in which shall be entered, at a minimum, the following data: date of dispensing and prescription number. The dispensing pharmacist must manually record his/her name or initials on each data entry at the time of dispensing; or, as an alternative to the recommended procedure of manually initialing every data entry, each individual pharmacist involved in dispensing drugs must enter into a tamper evident log book, at a minimum, the following data for each prescription filled: date of dispensing; prescription number; patient name; name, strength (if applicable), and quantity of drug; identification of pharmacy and pharmacist; and 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. Any such log book must be maintained at the licensed location employing such a system for a period of three years from the date of dispensing.

(d) Any such automated data processing 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. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any drug (by either brand or generic name or both). Such printout must indicate the name of the prescriber, name and address of the patient, quantity dispensed, date of dispensing, name or initials of the dispensing pharmacist, and the prescription number. In any automated data processing system employed by a pharmacy, the central recordkeeping location must be capable of sending the

~~printout to the pharmacy within three working days, excluding holidays and weekends, and verify the printout transmittal capability of the system by documentation (e.g., postmark).~~

~~(e) In the event that the automated data processing system experiences down-time, a record of all refills dispensed during such time must be recorded on the back of the original prescription, and such data entered into the automated data processing system as soon as it is available for use again. 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 an automated data processing system of prescription records must develop a method of record-keeping capable of providing retrieval (via CRT display or hard-copy printout), within three working days, excluding holidays and weekends, of prescription order information for all prescriptions filled or refilled within the previous three years. This shall include, at a minimum, the following data: pharmacy name and address; original prescription number; date of issuance of the original prescription order by the practitioner; full name and address of the patient; full name and address of the practitioner; directions for use; name, strength, dosage form, quantity of the drug prescribed (and quantity dispensed if different from the quantity prescribed); total number of refills authorized by the prescribing practitioner; total number of refills dispensed to date for that prescription order; date of refill; location where the refill was dispensed if different; and name or initials of the dispensing pharmacist. Such data must be accessible by patient profile, alphabetically or serially by prescription number.~~

~~(g) Any pharmacy intending to maintain records of dispensing at a location other than the place licensed with the board of pharmacy must first send notification to the board; if not contested within sixty days, it will stand as approved.~~

~~(h) The automated data processing system must satisfy all information requirements of rule 4729-5-24 of the Administrative Code, including invalidation of the original prescription record, when transferred between pharmacies accessing the same prescription records or between pharmacies of the same ownership. However, if those systems accessing the same prescription records have the capability of canceling the original prescription record, then all of the requirements of this rule are deemed to have been met.~~

(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) Records of dispensing or administration 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) Any person, other than those listed in paragraphs (G)(1) to (G)(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 for only one year from the date of the consent. 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.~~

~~(H) 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.~~

~~(I)~~ (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.

~~(J) All such records, including consents, memoranda of emergency disclosures, and written requests pursuant to paragraph (G)(7) of this rule, shall be kept on file at the pharmacy for a period of three years in a readily retrievable manner.~~

(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.

4729-5-19 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~~ RULES 4729-5-17 AND 4729-5-26 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~~ RULES 4729-5-17 AND 4729-5-26 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 COMPUTERIZED RECORDKEEPING SYSTEMS.

IF A COMPUTERIZED RECORDKEEPING SYSTEM IS BEING USED AS AN ALTERNATE RECORD-KEEPING SYSTEM PURSUANT TO RULE 4729-5-17 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;

(11) 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 ADMINSTRATIVE 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.

4729-5-27 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.

4729-5-28 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.

4729-9-01 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.

4729-9-16 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.

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

errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

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

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

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

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

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

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

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

(J) Wholesale distributors of dangerous drugs shall establish and maintain accurate and current lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(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.

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

Tim Benedict distributed copies of graphs and data regarding field staff activities for Fiscal Year 96 for review and discussion by the Board.

3:10 p.m. The meeting was recessed until 8:00 a.m., Wednesday, August 7, 1996.

WEDNESDAY, AUGUST 7, 1996

8:05 a.m. ROLL CALL

The following members of the State Board of Pharmacy reconvened in the "Truce" and "Shackleford" Rooms of Salt Fork State Park Lodge, Cambridge, 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.; Ruth Plant, R.Ph.; and Nicholas Repke, Public Member.

Also present were William Winsley, Assistant Executive Director; Nancy Little, Licensing Administrator; Tim Benedict, Compliance Administrator; David Rowland, Legal Affairs Administrator; and Robert Cole, Compliance Supervisor.

