



# OHIO STATE BOARD OF PHARMACY

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## ANNUAL REPORT TO THE OHIO PHARMACISTS ASSOCIATION

APRIL 24, 1998

### MISSION OF THE BOARD

*The Ohio State Board of Pharmacy shall act efficiently, consistently, and impartially in the public interest to pursue optimal standards of practice through communication, education, legislation, licensing, and enforcement.*

### GOALS

*The goals of the Ohio State Board of Pharmacy are to effectively and efficiently administer and enforce the laws governing the legal distribution of drugs and the practice of pharmacy. The purpose of these laws is to ensure the quality and safety of drugs administered or dispensed to Ohio's citizens; the competency of persons licensed to practice pharmacy in Ohio; and to prevent the diversion of drugs of abuse from the legal channels of distribution for illegal purposes.*

## **INTRODUCTION**

The Board is pleased to present this written report to the members of the Ohio Pharmacists Association at its 120<sup>th</sup> Annual Meeting. The presentation of an annual report to the association is a tradition that started with the establishment of the Board by the Ohio General Assembly in May 1884.

This is my last report to the Association as Executive Director of the Ohio Board of Pharmacy and I take this opportunity to thank you for the support provided to me by the Association's staff, officers, and members during my tenure with the Board. I also thank the officers and members of the Association for the reception held in my honor when I was installed as President of the National Association of Boards of Pharmacy in San Diego last year.

**HEALTH CARE AND A DISSATISFIED PUBLIC** - More than ever, we as health care professionals are reminded each day of how unhappy the public is with traditional medicine. Because of their dissatisfaction with traditional health care and allopathic medicines, the public is increasingly turning to and embracing alternative therapies. I predict that the trend will continue as the price of drugs continues to increase at the rates which we have seen thus far in the first quarter of this calendar year. This is especially true due to the price increases that are occurring for many generic drug products. The Board has received many complaints from consumers who have seen the cost of their generic prescriptions increase at least sixty fold. Many senior citizens are once again facing the problem of either purchasing food or their medications.

Citizens are also communicating to a greater degree than ever before with their elected representatives at both the federal and state level. Consequently, among the major topics being addressed by both Congress and state legislatures are quality health care issues and consumer access to alternative therapies. The major questions resulting from all of the legislative activity is whether or not access to and the quality of health care will improve without significant increases in costs.

Of major significance to practicing health care professionals is the fallout from consumer dissatisfaction with the present health care system's inability to adequately manage pain for both terminal cancer patients and patients suffering from chronic intractable pain. The degree of dissatisfaction has risen to the point that special interest groups such as "Death with Dignity" are calling for disciplinary action by medical boards against those doctors who fail to adequately manage a patient's pain. One can only wonder if the next step is the criminalization of "failure to adequately treat or manage pain" and the criminal prosecution of health professionals who fail to meet the standards set in law.

Why are a large number of practicing health professionals not able to adequately manage pain? Is it due to failure to continue their education and a continuing competency issue? Is it a lack of understanding and knowledge regarding drug law enforcement, licensing and regulatory agencies responsibilities and authority? Are we asking too much of the individual health care professional and is it more of a system problem rather than a failure on the part of individual health professionals? Or is it all of these factors?

Consumers in this country expect the best in medical treatment and are continually being told that our system is the best health care system in the world. Unfortunately, reality is that it is only as good as the practicing health care professional's *understanding and knowledge* regarding current and effective modalities of treatment. The system is also only as good as the tools used by health professionals in making health care decisions.

It is also becoming evident that quality health care can only result from a collaborative effort among the different health professionals. The system must provide each health care professional with the ability to be involved and apply their knowledge and skills collectively in caring for the patient. A collaborative approach will be successful only if the participants share information and effectively communicate with each other.

**COST-EFFECTIVE HEALTH CARE & MANAGED HEALTH CARE** - As a health care professional and consumer exposed to market-driven health care reform and the continuing and incessant demand that health care be cost-effective, I wonder what went wrong, when and how. Who was responsible for health care costs increasing or "getting out of hand" - health care professionals, government, industry, or consumers?

What must we do as health care professionals to meet the expectations of the public? What changes do we need to make in order to ensure that every health care professional has the ability to provide cost-effective health care?

**MARKET SHARE & HEALTH CARE** - Marketing of pharmaceuticals has always had a significant impact on health care in the United States. The impact has been both positive and negative. Marketplace forces have resulted in significant investments in the development and marketing of new drug entities in order to capture the greatest share of the market possible. Without the marketplace incentives, many of the advances in drug therapy would not have occurred.

The marketplace did not work, however, with those medical problems where the market and potential profit was not significant in comparison to the costs involved in developing a new drug or therapy. In these instances, the federal government stepped in with the "orphan drug" program in order to encourage the development of new and better treatment modalities for those medical conditions where the potential for profit is less than the expenditures required.

Until recent years, each new product had to be better than the ones presently in the market place or at least those who made the decisions as to which products would be used had to be convinced that they were better. Unfortunately, today this is not the case in the era of managed care and market share. Market share today is based upon the amount of financial incentives that the person making the decision can garner as to which products will be used in treating patients. Increasingly decisions regarding what drug is to be used in treating patients are not based on what is best for the patient nor what is cost-effective under normal marketplace conditions.

**Cost-Effective Drug Therapy Decisions And The Marketplace** - A recent Associated Press article posted from Santa Fe, New Mexico was titled "**Doctors often turn to new drugs Ads may influence prescription choices, researchers find**". The article stated that "Studies find doctors frequently fail to prescribe some lifesaving older drugs for their patients with bad hearts and high blood pressure, while overusing newer, less effective medicines." The article continued with the following observations:

- Research by doctors from the Massachusetts General Hospital in Boston and presented at an epidemiology conference sponsored by the American Heart Association *"is the latest to lament the slow, often erratic way that new medical knowledge makes its way into everyday practice, as well as the influence of drug company marketing campaigns."*
- *"the result is often less-than-ideal treatment with overpriced drugs."*
- *"Beta blockers, along with diuretics, are also considered to be the best treatments for high blood pressure. They are often available in generic form and cost pennies a day. But many doctors instead prescribe calcium blockers, which came into widespread use in the late 1980s. These drugs are still largely protected by patents and often cost \$2 or \$3 a day."*
- A review of 210 issues of the New England Journal of Medicine by the researchers revealed that *"In 1985, 12 percent of the advertising was for beta blockers, 5 percent for calcium blockers and 4 percent to diuretics. By 1996, 27 percent of the magazine's drug ads were for calcium blockers. The journal did not carry a single ad for beta blockers or diuretics that year. One of the researchers, Dr. Thomas Wang, "said he believes this and other promotions - such as free samples and education programs sponsored by drug companies - at least partly explain the underuse of beta blockers."*

The increasing use of formularies and "preferred drug" programs by pharmacy benefit managers has significantly changed the dynamics of the marketplace forces. This phenomenon has shifted the decision as to what drugs will be prescribed and dispensed from the individual health professional interfacing with and providing professional services to the patient to a corporate official. The corporate official's decision is not necessarily based on what is in the best interest of the patient but the officers and/or stockholders of the corporation.

## **114 YEARS OF PROFESSIONAL PEER REVIEW (1884-1998)**

### **AUTHORITY AND RESPONSIBILITY**

Many laws regarding drugs and their legal distribution have been enacted over the last 114 years by the Ohio General Assembly. These laws have provided the Ohio Board of Pharmacy with the responsibility for administering and enforcing all of the state laws governing the legal distribution of drugs. These laws include the Pharmacy Practice Act; Controlled Substance Act; Dangerous Drug Distribution Act; Pure Food and Drug Act; and the Criminal Code dealing with drugs.

The wide scope of the Board's responsibilities establishes it as the single state agency where the public, health care practitioners and providers, other government agencies, other drug law enforcement agencies, and criminal justice employees may obtain information regarding drugs and the laws or rules governing their distribution in Ohio. These responsibilities result in the Board members having to devote a considerable amount of time conducting Board business.

Board members not only attend and participate in the regularly scheduled business meetings but also participate in special (usually one day) meetings for the purpose of considering a request for a summary suspension of a license, other business items requiring an immediate decision, and meetings regarding specific aspects of the operations of the Board and other health professions or organizations.

As the single state agency responsible for administering and enforcing the laws governing the legal distribution of drugs in Ohio, the Board of Pharmacy impacts on all of the other health professions and health care providers that use drugs in the course of their professional practice or business. The breadth of the Board's responsibilities is demonstrated by the large number of different types of dangerous drug distributors (*see table on Page 37*) licensed with the Board.

Decisions rendered by the Board of Pharmacy impact on every Ohio citizen as well as citizens of other states since the Board's responsibilities and authority also extends to both over-the-counter and prescription medications. The Board is not only responsible for the quality of these products purchased and used by Ohio citizens but also the conditions under which they may be obtained and legally possessed. No other licensing or regulatory board has the broad scope of authority nor enforcement tools as the Ohio Board of Pharmacy to meet its mandated responsibilities.

Radical changes which have occurred during the last few years in the health care delivery system has extended the Ohio Board of Pharmacy's impact throughout the United States. The Board of Pharmacy is the only licensing board in Ohio that licenses and regulates businesses located in Ohio that provide health care services to citizens of Ohio and other states as well as dangerous drug distributors who are located in other states and who provide drugs to Ohio's citizens. As demonstrated by the following table, the Ohio Board licenses wholesale and terminal distributors who are located in 42 other states, the District of Columbia, and Puerto Rico.

**OUT-OF-STATE DANGEROUS DRUG DISTRIBUTORS**  
 FY 97 and FY 98 td (as of 12/31/97)

STATE	FY 97			FY 98 td		
	# WDDD	# TDDD	TOTAL	# WDDD	# TDDD	TOTAL
Alabama	8	2	10	7	1	8
Arkansas	1	0	1	2	0	2
Arizona	9	3	12	7	2	9
California	46	5	51	45	3	48
Colorado	7	1	8	6	1	7
Connecticut	8	0	8	8	0	8
District of Columbia	1	0	1	1	0	1
Delaware	3	0	3	3	0	3
Florida	29	14	43	29	12	41
Georgia	22	1	23	20	0	20
Iowa	3	2	5	3	1	4
Illinois	36	5	41	38	4	42
Indiana	29	13	42	27	7	34
Kansas	2	1	3	2	0	2
Kentucky	20	14	34	19	8	27
Louisiana	3	0	3	4	0	4
Massachusetts	15	2	17	15	2	17
Maryland	6	4	14	10	3	13
Michigan	29	7	36	25	6	31
Minnesota	8	1	9	7	1	8
Missouri	15	2	17	16	2	18
Mississippi	4	2	6	3	2	5
North Carolina	12	1	13	11	0	11
North Dakota	1	0	1	1	0	1
Nebraska	2	1	3	2	0	2
New Hampshire	1	0	1	1	0	1
New Jersey	49	2	51	49	2	51
New Mexico	2	2	4	2	1	3
Nevada	5	3	8	5	1	6
New York	45	1	46	47	0	47
Oklahoma	4	1	5	4	1	5
Oregon	0	0	0	0	1	1
Pennsylvania	38	26	64	34	17	51
Puerto Rico	3	0	3	3	0	3
South Carolina	6	1	7	6	0	6
South Dakota	0	1	1	0	1	1
Tennessee	20	6	26	19	3	22
Texas	24	9	33	26	5	31
Utah	2	0	2	2	0	2
Vermont	1	0	0	1	0	1
Virginia	8	2	10	8	1	9
Washington	3	1	4	3	1	4
Wisconsin	8	1	9	8	1	9
West Virginia	8	13	21	9	9	18
<b>TOTALS</b>	<b>550</b>	<b>150</b>	<b>700</b>	<b>538</b>	<b>101</b>	<b>618</b>

WDDD = Wholesale Distributors of Dangerous Drugs    TDDD = Terminal Distributors of Dangerous Drugs

The scope of the Board's authority and responsibilities also extends to drug crimes and the majority of the complaints received by the Board involve four sections of Ohio Revised Code Chapter 2925. (Drug Crimes): theft of drugs; trafficking in drugs; deception to obtain; and forgery of drug documents (*see table on Page 54*). Due to its law enforcement responsibilities, the Ohio Board of Pharmacy is the only state agency that is legally mandated to cooperate with all agencies charged with enforcing both state and federal laws governing the legal distribution of drugs in Ohio. These agencies include local law enforcement (city, township, county); United States Department of Health and Human Services [Inspector General's office, Food and Drug Administration (FDA), and Consumer Product Safety Commission]; and the United States Department of Justice [Drug Enforcement Administration (DEA) and Federal Bureau of Investigations (FBI)].

**BOARD MEETINGS**

**Fiscal Year 97 (July 1, 1996 - June 30, 1997) Meetings**

The Board held eight regularly scheduled meetings of the full Board in FY 97 for a total of 34 days. One special one-day Board meeting was held in FY 97 for the purpose of considering evidence regarding the summary suspension of pharmacists' licenses whose continued practice or method of distributing controlled substances presented a danger of immediate and serious harm to others. An adjudication hearing was also conducted during this one-day meeting for the purpose of considering evidence and testimony regarding whether or not a pharmacist's license that was summarily suspended due to a felony drug abuse conviction should be reinstated. The license was reinstated by the Board following the hearing and the license to practice placed on probation for one year. Only one of the 11 summary suspensions (*see table on Page 56*) issued by the Board in FY 97 were issued following a special one-day meeting of at least five voting members.

**Fiscal Year 98 (through April 15, 1998) Meetings**

Ten meetings of the full Board have been held to date for the purpose of conducting official Board business and conducting Chapter 119. Adjudication Hearings. Each of these meetings were three days in length (Monday - 8 a.m. through Wednesday- 5 p.m.). Two more regular business meetings are scheduled for the remainder of this fiscal year (May and June). The two remaining business meetings for this year, and the 12 regular business meetings that are tentatively scheduled for FY 99 (July 1, 1998 - June 30, 1999), are three days in length (Monday - 8 a.m. through Wednesday - 5 p.m.).