The Board began a discussion of the proposed budget for the next biennium. Mrs. Plant moved that the Board go into Executive Session for the purpose of discussing personnel matters. The motion was seconded by Mr. Repke and approved following a Roll Call vote conducted by President Neuber: Adelman-Yes, Lamping-Yes, Littlejohn-Yes, Maslak-Yes, Plant-Yes, and Repke-Yes.

5:00 p.m. The Board recessed until Thursday, August 8, 1996 at 8:00 a.m.

THURSDAY, AUGUST 8, 1996

8:18 a.m. ROLL CALL

The following members of the State Board of Pharmacy reconvened in the "Truce" and "Shackleford" Rooms of Salt Fork State Park Lodge, Cambridge, Ohio in Executive Session and continued their discussion of personnel matters and the proposed budget for the FY 98-99 biennium:

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.; Ruth Plant, R.Ph.; and Nicholas Repke, Public Member.

10:30 a.m.

RES. 97-012 The Executive Session was concluded and decisions reached by the Board were discussed with staff who joined the Board. Staff was informed by the Board President that the following decisions had been reached regarding the budget proposal:

1. Provide funds for the reclassification of the Executive Director's position and funds for a six month overlap (July 1, 1998 - December 31, 1998) in the event that a person from the outside is hired as the new Executive Director.

2. Create the Information Systems Administrator position (Registered Pharmacist); redefine the Licensing Administrator's position to include only licensing responsibilities; and redefine the Assistant Executive Director's position as the Information Management/Quality Assurance Administrator.

3. Add three clerical/technical positions in the office, one at a supervisory level.

4. Add one new Compliance Specialist (Registered Pharmacist) in the field.

12:00 p.m. The Board recessed for lunch.

1:13 p.m. The Board reconvened the meeting and Mrs. Plant moved that the Minutes of the June 24, 25, 26, 27, 28, 1996 meeting be approved as amended. The motion was seconded by Mr. Lamping and approved (Aye-5/Nay-0/Abstain-1[Adelman]).

Mrs. Plant moved that the Minutes of the Meeting of July 24, 1996 be approved. The motion was seconded by Mr. Repke and approved (Aye-5/Nay-0/Abstain-1[Adelman]).

RES. 97-013 The Executive Director presented the invoice for the Annual Membership dues for the National Association of State Controlled Substance Authorities. Mr. Lamping moved that the Board approve payment of the $150 membership dues for July 1, 1996 through June 30, 1997. Mr. Repke seconded the motion and it was approved (Aye-6/Nay-0).

RES. 97-014 The Board next considered the petition of Lite & Rite to except OPTIMA™ from Schedule V of Ohio's Controlled Substance Schedules pursuant to Ohio Revised Code Section 3719.44 and Ohio Administrative Code Chapter 4729-12. Following discussion of the petition and consideration of the information provided, Mr. Maslak moved that the petition be denied for the following reasons:

1. The product is not distributed, advertised, and promoted in a manner which reduces the likelihood of inappropriate use and/or abuse.

2. The labeling and the name of the product does not reduce the likelihood of inappropriate use and/or abuse.

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

Staff distributed copies of Am. Sub. S.B. 246 and Am. Sub. H.B. 162 to the Board members for their review and consideration during the September Board meeting regarding their implementation, possible Chapter 119. rules, and development of policies. Both bills have been passed by the General Assembly and will be effective before the end of this calendar year.

RES. 97-015 The Board then discussed the Second International Conference on Pharmaceutical Competence which will be held Saturday, September 7, 1996 through Tuesday, September 10, 1996 in Hawaii. Mrs. Adelman moved that the Board authorize the Board President and Executive Director to attend this Conference and that they be reimbursed for all expenses pursuant to state law and rules adopted by the Office of Budget and Management. Mr. Littlejohn seconded the motion and it was approved (Aye-6/Nay-0).

President Neuber announced that the Recruitment Committee would next meet at 7:00 a.m. on Tuesday, September 17, 1996.

Tim Benedict then presented a report regarding the licensees and registrants who are on probation. Three problem areas were identified by Mr. Benedict and the Board directed that he follow up regarding the problems and report back to the Board in September.

RES. 97-016 The Board then reviewed the applications of the following applicants for approval as an in-state provider of continuing pharmacy education:

Children's Medical Center; Dayton	036-262
Robinson Memorial Hospital; Ravenna	036-257
Evelyn Diaz R.Ph., C.D.E.; Cleveland	New

Following a review of the applications and the recommendations of the members of the Advisory Committee on Continuing Pharmacy Education, Mrs. Plant moved that the applicants be approved by the Board. The motion was seconded by Mr. Maslak and approved by the Board (Aye-6/Nay-0).

The Board then discussed a tentative meeting schedule for FY 98. Following discussion, the following dates have been identified as tentative meeting dates:

July 14, 15, 16, 1997	January 12, 13, 14, 1998
August 11, 12, 13, 1997	February 9, 10, 11, 1998
September 8, 9, 10, 1997	March 9, 10, 11, 1998
October 6, 7, 8, 1997	April 6, 7, 8, 1998
November 17, 18, 19, 1997	May 4, 5, 6, 1998
December 8, 9, 10, 1997	June 8, 9, 10, 1998

The Board also directed staff to resume scheduling hearings for Fridays of Board meeting weeks.

Robert Cole, Compliance Supervisor, then conducted an inservice regarding drug accountability audits with the Board members.

4:10 p.m. The Board recessed until Friday, August 9, 1996 at 8:00 a.m.

FRIDAY, AUGUST 9, 1996

8:13 a.m. ROLL CALL

The following members of the State Board of Pharmacy reconvened in the "Truce" and "Shackleford" Rooms of Salt Fork State Park Lodge, Cambridge, Ohio:

Suzanne L. Neuber, R.Ph. (President); Diane Adelman, R.Ph.; Paul Lamping, R.Ph. Joseph Maslak, R.Ph.; Ruth Plant, R.Ph.; and Nicholas Repke, Public Member.

The Board was joined by the following staff members: William Winsley, Assistant Executive Director; Nancy Little, Licensing Administrator; Tim Benedict, Compliance Administrator; David Rowland, Legal Affairs Administrator; and Robert Cole, Compliance Supervisor.

Mr. Repke moved that the Board go into Executive Session for the purpose of discussing the investigation of complaints and charges against licensees and registrants of the Board. The motion was seconded by Mr. Maslak and a roll call vote was conducted by President Neuber as follows: Adelman-Yes, Lamping-Yes, Maslak-Yes, Plant-Yes, and Repke-Yes.

8:22 a.m.

RES. 97-017 The Executive Session was concluded and the meeting opened to the public. Mrs. Plant moved that the Board summarily suspend the license of Mark Schirtzinger, R.Ph. (03-3-17133) for the reason that there is clear and convincing evidence that the continuation of his professional practice and method of distributing controlled substances presents a danger of immediate and serious harm to others. The motion was seconded by Mr. Lamping and approved by the Board (Aye-5/Nay-0).

Compliance Supervisor Robert Cole distributed a memorandum establishing new territories for the Pharmacy Board Specialists for the Board's information.

Licensing Administrator Nancy Little reviewed her written report on licensing activities and issues.

8:30 a.m.

Board member Amonte Littlejohn arrived and joined the meeting.

RES. 97-018 The Board continued discussion regarding the FY 98-99 biennial budget proposal. The Board decided that they would agree to a 50% increase in all fees to address the funding crisis created by the enactment of Am. Sub. S.B. 2 by the General Assembly. The Board also agreed to increase the registered pharmacist fees by fifty percent effective July 1, 1997 through Controlling Board action in order to ensure that the money is received during the first fiscal year of the new biennium (FY 98).

Further discussion was held regarding the tentative calendar for FY 98. The Executive Director informed the Board members that he had spoken to both Mr. Cavendish and Mr. Hanna and that they did not have any problem with the proposed schedule. A final decision was delayed until the September meeting when all Board members are present.

10:25 a.m.

John Cassady, Dean of The Ohio State University College of Pharmacy; Ken Hale, Assistant Dean; and Jerry Cable, Director of Experiential Programs joined the Board. The purpose for meeting with the Board was to present the proposed entry-level Pharm.D. program that they are planning to implement during the Autumn Quarter of 1998 and to answer any of the Board members' questions.

11:30 a.m.

The presentation was completed and Mr. Repke moved that the Board receive Per Diem as follows:

PER DIEM	7/24	7/30	8/6	8/7	8/8	8/9	Total
Adelman		1	1	1	1	1	5
Cavendish	1	-	-	-	-	-	1
Hanna	-	-	-	-	-	-	0
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	4
Plant	1	-	1	1	1	1	5
Repke	1	-	1	1	1	1	5

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

11:35 a.m. Mr. Maslak moved that the business meeting be adjourned. The motion was seconded by Mrs. Adelman and approved (Aye-6/Nay-0).

/s/ *Suzanne L. Neuber* /d/ *9/18/96*

Date

Suzanne L. Neuber, President

/s/ *Franklin Z. Wickham*

Franklin Z. Wickham, Executive Director