<u>FY</u>	<u>Number of Meetings</u>	<u>Meeting Days</u>	<u>Days of Per Diem</u>	<u>Hearings Held</u>	<u>Notices Considered</u>	<u>Hearings Pending</u>
98td	10	27td	247td	20	3	9td
97	9	34	293	50	7	10
96	12	40	338	49	7	22
95	14	43	409	51	8	16
94	11	40	401	46 [2]	9	33
93	13	38	341	38	6	47
92	9	38	321	61	7	19
91	8	33	272	37 [15]	38	10
90	8	37	306	98	NA	33

*[Hearings held by one member serving as Hearing Officer]*

NA - not available    td - to date (as of 04/15/98)

Each meeting of the Board is open to the public and the following is a tentative schedule of the meetings through the end of FY 99:

**TENTATIVE BOARD MEETING SCHEDULE**

<u>Date</u>	<u>Time</u>	<u>Location</u>	<u>Purpose</u>
05/04/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
05/05/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
05/05/98	1pm-3pm	77 S. High Street, Room 1922	Reciprocity Hearing
05/05/98	1:30pm-5pm	77 S. High Street, Room 1919	Phar Oper Directors
05/06/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
06/08/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
06/09/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
06/09/98	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
06/10/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
07/02/98	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
07/06/98	8am-5pm	King's Island Inn; King's Mills, Ohio	Board Meeting
07/07/98	8am-5pm	King's Island Inn; King's Mills, Ohio	Board Meeting
07/08/98	8am-5pm	King's Island Inn; King's Mills, Ohio	Board Meeting
08/03/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
08/04/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
08/04/98	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
08/05/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
09/08/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
09/09/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
09/09/98	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
09/10/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
10/05/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
10/06/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
10/06/98	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
10/07/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
11/02/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
11/03/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
11/03/98	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
11/04/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
12/07/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
12/07/98	1pm-3pm	77 S. High Street, Room 1919	Rules Hearing
12/08/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
12/08/98	1pm-3pm	77 S. High Street, Room 1919	Reciprocity Hearing
12/09/98	8am-5pm	77 S. High Street, Room 1914	Board Meeting
01/04/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
01/05/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
01/05/99	1pm-3pm	77 S. High Street (Room Not Confirmed)	Reciprocity Hearing
01/06/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
02/08/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting

<u>Date</u>	<u>Time</u>	<u>Location</u>	<u>Purpose</u>
02/09/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
02/09/99	1pm-3pm	77 S. High Street (Room Not Confirmed)	Reciprocity Hearing
02/10/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
03/08/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
03/09/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
03/09/99	1pm-3pm	77 S. High Street (Room Not Confirmed)	Reciprocity Hearing
03/10/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
04/05/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
04/06/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
04/06/99	1pm-3pm	77 S. High Street (Room Not Confirmed)	Reciprocity Hearing
04/07/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
05/03/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
05/04/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
05/04/99	1pm-3pm	77 S. High Street (Room Not Confirmed)	Reciprocity Hearing
05/05/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
06/07/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
06/08/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting
06/08/99	1pm-3pm	77 S. High Street (Room Not Confirmed)	Reciprocity Hearing
06/09/99	8am-5pm	77 S. High Street (Room Not Confirmed)	Board Meeting

The only meeting dates that do not appear on this tentative schedule are those needed to consider the results of an investigation regarding an impaired pharmacist, wholesaler of dangerous drugs whose method of distributing controlled substances presents a danger of immediate and serious harm to others, or special meetings called to consider an important matter that needs to be decided before the next regularly-scheduled Board meeting. A notice of these meetings is mailed at least 24 hours prior to the meeting to those individuals and organizations that subscribe to the "Sunshine Notice" service of the Board. This service presently costs \$25.00 per fiscal year (July 1 to June 30) and includes not only notices of meetings but also notices of Chapter 119. Public Rules Hearings, State Board Newsletters, Compliance Bulletins, and News Releases. Subscriptions must be renewed annually by the first day of July of each fiscal year.

Anyone planning to attend a Board meeting should contact the Board office at least two weeks prior to the tentative published date to confirm the date, time, and location. All of the meetings, with the month of July being an exception, are held in the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio.

**BOARD OF PHARMACY PERSONNEL**

**MEMBERS OF THE BOARD**

- Diane Cohen Adelman, R.Ph.; Beachwood [Term Expires 06/30/2000]***
- Robert B. Cavendish, R.Ph.; Johnstown [Second Term Expires 06/30/2000]***
- John L. Hanna, R.Ph.; Hillsboro [Term Expires 06/30/1998]***
- Paul F. Lamping, R.Ph.; Cincinnati [Second Term Expires 06/30/1999]***
- Amonte B. Littlejohn, R.Ph.; Cleveland Heights [Second Term Expires 06/30/2001]***
- Joseph J. Maslak, R.Ph.; Canal Winchester [Term Expires 06/30/1998]***

**Suzanne L. Neuber**, R.Ph.; Sylvania [Second Term Expires 06/30/2001]

**Ruth A. Plant**, R.Ph.; Hudson [Second Term Expires 06/30/1999]

**Nicholas R. Repke**, Public Member; Gahanna [Second Term Expires 06/30/2000]

**ADMINISTRATIVE SECTION**

**EXECUTIVE DIRECTOR**

*Franklin Z. Wickham, R.Ph.*

**ASSISTANT EXECUTIVE DIRECTOR / DIRECTOR OF INTERNSHIP**

*William T. Winsley, R.Ph.*

**ADMINISTRATIVE ASSISTANT**

*Sandra Butler*

**FISCAL SPECIALIST**

*Karen Prather*

**OFFICE ASSISTANT / RECEPTIONIST**

*Rosemary Jones*

**INFORMATION SYSTEMS SECTION**

**INFORMATION SYSTEMS ADMINISTRATOR**

*Nancy L. Little, R.Ph.*

**PROGRAMMER/ANALYST**

*Matthew Cooke*

**LICENSING SECTION**

**LICENSING ADMINISTRATOR**

*William McMillen, R.Ph.*

**CERTIFICATION/LICENSING EXAMINERS**

**Internship and License Exams Coordinator**

*Mary Flovin*

**Pharmacists and Reciprocity Coordinator**

*Yolanda Ferguson*

**Continuing Pharmacy Education Coordinator**

*Brenda Gouhin*

**Dangerous Drug Distributors Coordinators**

*Erika Curtis*

*Sharon Prentice*

**LEGAL AFFAIRS SECTION**

**LEGAL AFFAIRS ADMINISTRATOR**

*David L. Rowland, J.D.*

**LEGAL AFFAIRS SECRETARY**

*Susan Orr*

**DRUG IDENTIFICATION COORDINATOR**

*Debra Smith*

**BOARD COUNSEL - OFFICE OF THE ATTORNEY GENERAL**

**ASSISTANT ATTORNEY GENERAL**

*Sally Ann Steuk, Esq.*

**COMPLIANCE SECTION**

**COMPLIANCE ADMINISTRATOR**

*Timothy J. Benedict, R.Ph.*

**COMPLIANCE SUPERVISOR**

*Robert L. Cole*

**COMPLIANCE SPECIALISTS**

*Robert Amiet, R.Ph.*

*Elaine Jones, R.Ph.*

*Mark Keeley, R.Ph.*

*Paul Kover, R.Ph.*

*Louis (Bob) Mandi, R.Ph.*

*Joann Predina, R.Ph.*

**COMPLIANCE AGENTS**

*David Avery*

*Frank Bodi*

*Michael Cluxton*

*Dale Fritz*

*Carl Frost*

*David Gallagher*

*Joseph Holliday*

*Kevin Kinneer*

*Lynn Mudra*

*William Padgett*

*George Pavlich*

*Christopher Reed*

*James Reye*

*Fred Williams*

**COMPLIANCE SECRETARIES**

*Kathi Baker*

*Laurie Sturtz*

**BOARD MEMBER APPOINTMENTS**

**Board Members Reappointed** (*Term of Office: July 1, 1997 - June 30, 2001*)

Mr. Amonte Littlejohn was re-appointed for a second four-year term by Governor Voinovich. Mr. Littlejohn is a resident of Cleveland, Ohio and holds a B.S. in Pharmacy from the University of Toledo College of Pharmacy as well as a M.B.A. from Cleveland State University. Mr. Littlejohn is President of the Board this fiscal year (98) and is employed by Personal Physician Care, Inc. in Cleveland, Ohio.

Mrs. Suzanne Neuber was also re-appointed to the Board for a second four-year term. Mrs. Neuber is also a graduate of the University of Toledo and is employed by Westhaven Services Co., a division of Omnicare, Inc. Westhaven Services Co. provides pharmacy services to long-term-care facilities in northwestern Ohio. Mrs. Neuber's Board member responsibil-

ity this fiscal year is personnel and she serves as the Chair of the Executive Director recruitment committee.

**Board Member Responsibility Appointments**

Each fiscal year, the Board reorganizes by electing a president and vice-president during the April or May Board meeting. The new officers for the next fiscal year are installed at the last meeting of the current fiscal year (June). In July or August, the Board president assigns the individual members certain areas of responsibility regarding the operations of the Board. The following appointments are in effect for the current fiscal year (98):

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

Meetings of the following Board committees also contributed to the workload of the Board members:

Ad Hoc Advisory Committee on Rule Review	Mrs. Adelman, Mr. Cavendish
Nurse Practitioner Formulary Committee	Mr. Hanna
Ohio Tuberculosis Coalition	Mr. Maslak
Recruitment Committee	Mr. Littlejohn, Mrs. Adelman, Mrs. Neuber, Mrs. Plant, and Mr. Repke

**PREPARING FOR TOMORROW**

Following my notification of the Board early in fiscal year 1996 (1995 Calendar year) that I would be retiring as Executive Director on December 31, 1998, arrangements were made to hold a special planning meeting regarding the recruitment and appointment of a new executive director. A retreat was held by Board and administrative staff in October of 1995 to outline the necessary steps in identifying and hiring a replacement. A timetable was established with the goal of identifying the replacement by July 1, 1998 and provides a six-month transition period prior to my leaving State employment.

A recruitment committee consisting of Board members Wayne Miller, Suzanne Neuber, Ruth Plant, and Nicholas Repke was appointed by the President at the November 1995 meeting. The first meeting of the committee was held during the January 1996 Board meeting and consensus reached that additional meetings would be scheduled when needed during the dates the regular Board meetings were being held.

One of the problems faced by the Board in filling the position was the fact that the pay range for the position was equivalent to that of the field staff pharmacists and that their actual compensation would be greater than that of the Executive Director due to longevity, additional step raises beyond those available to the Executive Director and the fact that the field staff pharmacists are paid time-and-a-half for any time worked beyond eighty hours in two weeks. The committee identified the data required for documenting the need to reclassify the executive director's position and increase the pay range to reflect the current responsibilities of the position and the marketplace.

Meetings of the committee continued to be held as needed during regular meetings of the Board to review the information obtained by committee members and staff. Procedures for recruiting and identifying qualified candidates were also established during these meetings.

**Funding** - With the goal of appointing an Executive Director-designate by July 1, 1998 at a new pay range and reclassified position, the Board needed to obtain the required funding in the 1999 fiscal year budget. Operating Budget Guidance for the fiscal years 98-99 biennial budget was received from the Office of Budget Management on or about July 5, 1996 with notification that the Board's budget request must be submitted by August 19, 1996.

Budget criteria was established by the Board members on August 8, 1996, the budget documents completed by staff, and submitted to the Office of Budget and Management (OBM) by the August 19 deadline. Meetings and discussions were then held with the senior fiscal analyst assigned to the Board by OBM during the months of September, October, and November, 1996 to clarify data regarding the Board's budget request and supporting documentation. Board staff also met with the Legislative Budget Office fiscal analyst on January 14, 1997.

The criteria established by the Board during the August meeting and incorporated into the budget request remained intact and were included in the Governor's budget. The Governor's budget was submitted to the 121st General Assembly in January 1997. The Board was notified by the Chairman of the subcommittee scheduled to consider the Board's proposal that they would receive testimony by Board representatives on February 18, 1997.

The budget for the 1998-1999 biennium was adopted by the Legislature effective June 30, 1997 and the Board's funding request approved.

**Reclassification of Executive Director Position** - The Board's request and documentation to reclassify the Board of Pharmacy's Executive Director position was submitted by President Suzanne Neuber on December 6, 1996 to the Division of Human Resources, Ohio Department of Administrative Services. The request was summarily denied by the Department Division on December 19, 1996. Additional data was obtained and a new letter submitted once again by the Board President on January 23, 1997 requesting that the position be reclassified. The second request was approved and the position reclassified on July 20, 1997 following a public hearing conducted by the Ohio Department of Administrative Services on June 12, 1997.

The long-range planning retreat held in October 1995 also identified the need to revise the organizational structure of the Board to improve operations and reflect changes occurring in the area of data processing, information management, and the fact that licensing examinations are no longer administered by the Board. In September of this year, the Assistant Executive Director and Board staff will no longer be involved in the administration of licensing examinations due to the implementation of the computer-adaptive Multistate Pharmacy Jurisprudence Examination (MPJE) by the National Association of Boards of Pharmacy.

Certain job responsibilities of the administrative staff also needed to be revised and the appropriate positions reclassified according to state personnel laws and rules. This was due to the increasing demands being placed on government agencies to make more information about health professionals and health care providers readily available to the public.

**WORKLOAD**

The workload of the Ohio Board of Pharmacy continues to grow with increasing exposure to and recognition by the public, businesses providing health care, law enforcement agencies, news sources (television, newspapers, magazines, trade publications), law firms representing health care businesses, and health care professionals throughout the United States. The number of inquiries for information, consumer complaints, and reports of alleged illegal activity involving drugs and health care professionals continue to increase in number.

The Ohio Board of Pharmacy has a high profile regarding the public and other state and federal agencies. This is due to the Board's expertise and responsibilities regarding drugs and drug products. The majority of telephone calls received from the public begin with a request to speak with a pharmacist - someone who understands drugs and can deal directly with their questions and concerns regarding the drugs that they are taking or have heard about in the press or lay publications. A large number of these calls are also complaints or allegations that individuals, health professionals, and/or the lay public are violating federal and/or state drug laws.

<b>Incoming Telephone Calls</b> <i>(front desk - receptionist only)</i>			
<u>FY</u>	<u>R.Ph. (%)</u>	<u>Other Staff (%)</u>	<u>Total</u>
98td	4,442 (32%)	9,481 (68%)	13,923
97	10,057 (43%)	13,293 (57%)	29,552
96	10,057 (43%)	13,293 (57%)	23,350
95	7875 (33%)	15,677 (67%)	23,552
<i>td = to December 31, 1997</i>			

### **Information Technology - Consumer Services and Effective Communication**

Unlike many government agencies and private businesses, the Ohio Board of Pharmacy does not use voice mail or an answering system in responding to telephone calls to the office. Each phone call during normal business hours (8 a.m. to 5 p.m. Monday through Friday) are answered promptly by a receptionist and the individual transferred to an office staff member who can answer the callers question or respond to their request for information or forms. If the individual the caller wishes to speak to is not available, a message is taken and the call returned unless another staff member can handle the request.

The Board also utilizes a computer-based paging system for the purpose of immediately contacting employees in the field. This tool provides management with the ability to be in immediate contact with a compliance agent or compliance specialist when necessary.

The Board continually strives to improve the level of communication with its customers. The creation of the new Information Systems Administrator's position will enable the Board to implement several programs that have been on hold due to workload and insufficient time. These programs include broadcast faxing and providing each Board employee with the ability to access the Internet and answer requests for information using e-mail.

The Board's Web site will also eventually include forms that can be downloaded and printed or completed for use by persons licensed and registered with the Board as well as application forms for use by person wishing to apply for licensure or registration. This year's Jurisprudence Quiz that was included in the February 1998 State Board Newsletter was posted on the Web on February 9, 1998 so that it could be downloaded and printed. The state sections of the State Board Newsletters have also been posted on the Board's Home Page (see *Page 46 for more detail*) and can be downloaded and printed as well.

The move to Computer-Adaptive Tests by the National Association of Boards of Pharmacy provided the Board with the opportunity to revise the duties and responsibilities of the Assistant Executive Director as an Information Management/Quality Assurance Administrator. As can be noted from previous reports to the Association, the Board of Pharmacy has aggressively incorporated information technology into its operations in order to improve its ability to carry out its mission in a cost-effective manner since 1983.

Redefining the Assistant Executive Director's position and adding the new Information Systems Administrator's position this fiscal year provides the Board with the ability to continually improve and expand its records management and service delivery systems. Solid information management is essential to the success of the Board of Pharmacy in effectively carrying out its responsibilities as we enter the next millenium. The Board also needs to increase its customers' access to information maintained by the Board as well as respond in a timely manner to requests for information or forms.

### **Drug Laws of Ohio**

Another update of the official printed edition of the Drug Laws of Ohio will be released by the publisher, Banks-Baldwin, in May. This is the ninth update published by Banks-Baldwin since the Board contracted with the company in 1992 to print an official copy of the Drug Laws of Ohio.

All Ohio Registered Pharmacists will also be receiving a notice that the Board has entered into an agreement to provide the Drug Laws of Ohio on CD-Rom. Conway-Greene, a Cleveland firm, will be providing the publication and updates on CD-Rom beginning this month.

### **Pharmacy Practice Act Revisions**

On March 25, 1998, the Ohio General Assembly adopted Sub. Senate Bill 66 - the most significant revision of the Pharmacy Practice Act in the history of Ohio pharmacy. The last major revision of the Pharmacy Practice Act occurred in 1984. Amended Sub. S.B. 66 expands the definition of the "practice of pharmacy" to include pharmacist care with the authority for an individual pharmacist to enter into a "consult agreement" with a physician to "manage an individual's drug therapy".

Other significant changes resulting from the enactment of Sub. S.B. 66 include the deletion of the term "practitioner" from the state laws governing the legal distribution of drugs and the practice of pharmacy. This term has become meaningless with the increasing number of health professionals being authorized to prescribe drugs in the course of their professional practice. Accordingly, the term "practitioner" has been replaced with the term "prescriber" or the phrase "licensed health professional authorized to prescribe drugs." A prescriber means "an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's practice, including only the following: a dentist licensed under Chapter 4715. of the Revised Code; an advanced practice nurse approved under section 4723.56 of the Revised Code to prescribe drugs and therapeutic devices; an optometrist licensed under Chapter 4725. of the Revised Code to practice optometry under a therapeutic pharmaceutical agents certificate; a physician authorized under Chapter 4731 of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatry; a veterinarian licensed under Chapter 4741. of the Revised Code."

## **REVENUE/APPROPRIATIONS**

The Ohio Board of Pharmacy generates revenue through licensing and registration fees, examination fees, fees for services, imposing monetary penalties, and the collection of fines levied by the courts of Ohio for drug law violations. Additional revenue items have been added to the revenue source data this year due to the efforts of the new Assistant Attorney General assigned to the Board. Assistant Attorney General Sally Ann Steuk is aggressively pursuing the collection of delinquent monetary penalties imposed by the Board over the past 13 years. To date, a \$6,000 fine imposed by the Board in 1984 was paid in February of this fiscal year. This amount is designated as a "past Board monetary penalty". The amount of these past monetary penalties that have been collected during any fiscal year is noted in the footnotes of the Sources of Revenue table that appears on the next page.

The second new category of revenue listed this year is the amount collected through settlement agreements negotiated by the new Assistant Attorney General. The amount collected in previous years through settlement agreements was insignificant due to the inexperience of previous legal counsels assigned to the Board. This year to date, however, over forty thousand eight hundred dollars (\$40,800) has been collected pursuant to settlement agreements negotiated by the new assistant attorney general assigned to the Board.

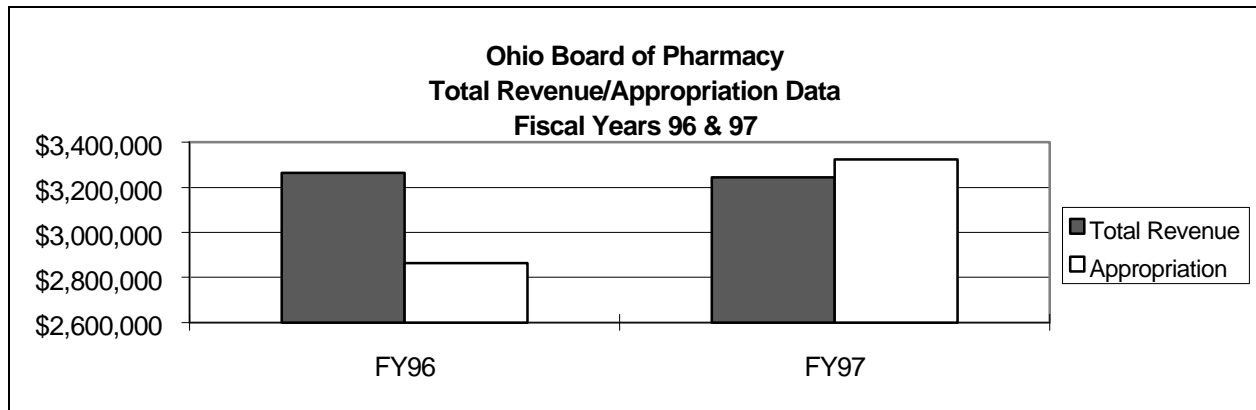
The Board also generates funds for drug law enforcement purposes through its investigation and criminal prosecution of persons violating provisions of Chapter 2925. of the Ohio Revised Code. These funds are derived from mandatory fines levied by the Ohio courts in cases involving the Board staff as well as asset forfeitures in state and federal cases.

Sixty-five percent (65%) of the revenue generated by the Board of Pharmacy during FY 96 and 66% during FY 97 came from licensing and registration fees and service fees. The following table indicates the percentage generated by the different sources of revenue for FYs 96 and 97. Monetary penalties are imposed by the Board as the result of a disciplinary hearing or settlement agreements while fines and bond forfeitures are imposed by the criminal courts in Ohio.

<b>SOURCES OF REVENUE - FISCAL YEARS 96 &amp; 97</b>				
<u>Revenue Sources</u>	<u>FY 96</u>	<u>%</u>	<u>FY 97</u>	<u>%</u>
Licensing/Service Fees	\$2,113,637	64.7	\$2,130,217	65.7
Monetary Penalties	63,700	2.0	42,750	1.3
<i>Board Orders</i>			(\$24,250)*	
<i>Settlement Agreements</i>			(\$18,500)	
<u>Fines</u>	<u>1,087,266</u>	<u>33.3</u>	<u>1,113,025</u>	<u>34.3</u>
<b>Total Revenue</b>	<b>\$3,264,603</b>		<b>\$3,243,164</b>	
<i>* past Board monetary penalty collected this fiscal year \$ 6,000</i>				

The total amount of revenue (licensing/registration fees and fines) collected by the Board of Pharmacy was 2.5% (\$81,155) less than the amount appropriated by the Legislature for use by the Board in carrying out its responsibilities as indicated in the following table. Due to cost-cutting measures implemented by Board staff, however, the actual expenditures for FY 97 was 8% less than the amount appropriated for operating expenses.

<b>TOTAL REVENUE/APPROPRIATION DATA</b>				
<u>FY</u>	<u>Total Revenue</u>	<u>Appropriation</u>	<u>Difference</u>	<u>%</u>
97	\$3,243,164	\$3,324,319	(\$81,155)	(2.5%)
96	3,264,603	2,862,792	401,811	12.3
95	3,103,341	2,374,296	729,045	23.5
94	2,676,469	2,205,761	470,708	21.3



The following table indicates the amount and percentage of the drug fines used to cover the Board's appropriation for FYs 92 through 97. One hundred percent (100%) of the drug fines collected in FY 97 were used by the Board of Pharmacy in carrying out its drug law enforcement responsibilities.

FY	Fine Revenue	Amount of Appropriation Covered By Fine Revenue	% of Fine Revenue
97	\$1,113,025	\$1,113,025	100.0
96	\$1,087,266	\$749,155	68.9
95	953,781	262,811	27.6
94	882,601	474,492	53.8
93	689,170	424,036	61.5
92	630,116	630,116	100.0

All fines imposed by courts for violations under Ohio Revised Code Section 2925.03 have been divided among the law enforcement agencies responsible for the case since November 20, 1990 (effective date of H.B. 258). Fifty percent (50%) of fines imposed by the courts for violations of all other sections of Ohio Revised Code Chapter 2925. (Drug Crimes) are deposited into the Treasury of the State of Ohio. The remaining 50% is divided among the law enforcement agencies responsible for the case according to the extent of their involvement and deposited with the appropriate government agency (e.g.-city or county treasurer, etc.).

Recognizing the decreasing amount of revenue that the State would realize from drug fines due to H.B. 258 when it was enacted by the Legislature, and the fact that the Board of Pharmacy is involved in many cases involving drug law violations, the Legislature amended O.R.C. Section 4729.65 (S.B. 218 effective 10/11/91) to provide the Board of Pharmacy with the ability to qualify for moneys realized from mandatory fines levied by the courts of Ohio and asset forfeitures. Accordingly, the Board is receiving its share of the mandatory fines and asset forfeitures resulting in prosecution of individuals violating both state and federal law. The law restricts the use of these funds and they may only be used to subsidize the drug law enforcement efforts of the Board.

O.R.C. § 4729.65 (B)(1)(a): *There is hereby created in the state treasury the board of pharmacy drug law enforcement fund. All moneys that are derived from any mandatory fines or forfeited bail to which the board may be entitled under [divisions (J) and (K) of section 2925.03] or division (B)(5) of section 2925.42 of the Revised Code and all moneys that are derived from forfeitures of property to which the board may be entitled pursuant to Chapter 2925. of the Revised Code, section 2923.32, 2923.35, or 2933.43 of the Revised Code, any other section of the Revised Code, or federal law shall be deposited into the fund. .... The moneys in the fund shall be used solely to subsidize the drug law enforcement efforts of the board.*

The Board's Drug Law Enforcement Fund received \$114,639 during FY 97. Federal and state laws restrict the use of these funds. Predicting the amount of funds that could be received by the Board from this revenue source during any fiscal period is an impossible task due to the many factors influencing the progress and final outcome of criminal drug law cases involving Board personnel. These funds are not included in the Fee Revenue/-Appropriation Data table on Page 21. The total revenue amount listed in that table includes only those funds which may be used to cover expenses associated with the operation of the Board (i.e.-expenses such as rent, travel, and payroll).

<b>BOARD OF PHARMACY DRUG LAW ENFORCEMENT FUND</b>			
<u>FY</u>	<u>Amount Collected</u>	<u>Difference</u>	<u>% Change</u>
97	\$114,638.72	\$ 77,811.97	211.3
96	\$ 36,826.75	(\$ 55,011.49)	(59.9)
95	\$ 91,838.24	\$ 23,159.28	33.7
94	\$ 68,678.96	(\$ 85,350.03)	(55.4)
93	\$154,028.99	\$109,791.23	71.2
92	\$ 44,237.76	\$ 43,862.76	99.1
91	\$ 375.00		

In order to insure that the Board continues to generate sufficient revenue to cover its cost of operations and continue to improve services, the Board continues to seek authority to recover the costs of conducting investigations of licensees and registrants guilty of violating state and federal drug laws. Representative Bryan Williams introduced House Bill 532 on July 8, 1997 to amend Sections 4729.16, 4729.56, and 4729.57 of the Ohio Revised Code for this purpose.

Other cost-containing provisions in the proposed legislation would provide the Board of Pharmacy with the authority to conduct a telephone conference call when considering the results of an investigation where a summary suspension of a license or registration might be necessary to protect the public (see Page 55 for more detail regarding Summary Suspensions). Both the Ohio Board of Nursing and the Ohio Medical Board have this authority in their practice acts. Present law requires the Board of Pharmacy, however, to call a special meeting of at least five voting members to hear the evidence. In many instances these meetings are difficult to schedule since Board members live and practice throughout the state and some require four to six hours travel time in order to come to Columbus for a meeting that normally is less than an hour in length. The cost of conducting such a meeting ranges between \$800 and \$1,100 per meeting depending upon which Board members are able to attend the meeting on such short notice.

**HISTORICAL FINE/BOND FORFEITURE DATA**  
 (Funds Deposited in General Revenue Fund)

Fiscal Year	Amount Collected	Difference	% Change
97*	\$1,113,025 <sup>16</sup>	- \$ 37,941	3.3% decrease
96	\$1,150,966 <sup>15</sup>	+ \$159,110	16.0% increase
95	\$ 991,856 <sup>14</sup>	+ \$170,066	20.7% increase
94	\$ 821,790 <sup>13</sup>	+ \$ 57,363	6.9% increase
93	\$ 764,427 <sup>12</sup>	+ \$134,311	17.5% increase
92	\$ 630,116 <sup>11</sup>	- \$ 37,272	5.6% decrease
91	\$ 667,388 <sup>10</sup>	- \$152,251	19% decrease
90**	\$ 819,639 <sup>9</sup>	- \$ 23,282	3% decrease
89	\$ 842,921 <sup>8</sup>	+ \$ 54,692	7% increase
88	\$ 788,229 <sup>7</sup>	+ \$ 3,344	0.4% increase
87	\$ 784,885 <sup>6</sup>	+ \$117,742	18% increase
86	\$ 667,143 <sup>5</sup>	- \$ 21,180	3% decrease
85	\$ 688,323 <sup>4</sup>	+ \$ 97,375	16% increase
84	\$ 590,948 <sup>3</sup>	- \$ 40,144	6% decrease
83	\$ 631,092 <sup>2</sup>	- \$ 15,316	2% decrease
82***	\$ 646,408 <sup>1</sup>	+ \$132,491	26% increase
81	\$ 513,913	+ \$ 78,698	18% increase
80	\$ 435,219	+ \$168,496	63% increase

\* S.B. 2 provisions effective July 1, 1996 (see following narrative)

\*\* S.B. 258 (effective 11/20/90) decreased the amount of drug crime fines deposited into the General Revenue fund due to mandatory drug crime fines and their distribution to local and state drug law enforcement agencies rather than the State's General Revenue fund.

\*\*\* Am. H.B. 135 enacted (effective 10/6/81)

Monetary penalties imposed by the Board (included in totals above).

1 \$ 2,350	6 \$152,050	11 \$21,432	16 \$24,250
2 \$ 2,375	7 \$ 74,033	12 \$75,257	
3 \$11,700	8 \$ 86,261	13 \$31,533	
4 \$28,150	9 \$ 63,639	14 \$38,075	
5 \$30,850	10 \$ 33,650	15 \$64,800	

The licensing and regulatory boards are expected to generate sufficient revenue from licensing fees and fees for services in order to cover operating expenses. The Board of Pharmacy, however, collects fines levied by the courts in Ohio for drug law violations and this revenue is included in the total revenue estimates of the Board for appropriation purposes. This is due to the fact that the Board has drug law enforcement responsibilities as well as the licensing and regulation of the practice of pharmacy and the legal distribution of drugs in Ohio.

The amount of revenue that the Board receives from this source should significantly decrease during FY 98 due to the enactment of Sub. S.B. 2 by the 121st General Assembly (Criminal Sentencing/Criminal Law changes) on June 29, 1995. Sub. S.B. 2 also made further changes in the distribution of drug fines effective July 1, 1996, the beginning of FY 97.

It is anticipated that the provisions of this legislation will eventually decrease the drug fine revenue collected by the Board of Pharmacy by approximately 85 to 90 percent. The full impact of Sub. S.B. 2 has not yet been fully realized as of this date.

In order to assess the impact of the legislation on the Board's revenue, Board staff created the following table that identifies the sections of the Ohio Revised Code that will continue to be paid to the Board of Pharmacy as of July 1, 1996 and the amount collected pursuant to these sections during FYs 94, 95, and 96. The table also provides the total amount of fine revenue that would have been distributed to the local law enforcement agencies under the provisions of Sub. S.B. 2 had it been in effect during FYs 94, 95, and 96. The table this year includes the actual amounts collected during FY 97 and FY 98 as of March 30, 1997.

PROJECTED IMPACT OF SUB. S.B. 2 ON BOARD FINE REVENUE					
	<u>FY 94</u>	<u>FY 95</u>	<u>FY 96</u>	<u>FY 97</u>	<u>FY98td</u>
<b>Total Fines Received</b>	<b>\$778,191</b>	<b>\$956,233</b>	<b>\$1,086,116</b>	<b>\$1,088,775</b>	<b>\$827,515</b>
Sections Continued					
2923.02	na	na	na	39,579	24,883
2925.12	3,637	4,876	4,129	5,420	7,050
2925.14	59,193	128,507	115,233	313,710	345,877
2925.31	1,021	2,010	2,171	3,821	2,959
2925.32	0	50	10	0	0
3715.65	0	250	250	0	0
3719.08	0	0	820	180	100
3719.16	285	365	470	2,248	200
3719.21	267	0	0	500	0
3719.41	0	200	0	0	100
3719.81	300	0	0	0	0
4507.02	0	20	0	0	150
4511.19	50	75	0	0	0
4729.28	530	34	0	300	200
4729.51	181	2,125	13	693	20
<b>Total To Board</b>	<b>\$65,464</b>	<b>\$138,512</b>	<b>\$123,096</b>	<b>\$366,451</b>	<b>\$381,539 td</b>
<b>Total* To Local Law Enforcement</b>	<b>\$712,727</b>	<b>\$817,721</b>	<b>\$963,020</b>	<b>\$722,324</b>	<b>\$445,976 td</b>
<p style="text-align: center;">*For crimes committed after 07/01/96                      td = 03/30/98                      na = not applicable</p>					

The following table illustrates the amount of revenue generated from licensing fees and fees for services for FYs 86 through 97. This revenue source generated \$2,130,217 in FY 97 or approximately \$16,580 (0.78%) more than the amount collected in FY 96.

FEE REVENUE / APPROPRIATION DATA				
<u>FY</u>	<u>Fee Revenue</u>	<u>Appropriation</u>	<u>Difference</u>	<u>%</u>
97	\$2,130,217	\$3,324,319	\$(1,194,102)	(35.9)
96	2,113,637	2,862,792	(749,155)	(26.2)
95	2,111,485	2,374,296	(262,811)	(11.1)
94	1,762,335	2,205,761	(443,426)	(20.1)
93	1,258,073	1,757,366	(499,293)	(28.4)
92	1,092,567	1,738,243	(645,709)	(37.1)
91	1,319,067	1,661,904	(342,837)	(20.6)
90	1,194,025	1,581,579	(387,554)	(24.5)
89	926,008	1,426,895	(500,887)	(35.1)
88	837,628	1,498,011	(660,383)	(44.1)
87	739,535	1,127,172	(387,637)	(34.4)
86	741,635	1,177,192	(435,557)	(37.0)

Ohio State Board of Pharmacy  
**LICENSING/REGISTRATION REVENUE DATA**  
 (includes fees for services/publications)

<u>Fiscal Year</u>	<u>Amount Collected</u>	<u>Difference</u>	<u>% Change</u>
97	\$2,130,217	+ \$ 16,580	0.8 % increase
96	2,113,637	+ 2,152	0.1% increase
95 <sup>7</sup>	2,111,485	+ 349,150	20% increase
94	1,762,335	+ 504,262	40% increase
93 <sup>6</sup>	1,258,073	+ 165,506	13% increase
92 <sup>5</sup>	1,092,567	- 226,500	17% decrease
91	1,319,067	+ 125,042	11% increase
90 <sup>4</sup>	1,194,025	+ 268,017	29% increase
89	926,008	+ 88,380	11% increase
88 <sup>3</sup>	837,628	+ 98,093	13% increase
87	739,535	- 2,100	3% decrease
86	741,635	+ 55,042	8% increase
85	686,323	- 6,573	1% decrease
84	692,896	- 26,602	4% decrease
83	719,498	+ 203,000	39% increase
82 <sup>2</sup>	516,494	+ 24,136	5% increase
81	492,358	+ 43,349	10% increase
80	449,009	+ 26,977	6% increase
79	422,788	+ 19,756	5% increase
78	403,032	+ 28,790	8% increase
77	374,242	+ 5,315	1% increase
76	368,927	+ 72,696	25% increase
75 <sup>1</sup>	296,231	+ 11,116	4% increase
74	285,115	+ 14,542	5% increase
73	270,573	- 13,170	5% decrease
72	283,743	+ 91,138	47% increase
71	192,605	+ 17,743	10% increase
70	174,862		

1 - Am. Sub. H.B. 300 enacted (1975 Drug Abuse and Controlled Substance Act)

2 - Am. Sub. S.B. 4 enacted (Emergency Medical Systems - three categories of dangerous drugs/differing fees/free satellite licenses/practitioner corporations & partnerships exempted from licensure)

3 - R.Ph. (07/01/88) and Dangerous Drug Distributor (08/10/87) license and registration fees increased to implement provisions of FY 88 appropriation to provide for an Administrative Assistant for Legal Affairs and clerical-technical support

4 - Licensing fees increased by Legislature (07/01/89) and Board (09/01/89)

5 - Revenue decreased due to fewer takeovers and licensing of same sites during the fiscal year

6 - The Drug Laws of Ohio publication has been granted to the Banks-Baldwin Law Publishing Company for handling and distribution

7 - Sub. H.B. 391 and S.B. 88 enacted (Retail sellers of Oxygen, food processors, and animal shelters)

Ohio State Board of Pharmacy  
 TOTAL REVENUE DATA

Fiscal Year	Licensing Fees	Drug Fines/ Bond Forfeitures	Total Collected	Difference	% Change
97	\$2,130,217	\$1,113,025	\$3,243,242	- \$ 21,361	0.6% decrease
96	2,113,637	1,150,966 <sup>7</sup>	3,264,603	+ 161,262	5% increase
95	2,111,485 <sup>6</sup>	991,856	3,103,341	+ 426,872	16% increase
94	1,762,335	914,134	2,676,469	+ 653,969	32% increase
93	1,258,073	764,427	2,022,500	+ 299,817	15% increase
92	1,092,567	630,116	1,722,683	- 168,956	9% decrease
91	1,224,250	667,388	1,891,639	- 122,005	6% decrease
90	1,194,025 <sup>4</sup>	819,639 <sup>5</sup>	2,013,644	+ 244,715	14% increase
89	926,008	842,921	1,768,929	+ 143,072	9% increase
88	837,628 <sup>3</sup>	788,229	1,625,857	+ 101,437	7% increase
87	739,535	784,885	1,524,420	+ 115,642	8% increase
86	741,635	667,143	1,408,778	+ 34,132	3% increase
85	686,323	688,323	1,374,646	+ 90,802	7% increase
84	692,896	590,948	1,283,844	- 66,746	5% decrease
83	719,498	631,092	1,350,590	+ 187,688	16% increase
82	516,494 <sup>2</sup>	646,408	1,162,902	+ 156,627	16% increase
81	492,358	513,917	1,006,275	+ 122,047	14% increase
80	449,009	435,219	884,228	+ 194,724	28% increase
79	422,788	266,723	689,504	+ 56,773	9% increase
78	403,032	229,699	632,731	+ 51,461	9% increase
77	374,242	207,028	581,270	- 58,963	9% decrease
76	368,927	271,306	640,233	- 39,436	6% decrease
75	296,231	383,438 <sup>1</sup>	679,669	+ 106,069	18% increase
74	285,115	288,485	573,600	+ 110,090	24% increase
73	270,573	192,937	463,510	+ 73,873	19% increase
72	283,743	105,894	389,637	+ 129,691	50% increase
71	192,605	67,341	259,946	+ 66,398	34% increase
70	174,862	18,686	193,548		

1 - Am. Sub. H.B. 300 enacted (1975 Drug Abuse and Controlled Substance Act)

2 - Am. Sub. S.B. 4 enacted (Emergency Medical Systems - three categories of dangerous drugs/differing fees/free satellite licenses/practitioner corporations & partnerships exempted from licensure)

3 - R.Ph. (07/01/88) and Dangerous Drug Distributor (08/10/87) license fees increased to implement provisions of FY 1988 appropriation to hire Administrative Assistant for Legal Affairs and clerical support

4 - Licensure fees increased to cover greater percentage of appropriation (Budget Bill and Controlling Board action)

5 - H.B. 258 was enacted by the General Assembly in Calendar Year 1990 and will decrease the amount of drug crime fines deposited into the General Revenue fund due to mandatory drug crime fines and their distribution to drug law enforcement agencies

6 - Sub H.B. 391 (07/21/94)& S.B. 88 (06/29/94)enacted (retail sellers of Oxygen, food processors, non-territorial pharmacies, animal shelters)

7 - Sub. S.B. 2 (07/01/96) resulted in larger percentage of drug fines being distributed to local law enforcement agencies.

## LICENSING

The licensing of individuals to practice pharmacy is one of the mechanisms for protecting the public by ensuring that candidates are qualified to practice pursuant to the provisions of the Pharmacy Practice Act.

### PHARMACY INTERNS

College students who are pursuing an entry-level degree in Pharmacy may obtain a license to practice pharmacy under the personal supervision of a pharmacist if they meet the following qualifications:

1. Are of good moral character and habits;
2. Are not addicted to or abusing drugs or liquor; and
3. • Have successfully completed forty-eight semester or seventy-two quarter hours of college and have been accepted into a school or college of pharmacy recognized and approved by the board, or
  - Have obtained a first professional degree in pharmacy from a program which has been recognized and approved by the board, or
  - Have established education equivalency by obtaining a Foreign Pharmacy Graduate Examination Commission certificate, and have established proficiency in spoken English by successfully completing the Test of Spoken English (TSE) or its equivalent.

### PHARMACISTS

#### Licensure by Examination

Competency is determined initially through the use of examinations. In order to qualify to sit for an examination for licensure as a pharmacist, individuals must:

1. Be of good moral character;
2. Be a graduate of an accredited program in pharmacy or if a graduate of a foreign college of pharmacy have obtained a Foreign Pharmacy Graduate Examination Committee certificate;
3. Have successfully obtained 1500 hours of practical experience in a pharmacy; and
4. If a foreign pharmacy college graduate, demonstrate his/her proficiency in the English language (written and spoken).

### **Foreign Pharmacy Graduate Equivalency Examination (FPGEE)**

The Ohio Board of Pharmacy utilizes the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) in order to determine whether or not a foreign pharmacy graduate's education is equivalent to a graduate from a college of pharmacy in the United States. This examination is a comprehensive measure of the foreign pharmacy graduate's knowledge of pharmacy. It is a written examination that includes between 300 and 400 multiple-choice questions and is given in English. The exam is comprised of the following five major content areas: pre-clinical sciences, pharmaceutical sciences, biomedical sciences, social and behavioral sciences, and pharmaceutical services management.

Foreign pharmacy graduates qualify to sit for the licensure examination in Ohio by successfully completing the Foreign Pharmacy Graduate Equivalency Examination, the Test of English as a Foreign Language (TOEFL), the Test of Spoken English (TSE), and obtaining 1500 hours of internship following registration as a pharmacy intern.

### **North American Pharmacist Licensure Examination (NAPLEX)**

The National Association of Boards of Pharmacy (NABP) and its member states began using the new computer-adaptive North American Pharmacist Licensure Examination (NAPLEX) in March of 1997.

Computer-adaptive examinations utilize state-of-the-art technology to assess whether a candidate can competently practice as an entry-level pharmacist. Computer-adaptive tests select questions that target a candidate's ability level. The computer-programmed test continuously estimates each candidate's ability level based on responses to the test questions and then selects the most appropriate questions for the individual.

In order to pass the exam, the candidate's ability must meet or exceed a pre-determined level of minimum competence as established by a diverse national panel of practicing pharmacists, educators, and regulators. The process of selecting questions tailored to the candidate's ability level allows fewer questions to be administered on the exam.

The NAPLEX exam consists of 185 test items compared to the 350 questions included on the previously administered paper-and-pencil NABPLEX. Consequently, testing time is less. The NAPLEX administration takes only four hours and fifteen minutes to complete compared to the eight hours required for the NABPLEX.

Computer-adaptive exams also provide the opportunity to administer the examinations more often than three times a year and at many different sites. The NAPLEX was administered during four uniform testing windows during 1997 and 1998 as indicated in the following table. . Candidates no longer have to come to one central location in order to take the examination since the NAPLEX is administered by Sylvan Technology Centers. Sylvan testing centers are located in approximately 220 cities scattered throughout the United States and its territories. Sylvan testing centers were available to candidates for taking the NAPLEX in the following Ohio cities: Akron, Cincinnati, Columbus, Dayton, Mentor, Niles, Reynoldsburg, Solon, Strongsville, and Toledo.

**NAPLEX TESTING WINDOWS**

<u>Calendar Year 1997</u>	<u>Calendar Year 1998</u>
March 24 - 29, 1997	February 9 - 21, 1998
June 9 - August 15, 1997	June 22 - August 15, 1998
October 6 - 11, 1997	October 12 - 24, 1998

The NAPLEX's development was based on competency statements that were validated by pharmacists in both the United States and Canada.

**Ohio Jurisprudence Examination and  
Multistate Pharmacy Jurisprudence Examination (MPJE)**

The third mechanism used to assess a candidate's ability to practice in Ohio has been a Jurisprudence examination compiled by the Board. The pencil-and-paper exam compiled by the Ohio Board of Pharmacy tests the candidate's knowledge regarding laws and regulations governing the legal distribution of drugs and consists of 70 questions. Candidates have 90 minutes to complete the exam.

The new computer-adaptive Multistate Pharmacy Jurisprudence Examination (MPJE) will begin to be used by NABP and its member states, including Ohio, in October of this year. The MPJE will test a candidate's knowledge of state laws as well as federal laws and regulations.

Advanced computer technology now provides NABP with the ability to develop a program that will automatically select test questions according to the requirements of an individual state and without conflicting with existing federal laws. The MPJE is based on a nationally uniform blueprint of jurisprudence competencies applicable to the practice of pharmacy, yet accommodates the differences from state to state.

**Candidate's Review Guide**

One of the services provided by the National Association of Boards of Pharmacy (NABP) is review guides for exam candidates. A computerized Candidate's Review Guide is presently available for purchase by exam candidates for the NAPLEX and will be available for the MPJE once it has been implemented later this year. These guides help prepare the candidates for the examinations by explaining the computer-adaptive approach and by providing a large number of sample questions.

The guides also contain tutorials that help the candidate prepare for taking the exam on a computer, including how to use the mouse, how to scroll through the patient profiles, and how to use the testing tools. The NAPLEX guide also provides an on-screen calculator that is available for use by the candidate when actually taking the NAPLEX. The guides are available on 3½-inch, IBM-compatible disks, complete with loading and operating instructions.

**Licensure by Examination**

The following table provides data concerning the number of candidates sitting for the licensure examinations in Ohio since FY 86, the number of candidates who were successful in all required examinations, and the number who were not. The figures for FY 98 are current through the February 1998 window.

PHARMACY PRACTICE ACT LICENSURE EXAMINATION STATISTICS				
FY	Number of Candidates	Number Successful	Number Failing	Per Cent Failing
98td <sup>2</sup>	504	440	64	12.7 %
97 <sup>1</sup>	210	169	41	19.5 %
96	549	442	107	19.5 %
95	496	408	88	17.7 %
94	510	424	86	20.3 %
93	437	353	84	19.2 %
92	358	323	35	9.8 %
91	391	356	35	9.0 %
90	401	373	28	7.0 %
89	369	346	23	6.2 %
88	328	303	25	7.6 %
87	337	315	22	6.5 %
86	338	304	34	10.0 %

*td - as of February 21, 1998*

*1 - does not include candidates who tested during NAPLEX testing window of June 9 - August 15, 1997*

*2 - includes candidates who testing during NAPLEX testing window of June 9- August 15, 1997*

**Testing for Competency To Practice (License Reinstatement)**

Through September of this year, the Board will continue to use the NAPLEX and a state Jurisprudence exam whenever a pharmacist's competency to continue in the practice of pharmacy is in doubt due to substance abuse, mental impairment, repeated violations of federal and state laws, or when a pharmacist has not continuously practiced pharmacy in another state and let his/her license lapse for a period longer than three years.

Three State Jurisprudence exams were administered in FY 97 and three State Jurisprudence exams have been administered to-date in FY 98 pursuant to adjudication orders issued by the Board.

### **Licensure by Reciprocity (Licensure Transfer)**

One of the major purposes of the National Association of Boards of Pharmacy is to facilitate the transfer of pharmacists' licenses between active members of the association. At the present time, pharmacists may freely and quickly transfer their licenses to practice between all of the states, Washington D.C., and Puerto Rico with the exceptions being the states of California and Florida.

One hundred seventy-eight (178) pharmacists transferred their licenses to Ohio in FY 97 and 128 pharmacists have transferred their licenses to practice in Ohio to-date in FY 98. Pennsylvania has had the largest number of pharmacists transferring their licenses to Ohio for fiscal years 94 (23), 95 (44), and 96 (35). West Virginia had the largest number of pharmacists reciprocating to Ohio in FY 97 (20). Pennsylvania was second with 18. Pharmacists transferred their licenses from 27 different states in FY 94; 35 in FY 95; 28 in FY 96, and 30 in FY 97.

Reciprocity hearings are held during regularly scheduled Board meetings. Two more reciprocity hearings are scheduled for FY 98.

The Board proposed to deny the applications of two pharmacists who wished to obtain a license to practice in Ohio by reciprocity (licensure transfer) in FY 98 to-date. Both applications were denied by the Board following Chapter 119. hearings.

The Boards, through the National Association of Boards of Pharmacy, utilize the Electronic Licensure Transfer Program (ELTP) computer network to decrease the amount of time required to transfer a license between states. The state boards presently use the system to verify the current status of pharmacists wishing to transfer their license to another state. Implementation of the system has not only decreased the amount of time required to reciprocate but has also simplified the application process for licensure transfer.

### **LICENSE RENEWAL**

#### **Pharmacy Interns/Pharmacists**

Twelve thousand eight hundred seventy-seven (12,877) applications for renewal were mailed to pharmacists in July of 1996 for the 1996-1997 licensure year. Four thousand one hundred twenty-two (4,122) pharmacists were required to report continuing pharmacy education. One thousand four hundred twenty-nine (1,429) renewal applications were mailed to pharmacy interns. Also, 59 interns who did not pass the June 1996 licensure exam were sent renewal applications to renew their intern license.

This fiscal year (98), 13,188 applications were mailed to pharmacists in July of 1997. Of these, 3,622 also received continuing pharmacy education report forms. Applications for renewal were also mailed the same week to 1,557 pharmacy interns, and 36 interns who did not pass the June 1997 licensure exam were sent renewal applications to renew their intern license.

The timeliness of issuing the licenses each year is directly related to the submission of a completed application form for renewal with the required fee and, if appropriate, other required documents. Applications that have not been completed or have not been submitted with the correct fee are returned to the applicant and the renewal license not issued until the problem has been corrected.

**1996-1997 Licensure Year (09/15/96 - 09/15/97)**

The Board office mailed licenses (identification cards) for the 1996-1997 licensure year to pharmacists and pharmacy interns as follows:

<b>LICENSES ISSUED 1996 STANDARD RENEWAL</b>			
<u>Date Issued</u>	<u>Total Number Licenses Issued</u>	<u>Pharmacists</u>	<u>Interns</u>
07/29/96	3109	2747	362
08/02/96	1880	1880	0
08/06/96	790	445	345
08/23/96	3745	3445	300
08/29/96	1843	1748	95
08/30/96	603	602	1
09/05/96	473	426	47
09/10/96	425	364	61
09/12/96	281	261	20
09/13/96	<u>168</u>	<u>150</u>	<u>18</u>
<b>SUB-TOTAL</b>	<b>13317 (92.7%)</b>	<b>12068 (93.7%)</b>	<b>1249 (83.9%)</b>
09/16/96	64	57	7
09/17/96	54	47	7
09/18/96	18	15	3
09/23/96	72	61	11
09/30/96	39	36	3
10/04/96	39	34	5
10/16/96	61	52	9
10/18/96	69	64	5
10/18/96	<u>13</u>	<u>13 (in audit)</u>	<u>0</u>
<b>SUB-TOTAL</b>	<b>429</b>	<b>379</b>	<b>50</b>
<b>TOTAL</b>	<b>13746</b>	<b>12447</b>	<b>1299</b>
<b>% RENEWED</b>	<b>95.7%</b>	<b>96.7%</b>	<b>87.3%</b>
<b>% LAPSED</b>	<b>4.3%</b>	<b>3.3%</b>	<b>12.7%</b>

**1997-1998 Licensure Year (09/15/97 - 09/15/98)**

The Board office mailed licenses (identification cards) for the 1997-1998 licensure year to pharmacists and pharmacy interns as follows:

LICENSES ISSUED 1997 STANDARD RENEWAL [R/A = Renewal Application]			
<u>Date Issued</u>	<u>Total Number Licenses Issued</u>	<u>Pharmacists</u>	<u>Interns</u>
8-16-97	3655	2317	438
8-22-97	3008	2653	355
8-28-97	2131	1926	205
8-29-97	150	145	5
9-2-97	174	174	0
9-3-97	1101	1019	82
9-4-97	525	506	19
9-7-97	483	477	6
9-9-97	1351	1271	80
9-9-97	75	69	6
9-10-97	381	377	4
9-11-97	32	32	0
9-12-97	79	78	1
9-12-97	3	3	0
9-14-97	100	100	0
9-14-97	13	13	0
9-15-97	232	204	28
9-15-97	49	44	5
TOTALS	11,227	10,117	1113
[TOTAL R/A MAILED]	[14,745]	[13,188]	[1557]
[% R/A RENEWED]	[76.1%]	[76.7%]	[71.5%]
9-16-97	32	28	4
9-19-97	68	65	8
9-21-97	4	4	0
9-22-97	32	28	4
9-24-97	48	46	2
10-3-97	75	68	7
TOTALS	13,801	11,647	1259
[TOTAL R/A MAILED]	[14,745]	[13,188]	[1557]
[% R/A RENEWED]	[93.6%]	[88.3%]	[80.9%]

### **Continuing Pharmacy Education**

Continued competency is ensured through license renewal. Ohio pharmacists and pharmacy interns are required to submit evidence that they are continuing their pharmacy education in order to qualify for renewal.

#### **Pharmacy Interns**

Pharmacy interns must be enrolled in a college of pharmacy in order to qualify for renewal. One hundred eighty-seven (187) pharmacy interns were required to obtain and return Certificates of Acceptance forms verifying that they were either enrolled in a college of pharmacy or that they had been accepted for enrollment with their renewal applications for the 1997-1998 licensure year. These pharmacy interns did not appear on the enrollment lists submitted to the Board by the four Ohio Colleges of Pharmacy at the beginning of the 1997-1998 academic year. If they were previously enrolled in one of the Ohio Colleges of Pharmacy, the Board needs to know whether or not they have transferred to a college of pharmacy in another state or if they have decided not to pursue a career in pharmacy.

#### **Pharmacists**

One-third of the pharmacists holding current licenses to practice in Ohio must submit evidence of successfully completing 45 hours of continuing pharmacy education (4.5 continuing education units [C.E.U.s]) every three years. Continuing pharmacy education must be obtained from providers who have been approved by the Board. Approved providers include national providers who have been approved by the American Council on Pharmaceutical Education and individuals or organizations located in Ohio who have submitted applications to the Board and have been approved as an in-state provider.

#### **Continuing Pharmacy Education Requirement - Jurisprudence**

Pharmacists who are required to report continuing pharmacy education towards renewal of their licenses for the 1998-1999 licensure year must have obtained 0.3 C.E.U. by participating in jurisprudence program(s) approved by the Board. Paragraph (A) of Ohio Administrative Code Rule 4729-7-02 (Requirements for renewal of a pharmacist identification card) was amended by the Board on February 15, 1995 and reads as follows:

Evidence of four and one-half C.E.U.s of approved continuing education shall be submitted with the application for renewal of a pharmacist identification card at intervals not to exceed three years. At least 0.3 C.E.U.s of the total required 4.5 C.E.U.s must be obtained from board approved programs in jurisprudence. Pharmacists required to report continuing education in 1996 must show evidence of 0.1 C.E.U. of jurisprudence. Pharmacists required to report continuing education in 1997 must show evidence of 0.2 C.E.U.s of jurisprudence. Pharmacists required to report continuing education in 1998 and after must show evidence of 0.3 C.E.U.s of jurisprudence. *[emphasis added]*

The jurisprudence requirement applies to:

- all pharmacists who hold a current license to practice pharmacy in Ohio and who reside and practice in the state; and
- those pharmacists who hold a current license to practice pharmacy in Ohio and are not practicing pharmacy in another state that requires continuing education in order to renew their license.

Pharmacists who are actively practicing pharmacy in another state where continuing education is required for renewal of their license to practice in that state may renew their Ohio identification card (license to practice) by using the following statement on their continuing pharmacy education report form:

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

*[Note: Do NOT Insert Your Ohio License Number In This Statement. DO Insert An Out-Of-State License Number And State Name Or The Report Form Will Be Rejected.]*

The February 1998 State Board Newsletter contained the third Jurisprudence Quiz for continuing education credit. Pharmacists successfully completing the quiz according to the instructions included in the February issues of the State Board Newsletter receive 0.1 C.E.U. in jurisprudence towards renewal of their license. A continuing education quiz in Jurisprudence is included by the Board in each February issue of the Newsletter and covers material appearing not only in the current February issue but also the material appearing in the previous three issues - May, August, and November. The continuing education report form includes a separate area for reporting approved jurisprudence courses.

Three thousand two (3,002) pharmacists took the February 1997 State Board Newsletter Jurisprudence examination for continuing pharmacy education credit. Pharmacists holding current licenses to practice in Ohio and who reside in 32 states, Brunei, England, Korea, and Canada used the February 1997 State Board Newsletter to obtain jurisprudence credit. One of the pharmacists participating in this program was serving in the military and had an APO mailing address. As expected, the majority of pharmacists taking the exam were from Ohio (2,675 or 89%). The next state having the largest participation was West Virginia with 60 Ohio licensed pharmacists. The following table lists the top ten states and the number participating from that state.

1997 February State Board Newsletter Jurisprudence Exam			
<u>State</u>	<u>No.</u>	<u>State</u>	<u>No.</u>
Ohio	2675	Florida	23
West Virginia	60	Indiana	18
Kentucky	44	Virginia	15
Pennsylvania	34	Nevada	12

Michigan	27	California/Illinois	10
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**Continuing Pharmacy Education Audit**

In order to spread out the administrative workload, the Board's continuing pharmacy education program requires that one-third of the registered pharmacists who hold current licenses to practice (identification cards) report the continuing pharmacy education that they have obtained in order to qualify for renewal each year. Consequently, 4,129 pharmacists reported continuing pharmacy education towards renewal of their licenses to practice for the 1997-1998 licensure year, and approximately 12% of those reporting were audited (514).

CONTINUING PHARMACY EDUCATION AUDIT					
FY	Date of Notice	Total Audited	Total PTD	Total Cleared Post-PTD	Total Denied (mon.pen.)
98	upon receipt	514	0	0	0
97	upon receipt	440	0	0	0
96	upon receipt	361	0	0	0
95	10/07/94	346	2	0	1 (2)
94	10/08/93	399	4	1	2 (1)
93	10/21/92	367	3	2	1
92	10/16/91	330	2	0	1*(1)
91	11/05/90	332	6	4	2
90	12/08/89	324	NA	NA	NA

*(mon.pen. = monetary penalty of \$100 imposed)*  
 NA-not available    PTD-proposed to deny    \*-one withdrew application

As discussed in last year's report, the procedure for conducting the continuing pharmacy education audit was changed during the 1995-1996 licensure year. The continuing pharmacy education audits are now conducted prior to issuing the license to practice. Identification cards are not issued until the pharmacists required to report continuing education credit have cleared the audit.

**DANGEROUS DRUG DISTRIBUTORS**

Licensing of sites engaged in the legal distribution of dangerous drugs is the foundation of drug law compliance and enforcement programs. Licensing requires a determination that those individuals wishing to engage in such activity meet certain qualifications. The Board does not license those that do not qualify.

This determination is made administratively by a careful review of the application and a background check of the applicant, their agents, officers, and employees. If the site being licensed is located in another state, the agency licensing the applicant in that state is contacted to verify if they are currently licensed in that state and whether or not their license is in good standing. If the applicant is licensed or registered with any federal drug law enforcement agency, a check is also made with that agency to verify licensure and determine the standing of such license.

New sites located in Ohio are licensed only after a Board compliance agent has visited the site and determined that they qualify. A continuing review of the licensee's qualifications for licensure is made during routine, unannounced compliance inspections. Renewal applications are also carefully reviewed each year to determine whether or not the license should be renewed.

The Board proposed to deny three applicants for licensure as terminal distributors of dangerous drugs and one applicant for licensure as a wholesaler of controlled substances in FY 98 to date. Two of the terminal distributor applications were denied following Chapter 119. hearings. The third terminal distributor application was withdrawn by the applicant before the adjudication hearing. The wholesale distributor license was issued following the public hearing.

**Wholesale Distributors of Dangerous Drugs  
 Manufacturers and Wholesalers of Controlled Substances**

The Dangerous Drug Distribution Act provides that all firms or businesses distributing dangerous drugs at wholesale in Ohio register with the Board of Pharmacy as a wholesale distributor of dangerous drugs. These firms register with the Ohio Board even if their place of business is located in another state. If the wholesale distributor of dangerous drugs is also engaged in the manufacture or wholesale distribution of controlled substances, they are licensed with the Board to engage in such activity. The following table illustrates the number of wholesale distributors (in-state and out-of-state) registered with the Board of Pharmacy as of June 30, 1997 and who hold manufacturer or wholesale licenses to also distribute controlled substances at wholesale in Ohio. The number registered as of April 6, 1998 appears in parentheses.

	WHOLESALE DANGEROUS DRUG DISTRIBUTORS			
	FY 97 (FY 98 TD)			
	Number <u>[MCS]</u>	Number <u>[WCS]</u>	Total <u>[MCS&amp;WCS]</u>	Number <u>[WDDD]</u>
In-state	8 (9)	208 (193)	216 (202)	525 (519)
Out-of-state	38 (36)	270 (253)	308 (289)	548 (532)
Totals	46 (45)	478 (446)	524 (491)	1073 (1051)
KEY: <i>[MCS] - manufacturer of controlled substances</i> <i>TD - as of 04/06/98</i> <i>[WCS] - wholesaler of controlled substances</i> <i>[WDDD] - wholesale dangerous drug distributor</i>				

**Terminal Distributors of Dangerous Drugs**

Ohio's Dangerous Drug Distribution Act provides for the licensing of most of the sites where dangerous drugs are stored in the state of Ohio for legal purposes. These purposes include the administration or dispensing of the drugs to patients (humans or animals) when diagnosing and/or treating illnesses or injuries. The drugs may also be used for purposes of teaching or in conducting research or drug analysis.

The sites where the dangerous drugs are stored for these purposes are licensed as terminal distributors of dangerous drugs. The Board has established 50 different classifications of terminal dangerous drug distributors for licensing and regulatory purposes. The table on Page 37 lists the different classifications and the number of licenses in each classification of terminal distributors as of April 1998.

The following table indicates the trends occurring among different categories of terminal distributors of dangerous drugs operating pharmacies in Ohio:

	FY 95	%	FY 96	%	FY 97	%	FY98TD	%
Retail Pharmacies	2229	84%	2211	83%	2205	80%	2170	79%
<i>Independent (1 outlet)</i>	606	27%	562	25%	512	23%	483	22%
<i>Small Chain (2-11 outlets)</i>	370	17%	337	15%	321	15%	301	14%
<i>Large Chain (12 or more)</i>	1258	56%	1312	59%	1372	62%	1385	64%
Hospital Pharmacies	231	9%	231	9%	226	8%	223	8%
Pharmacy serv. LTCF	48	1%	52	2%	53	2%	54	2%
Fluid Ther/HHC Pharmacy	83	3%	79	3%	80	3%	75	3%
Clinic Pharmacy	25	1%	28	1%	35	1%	35	1%
HMO Pharmacy	22	1%	24	1%	19	1%	15	1%
Mail Order Pharmacy	18	1%	15	1%	16	1%	15	1%
Nuclear Pharmacy	12	1%	13	1%	13	1%	14	1%
Non-Territorial Pharmacy					117	4%	142	5%
Non-Territorial Phar Svc LTCF					9	0.3%	9	0.3%
<b>Totals</b>	<b>2668</b>		<b>2653</b>		<b>2773</b>		<b>2752TD</b>	
	<i>TD - as of 04/10/98</i>							

Ohio's Dangerous Drug Distribution Act was amended in 1984 to provide for three different categories of dangerous drugs. The categories indicate those drugs which the licensed terminal distributor is permitted to purchase and possess for distribution or use in Ohio. The license may also be limited to certain drugs within a category of dangerous drugs. In these instances, the drugs are listed on the license addendum. The three categories of dangerous drugs are as follows:

**CATEGORY I** - Single dose injections of intravenous fluids, including saline, Ringer's lactate, five percent dextrose and distilled water, and other intravenous fluids or parenteral solutions included in this category by rule of the board of pharmacy, that have a volume of one hundred milliliters or more and that contain no added substances, or single-dose injections of epinephrine to be administered pursuant to division (B) of section 3303.08 of the Revised Code.

**CATEGORY II** - Any dangerous drug that is not included in category I or III.

**CATEGORY III** - Any controlled substance that is contained in schedule I, II, III, IV, or V.

The Category III license authorizes the person to possess, have custody or control of, and distribute Category I, II, and III dangerous drugs.

The following table lists the number of the six different categories of terminal distributor of dangerous drugs licensed by the Board.

<b>TERMINAL DISTRIBUTOR LICENSES BY CATEGORY</b>				
<i>(td - as of 04/10/98)</i>				
	<u>FY 95</u>	<u>FY 96</u>	<u>FY 97</u>	<u>FY98td</u>
Category I	3	1	1	1
Limited Category I	11	10	10	10
Category II	228	261	264	288
Limited Category II	769	1545	1720	1703
Category III	5575	5685	5869	5802
Limited Category III	1441	1438	1484	1537
<b>Total</b>	<b>8027</b>	<b>8940</b>	<b>9348</b>	<b>9341</b>

The number of Category I licenses has significantly decreased since this category was established by the Ohio General Assembly in 1984. This is due to the fact that Emergency Medical Technicians were authorized to administer epinephrine, a Category II dangerous drug once they have obtained the training required by the Emergency Medical Services Board (O.R.C. Section 4765.02). The decrease in Category I licenses also was due to the determination by the Federal Food and Drug Administration (FDA) in 1994 that medical-grade oxygen is a prescription drug. H.B. 391 was also adopted by the Ohio General Assembly in 1994 to provide the Board with the authority to license "retail sellers" of medicinal oxygen as limited terminal distributors of dangerous drugs. All Emergency Medical Systems now have a limited Category II or Category III terminal distributor license.

TERMINAL DISTRIBUTORS <u>Classification</u>	NUMBER LICENSED			
	<u>FY 95</u>	<u>FY 96</u>	<u>FY 97</u>	<u>FY98td</u>
Retail Pharmacy	2229	2211	2205	2170
<i>Independent (1 outlet)</i>	606	562	512	482
<i>Small Chain (2-11 outlets)</i>	370	337	321	300
<i>Large Chain (12 or more outlets)</i>	1253	1312	1372	1388
Hospitals	235	236	226	224
Fluid Therapy/Home Health Care	78	80	80	77
Pharmacy serving LTCF	47	54	53	53
Clinic Pharmacy	24	25	35	35
HMO	19	24	19	15
Mail Order Pharmacy-Located in Ohio	18	17	16	15
Nuclear Pharmacy	13	14	13	14
Specialty Pharmacy	5	5	7	9
Pharmacy/employees only	5	6	6	5
Non-territorial Pharmacy	46	76	116	143
Non-territorial Pharmacy serving LTCF/institutions	2	2	9	9
Health Care Facility Pharmacy	1343	1375	1417	1388
Pharmacy (contingency stock - LTCF)	4	5	7	7
Custodial Care	8	9	8	9
First Aid Dept.	324	324	322	324
Convalescent/rest/nursing home	11	9	8	8
DME (Medical Equipment) Pharmacy	2	3	5	8
Practitioner Corporation	245	246	249	254
Private Practitioners	22	23	41	36
Clinic	1008	1048	1151	1183
Home Health Care Agency	119	134	157	162
Correctional Institution	83	92	69	64
Mobile Clinic	1	1	1	2
Emergency Medical Systems	1405	1452	1517	1560
<i>Headquarters</i>	827	849	885	884
<i>Satellites</i>	578	603	632	676
Animal Euthanasia	14	22	26	29
Animal Control (dog wardns/humane soc. shlters)	44	40	41	41
Veterinary Facilities (includes zoos)	122	125	121	121
Laboratories/research	201	194	185	170
Teaching Institution	65	70	71	71
Sports Training Facility	11	10	13	16
Incinerators (Waste disposal)	8	10	9	3
Dog Trainer	21	25	35	31
Hospice	8	10	15	19
Corporate Headquarters	1	1	0	0
Physical Therapy	76	80	102	103
Retail Seller of Medical Oxygen	136	486	545	545
Oxygen Reseller - Contingency Stock	NA	354	409	381
Peritoneal Dialysis Center	NA	NA	NA	3
Other	23	16*	34**	35
<b>TOTAL LICENSED</b>	<b>8027</b>	<b>8940</b>	<b>9343</b>	<b>9342</b>

*TD – as of 04/14/98*                      *NA - not applicable*

\* *The Other classification of terminal distributors of dangerous drugs for FY 96 includes manufacturer-process use (4), food processors licensed to purchase nitrous oxide (10), SWAT EMS (1), group home drug use supervision (3), chemical treatment facility (2), blood banks (9), consulting pharmacies (1), non-emergency transport only (1), helicopters-physicians (2), and miscellaneous (14).*

\*\* *The Other classification of terminal distributors of dangerous drugs for FY 97 includes manufacturer-process use (5), SWAT EMS (2), group home drug use supervision (2), chemical treatment facility (3), blood banks (8), consulting pharmacies (1), non-emergency transport only (1), helicopters-physicians (2), food processors (nitrous oxide - 10).*

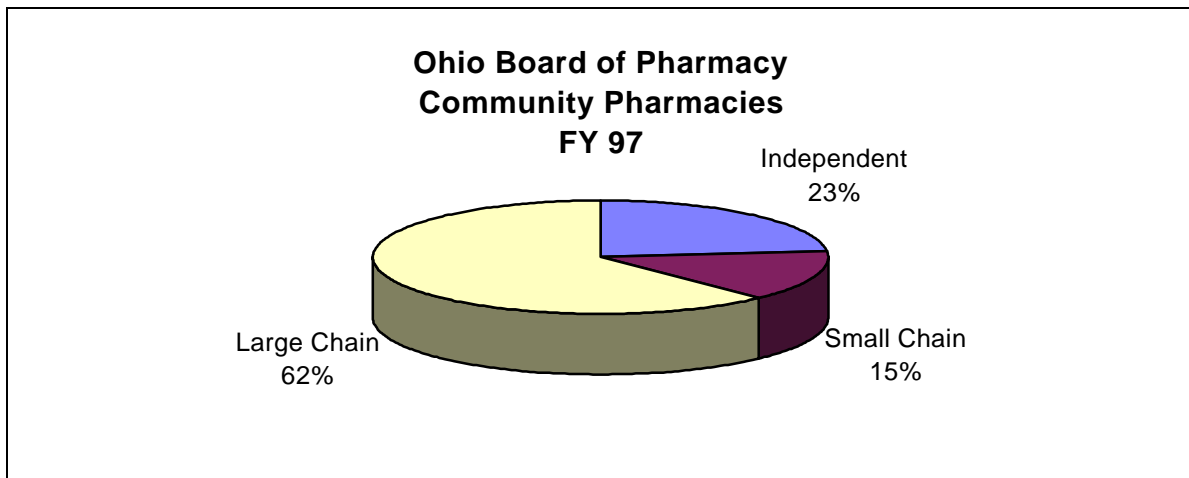
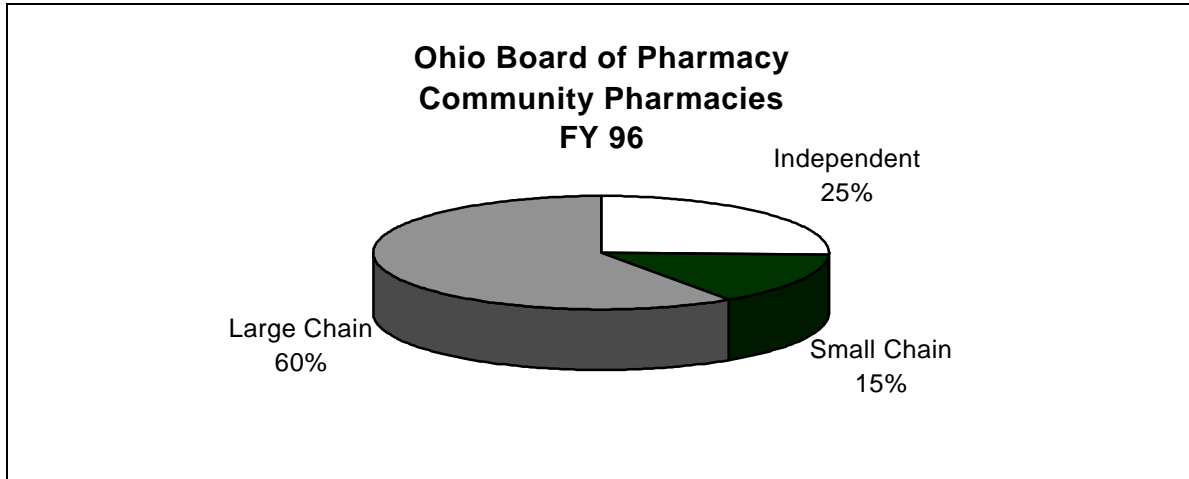
\*\*\* The Other classification of terminal distributors of dangerous drugs for FY 98 to date includes manufacturer-process use (4), SWAT EMS (2), group home drug use supervision (2), chemical treatment facility (3), blood banks (11), consulting pharmacies (0), non-emergency transport only (1), helicopters-physicians (2), food processors (nitrous oxide - 10).

Data concerning practice sites continues to document the decrease in the number of independent and small chain pharmacies licensed with the Board. In FYs 93, 94, and 95, the total number of independent pharmacies decreased by 188. Forty-four (44) independent pharmacies discontinued business during FY 96, 50 discontinued business in FY 97, and 30 thus far this fiscal year. Independent pharmacies have decreased by 25% (160 units) while the number of pharmacies operated by small chains decreased by 21% (81 units) since FY 94. In contrast, the number of pharmacies operated by large chains has increased by 17% (202 units).

Further documenting the continuing concentration of pharmacy ownership is the decreasing number of large chains owning and operating pharmacies in Ohio. The purchase of Revco Drug Stores and a small chain based in the Akron area by CVS of Woonsocket, Rhode Island has resulted in the majority of pharmacies in Ohio being operated by corporate entities based in other states. The only large corporate entity based in Ohio owning and operating pharmacies is the Kroger company. The following table ranks the five largest corporate entities owning and operating pharmacies in Ohio by the number of licensed units as of April 1, 1998.

<b>LARGE CHAINS</b> (owning & operating pharmacies in Ohio)		
<u>Corporation</u>	<u>Headquarters</u>	<u>Number of Ohio Pharmacies</u>
CVS/pharmacy	Woonsocket, RI	381
Rite Aid	Harrisburg, PA	316
Kroger	Cincinnati, OH	134
Kmart	Troy, MI	86
Walgreen	Deerfield, IL	66
Total		983 71%
Total # of large chain pharmacies in Ohio		1388 64%
Total # of Retail Pharmacies in Ohio		2170

Large chains showed the largest increase in the number of licensed practice sites. The number of retail pharmacies owned and operated by large chains (12 or more outlets) in the state of Ohio has increased every fiscal year since FY 91. The largest increase occurred during FY 93 when the Board licensed 76 large chain retail pharmacies. Large chains presently operate 64% of all retail pharmacies located in Ohio.



At the end of FY 94, there were 236 hospital pharmacies in Ohio. As of April 14, 1998, there were 224.

The following table consists of information generated by the Board's licensing system. "Active practice" includes pharmacists who are working full-time (40 hours or more per week) and those working part-time (less than 40 hours per week).

<u>REGISTRANTS AND PRACTICE SITE DATA</u>						
(As of June 30, 1997)						
<u>PHARMACY PRACTICE ACT</u>	<u>Total</u>	<u>%</u>	<u>Female</u>	<u>%</u>	<u>Male</u>	<u>%</u>
<b><u>REGISTERED PHARMACISTS</u></b>	<b>13368</b>	<b>100%</b>	<b>5567</b>	<b>41.6%</b>	<b>7801</b>	<b>58.4%</b>
<u>Active Practice</u>						
In Ohio	8535	100%	3632	42.6%	4903	57.4%
Out-of-state	2879	100%	1264	43.9%	1615	56.1%
<u>Active Practice Site In Ohio</u>						
Large chain (12+ outlets)	3508	100%	1470	41.9%	2038	58.1%
Private hospital	1618	100%	810	50.1%	808	49.9%
Independent (1 outlet)	1083	100%	290	26.8%	793	73.2%
Small chain (2-11 outlets)	443	100%	157	35.4%	286	64.6%
Government hospital (fed/state/local)	327	100%	158	48.3%	169	51.7%
Mail order pharmacy	397	100%	206	51.9%	191	48.1%
Clinic/Medical Bldg.	170	100%	70	41.2%	100	58.8%
Long-term care pharmacy	201	100%	92	45.8%	109	54.2%
HMO	130	100%	76	58.5%	54	41.5%
Military/V.A. hospital	110	100%	50	45.5%	60	54.5%
Fluid therapy pharmacy	88	100%	40	45.5%	48	54.5%
Nuclear pharmacy	43	100%	10	23.3%	33	76.7%
Pharmacy servicing nursing home(s)	149	100%	72	48.3%	77	51.7%
Nursing home	24	100%	15	62.5%	9	37.5%
<u>Pharmacy-related practice sites</u>						
Pharmaceutical manufacturer	27	100%	7	25.9%	20	70.1%
Pharmaceutical wholesaler	0	100%	0	0%	0	0%
<b><u>PHARMACY INTERNS</u></b>	<b>1452</b>	<b>100%</b>	<b>978</b>	<b>63.0%</b>	<b>574</b>	<b>37.0%</b>

The following tables provide "age by gender" data for the four main sites of practice in Ohio. These four practice sites account for 78% or 6,652 of the pharmacists engaged in active practice in Ohio. The numbers in the brackets indicate the number of practice sites in each of the four classifications of dangerous drug distributors.

<b>Independent Pharmacy [512]</b>			
(1 outlet)			
<u>Age By Gender Data as of June 30, 1997</u>			
(in-state only)			
<u>Age (years)</u>	<u>Female</u>	<u>Male</u>	<u>Total</u>
24 yrs or less	5	5	10
25 - 29	53	39	92
30 - 34	48	38	86
35 - 39	50	60	110
40 - 44	56	115	171
45 - 49	33	94	127
50 - 54	9	79	88
55 - 59	6	94	100
60 - 64	11	85	96
65 - 69	10	112	122
70 - 74	7	41	48
75 - 79	1	19	20
80 or greater	1	12	13
<b>TOTALS</b>	<b>290 (26.8%)</b>	<b>797 (73.2%)</b>	<b>1083</b>

<b>Large Chain Pharmacy [1372]</b>			
(12 or more outlets)			
<u>Age By Gender Data as of June 30, 1997</u>			
(in-state only)			
<u>Age (years)</u>	<u>Female</u>	<u>Male</u>	<u>Total</u>
24 yrs or less	61	21	82
25 - 29	520	297	817
30 - 34	321	252	573
35 - 39	237	202	439
40 - 44	178	296	474
45 - 49	73	278	351
50 - 54	29	181	210
55 - 59	32	190	222
60 - 64	12	167	179
65 - 69	3	108	111
70 - 74	2	30	32
75 - 79	1	13	14
80 or greater	1	3	4
<b>TOTALS</b>	<b>1470 (41.9 %)</b>	<b>2038 (58.1%)</b>	<b>3508</b>

Small Chain Pharmacy [321] (2 to 11 outlets)			
<u>Age By Gender Data as of June 30, 1997</u> (in-state only)			
<u>Age (years)</u>	<u>Female</u>	<u>Male</u>	<u>Total</u>
24 yrs or less	3	2	5
25 - 29	27	18	45
30 - 34	29	21	50
35 - 39	27	31	58
40 - 44	27	42	69
45 - 49	24	40	64
50 - 54	3	21	24
55 - 59	8	35	43
60 - 64	4	26	30
65 - 69	5	30	35
70 - 74	0	14	14
75 - 79	0	5	5
80 or greater	0	1	1
TOTALS	157 (35.4%)	286 (64.6%)	443

Private Hospital [226]			
<u>Age By Gender Data as of June 30, 1997</u> (in-state only)			
<u>Age (years)</u>	<u>Female</u>	<u>Male</u>	<u>Total</u>
24 yrs or less	24	16	40
25 - 29	159	90	249
30 - 34	184	93	277
35 - 39	165	132	297
40 - 44	162	179	341
45 - 49	68	148	216
50 - 54	20	75	95
55 - 59	15	29	44
60 - 64	9	23	32
65 - 69	3	12	15
70 - 74	1	7	8
75 - 79	0	3	3
80 or greater	0	1	1
TOTALS	810 (50.1%)	808 (49.9%)	1618

At the end of FY 97, the large chains employed 53% of the pharmacists actively practicing in retail pharmacies. Sixteen percent (16%) are actively practicing in independent pharmacies and seven percent (7%) in small chain pharmacies. The number of female pharmacists actively practicing in hospitals is almost the same as the number of male pharmacists.

All Ohio R.Ph. Age By Gender Data as of June 30, 1997 (in-state only)			
<u>Age (years)</u>	<u>Female</u>	<u>Male</u>	<u>Total</u>
24 yrs or less	120	53	173
25 - 29	977	578	1555
30 - 34	833	572	1405
35 - 39	742	644	1386
40 - 44	675	915	1590
45 - 49	329	767	1096
50 - 54	110	507	617
55 - 59	113	489	602
60 - 64	66	429	495
65 - 69	54	467	521
70 - 74	37	227	264
75 - 79	10	103	113
80 or greater	8	65	73
TOTALS	4074 (41.2%)	5816 (58.8%)	9890

## **REGULATION**

### **Ad Hoc Advisory Committee on Rule Review**

Each calendar year the Board appoints an Ad Hoc Advisory Committee on Rule Review. The members of this committee are volunteers and serve at their own expense. The Board of Pharmacy first established this committee in 1984 due to the enactment of the Regulatory Flexibility Act by the Ohio General Assembly. The sections of law making up this act requires each state agency to review each rule that effects individuals, small businesses, or small organizations at least once every five years.

The purpose of this review is to determine whether a rule should be continued without change, be amended, or rescinded, so as to minimize the economic impact of such rule on such persons. The following questions must be considered in reviewing each of the Board's rules:

- (1) Does the rule effect a "small business" (i.e.-an independently owned and operated business having fewer than 400 employees), or a "small organization (i.e.-an unincorporated association, sheltered workshop, or non-profit enterprise having fewer than 400 employees)?
- (2) Does the rule effect any individual in his or her capacity as an officer or employee of a "small business" or "small organization"?
- (3) Is the rule needed?
- (4) What is the nature of any written complaints or comments regarding the rule?

- (5) Does the rule duplicate, overlap, or conflict with other rules?
- (6) What is the degree of change that has occurred in the area affected by the rule in respect to technology, economic conditions, and other relevant factors?

The committee is appointed by the Board from lists of names submitted by organizations whose members are affected by rules adopted pursuant to the laws governing the practice of pharmacy and the legal distribution of drugs. Sub-committees are appointed in areas where members require a special expertise in addressing the required questions. For example, nuclear pharmacists serve as members of a subcommittee of the Ad Hoc Advisory Committee on Rule Review when the nuclear pharmacy rules are reviewed pursuant to the Regulatory Flexibility Act of 1984.

The following rules were reviewed by the 1997 Ad Hoc Advisory Committee on Rule Review:

<u>RULES SUBJECT TO REVIEW</u>	
<u>CALENDAR YEAR 1997</u>	
<u>Rule Number</u>	<u>Title</u>
4729-5-01	Definitions
4729-5-02	Identification card, photograph and signature
4729-5-03	Renewal of registration
4729-5-05	Change of name of registrant
4729-5-15	Practitioner
4729-5-18	Patient profiles
4729-5-20	Prospective drug utilization review
4729-5-22	Patient counseling
4729-9-05	Security requirements
4729-9-06	Disposal of dangerous drugs which are controlled substances
4729-9-08	Change in description of terminal dangerous drug facility
4729-9-09	Security of prescription blanks and D.E.A. controlled substance order forms
4729-9-10	Occasional sale
4729-9-13	Distributor of dangerous drug samples
4729-9-17	Storage of adulterated drugs
4729-11-01	Controlled substance schedule I
4729-11-02	Controlled substance schedule II
4729-11-03	Controlled substance schedule III
4729-11-04	Controlled substance schedule IV
4729-19-01	Definitions
4729-19-02	Prescriptions for sterile products
4729-19-03	Labeling
4729-19-04	Minimum standards for compounding parenteral or sterile product prescriptions

Twenty-three (23) rules were subject to review in 1997 pursuant to the Regulatory Flexibility Act. The committee, however, reviewed a total of 24 rules for possible amendment and

one new rule. The committee recommended that 11 of the rules subject to review not be changed, that 13 rules be amended, and one new rule be adopted by the Board.

The recommendations of the committee were proposed by the Board and a public rules hearing conducted on December 8, 1997. The Board adopted the one new rule and all but one of the proposed amended rules with an effective date of February 1, 1998. The Board substantially changed one proposed amended rule following the public rules hearing and refiled the revised proposed amended rule with the Joint Committee on Agency Rule Review (JCARR). The Board adopted proposed amended rule 4729-1-01 as refiled with JCARR with an effective date of April 1, 1998. A copy of the full text of the rules showing changes made may be obtained by contacting the Board office or by downloading the "Rules Effective in 1998 Showing Changes" under the What's New button on the Board's Internet Home Page:

**<http://www.state.oh.us/pharmacy/>**

The first meeting of the 1998 Ad Hoc Advisory Committee on Rule Review was held on March 24, 1998. The following rules are being reviewed by the 1998 Ad Hoc Advisory Committee on Rule Review:

<u>RULES SUBJECT TO REVIEW</u>	
<u>CALENDAR YEAR 1998</u>	
<u>Rule Number</u>	<u>Title</u>
4729-5-06	Pharmacist and pharmacy intern change of address and/or employment
4729-5-09	Prescription filing
4729-5-10	Prescription pick-up station
4729-5-31	Criteria for licensure by examination
4729-9-02	Minimum standards for a pharmacy
4729-9-14	Records
4729-9-21	Drugs compounded in a pharmacy
4729-9-22	Records of dangerous drugs
4729-10-01	Definitions
4729-10-02	Licensure
4729-10-03	Compliance
4729-10-04	Inspection
4729-13-01	Definitions
4729-13-02	Procedure for board of pharmacy approval as a laboratory
4729-13-03	Qualifications for a laboratory
4729-13-04	Recordkeeping
4729-13-05	Security controls for laboratories
4729-13-06	Responsible person for approved laboratories
4729-14-01	Definitions
4729-14-02	Procedure for licensure as an animal shelter
4729-14-03	Qualifications for licensure as an animal shelter
4729-14-04	Records of dangerous drugs
4729-14-05	Security controls for animal shelters
4729-14-06	Responsible person for an approved animal shelter

4729-15-01	Definitions
4729-15-02	Responsibility for nuclear pharmacy
4729-15-04	Labeling of radiopharmaceuticals
4729-15-05	Prohibitions

**COMMUNICATIONS**

**WORLD WIDE WEB**

**Ohio Board of Pharmacy Home Page**

**URL: <http://www.state.oh.us/pharmacy/>**

The Board's Home Page was placed on the World Wide Web on March 1, 1996. The following outlines the topics presently included under each button (heading below) on the Board's Home Page. Information on the Board's Home Page may be downloaded and printed from the World Wide Web.

**CONTENTS OF THE BOARD'S HOME PAGE ON APRIL 14, 1998**

<p><b>General</b></p> <ul style="list-style-type: none"> <li>• Mission Statement</li> <li>• Board Members and Staff</li> <li>• Annual Report – March 1996</li> </ul>	<p><b>Summaries of Laws/ Rules/Regulations</b></p> <ul style="list-style-type: none"> <li>• Rules Effective in 1996</li> <li>• Rules Effective in 1997</li> <li>• Rules Effective in 1998</li> <li>• The Legal Practice of Pharmacy</li> <li>• Prescriptions</li> <li>• Faxing Prescriptions</li> <li>• Controlled Substances/ Weight Loss</li> <li>• Samples</li> <li>• Fluid Therapy</li> <li>• Optometry Drugs</li> <li>• Ephedrine</li> <li>• C.S.A. Drug Abuse/ Misuse Report: Ephedrine</li> </ul>	<p><b>Registration/ Licensing</b></p> <ul style="list-style-type: none"> <li>• Registration As A Pharmacist By Exam</li> <li>• Registration As A Pharmacist By Reciprocity</li> <li>• Information Regarding Pharmacy Internship</li> <li>• Information Regarding Pharmacy Technicians</li> <li>• Continuing Pharmacy Education</li> <li>• Nonresident Terminal Distributor of Dangerous Drugs</li> <li>• Licensing of Animal Shelters for Euthanasia</li> </ul>	<p><b>Links to Other WWW Pages</b></p> <ul style="list-style-type: none"> <li>• NABP (National Assn. of Boards of Pharmacy)</li> <li>• OPA (Ohio Pharmacists Association)</li> <li>• NCPDP (National Council for Prescription Drug Programs)</li> <li>• Glaxo Wellcome's HELIX Network</li> <li>• Ohio Northern University College of Pharmacy</li> <li>• University of Cincinnati College of Pharmacy</li> <li>• Adherence, Inc.</li> </ul>
<p><b>Important Dates</b></p> <ul style="list-style-type: none"> <li>• Important Dates (Last Update 03/18/98)</li> </ul>	<p><b>FAQ</b></p> <ul style="list-style-type: none"> <li>• In Progress</li> </ul>	<p><b>C.P.E. News</b></p> <ul style="list-style-type: none"> <li>• Jurisprudence C.P.E. Information</li> <li>▪ State Board News - May 1996 - State Section</li> <li>▪ State Board News - Aug 1996 - State Section</li> <li>▪ State Board News - Nov 1996 - State Section</li> <li>▪ State Board News - Feb 1997 - State Section</li> <li>▪ State Board News - May 1997 - State Section</li> <li>▪ State Board News - Aug 1997 - State Section</li> <li>▪ State Board News - Nov 1997 - State Section</li> </ul>	<p style="text-align: center;"><b>E-Mail Board</b></p> <p style="text-align: center;">at</p> <p style="text-align: center;"><b><u><a href="mailto:bop_butler@ohio.gov">bop_butler@ohio.gov</a></u></b></p> <p style="text-align: center;">Click on address above!</p>

		<ul style="list-style-type: none"> <li>▪ State Board News - Feb 1998 - State Section</li> <li>▪ State Board News - Feb 1998 - Jurisprudence Quiz</li> <li>▪ Link to Adherence, Inc. page</li> </ul>	
<p><b>Board Minutes</b></p> <ul style="list-style-type: none"> <li>• JUN 24-28, 1996</li> <li>• JUL 24, 1996</li> <li>• AUG 6-9, 1996</li> <li>• SEP 16-19, 1996</li> <li>• OCT 21-25, 1996</li> <li>• DEC 2-6, 1996</li> <li>• JAN 27-31, 1997</li> <li>• MAR 3-7, 1997</li> <li>• APR 21-23, 1997</li> <li>• JUN 16-18, 1997</li> <li>• JUL 14-16, 1997</li> <li>• AUG 11-13, 1997</li> <li>• SEP 8-10, 1997</li> <li>• SEP 17, 1997</li> <li>• OCT 6-8, 1997</li> <li>• DEC 8-10, 1997</li> <li>• JAN 12-14, 1998</li> <li>• FEB 9-11, 1998</li> </ul>	<p><b>What's New</b></p> <ul style="list-style-type: none"> <li>• Sunshine Notice for April 6- 8, 1998 Board Meeting</li> <li>• Rules Effective in 1998 Showing Changes</li> <li>• Compliance Bulletin 97-003: Controlled Substance Scheduling of Butorphanol (STADOL NS &amp; STADOL injection) effective OCTOBER 31, 1997</li> <li>• Compliance Bulletin 97-002 Regarding Transfer of Prescription Information</li> <li>• Compliance Alert to All Salons Licensed By The Cosmetology Board Regarding Products Containing Ephedrine</li> <li>• C.S.A. Drug Abuse/ Misuse Report: Ephedrine</li> <li>• Compliance Bulletin 97-001 Regarding Ephedrine Exceptions Effective 03/31/97</li> <li>• Executive Director Position Opening</li> <li>• Annual Report - April 1997</li> <li>▪ State Board News - May 1997 - State Section</li> <li>▪ State Board News - Aug 1997 - State Section</li> <li>▪ State Board News - Nov 1997 - State Section</li> <li>▪ State Board News - Feb 1998 - State Section</li> <li>• State Board News - Feb 1998 - Jurisprudence Quiz--NOTE DEADLINE DATE</li> </ul>	<p><b>Fees</b></p> <ul style="list-style-type: none"> <li>• As of 07/01/97</li> </ul>	<p><b>In Progress</b></p>

The Home Page includes general information about the Board, tentative meeting schedules, the current official Minutes of the Board, Summaries of Laws, Rules, and/or Requirements regarding many topics, Compliance Bulletins, and reports published by the Board. Information about registration as a pharmacy intern, pharmacist, or dangerous drug distributor,

and current Newsletters will also be included on the Home Page as the documents are prepared for publication.

The World Wide Web continues to grow in its importance as a source of information. It has been reported that over 1000 Web pages are added to the Internet daily. Essentially a Web page is an information site and a particular Web site may contain thousands of documents consisting of many pages of information that can be easily accessed and printed out for reference purposes. All levels of government are using the Internet to make information readily available to the public.

The following three Web sites provide useful information:

<b>Ohio State Medical Board</b>	<a href="http://www.state.oh.us/medical/">http://www.state.oh.us/medical/</a>
<b>American Medical Association</b>	<a href="http://www.ama-assn.org/">http://www.ama-assn.org/</a>
<b>National Association of Boards of Pharmacy</b>	<a href="http://www.nabp.net">http://www.nabp.net</a>

The first two sites are helpful in obtaining information about physicians. The Ohio State Medical Board has a license search program that allows you to search their records regarding physicians licensed to practice in Ohio. You may search by last name and you can determine whether their license is in good standing or whether or not the State Medical Board has placed restrictions on a particular licensee's professional practice.

General information about physicians nationwide may be obtained from the AMA Web site through their "AMA Physician Select, On-Line Doctor Finder" program. General searches may be made for any physician in the United States by name or medical specialty. This file presently includes more than 650,000 doctors of medicine (M.D.) and doctors of osteopathy or osteopathic medicine (D.O.).

The National Association of Boards of Pharmacy Web site is new this year and provides copies of all the State Board Newsletters published through the Bureau of Voluntary Compliance. These documents may be downloaded and printed. The site also provides information regarding the association, its members, and publications. A current listing of all state boards of pharmacy, their addresses, and telephone numbers is maintained at this site and is linked if the particular state board has a Web site or e-mail address.

### **COMPLIANCE BULLETINS**

The Board's computer system provides the Board with the ability to communicate in a timely and cost-effective manner with those pharmacists or dangerous drug distributors having a "need to know" or whose professional practice/business has been or will be affected by laws, rules, or policy decisions made by state or federal regulatory agencies. Compliance bulletins are issued by the Board on an as-needed basis to those licensees and registrants being affected.

The Board has issued two compliance bulletins since last year's report. Compliance Bulletin 97-002 was mailed on September 2, 1997 to all pharmacists actively practicing pharmacy in Ohio. This bulletin discussed the transfer of prescription information when

requested by the patient as required by Ohio Administrative Code Rule 4729-5-24. The Board amended this rule with an effective date of July 1, 1997.

The second compliance bulletin (97-003 - Controlled Substance Scheduling of Butorphanol) was mailed to all Ohio Registered Pharmacists on October 22, 1997. This bulletin discussed the placement of all drug products containing butorphanol in Schedule IV by the Drug Enforcement Administration.

The Board also mailed a "Compliance Alert" for the first time in cooperation with the State Board of Cosmetology to the 20,000 beauty salons licensed in Ohio regarding products containing ephedrine and their classification as a Schedule V controlled substance in Ohio. The Compliance Alert was included in the State Board of Cosmetology's annual newsletter. The bulletin was prepared by the Board due to the large number of questions being received about the legal sale of these products in Ohio following the amendment of Ohio Revised Code Section 3719.41 by the General Assembly on March 31, 1997.

## **COMPLIANCE**

**L**icensing is a process by which government grants permission to engage in a particular business or profession. Licensing is an effective tool for enforcing laws and obtaining compliance in that it ensures that those individuals who are permitted to engage in the business are qualified. Licensure also provides the licensing agency with the opportunity to effectively monitor compliance with the laws and rules governing the business by conducting compliance inspections.

### **VOLUNTARY COMPLIANCE**

The Ohio Board of Pharmacy continues to educate pharmacists and the individuals responsible for the operation of pharmacies in Ohio regarding the importance of counseling patients and performing prospective drug utilization review when dispensing prescription medications. These efforts have included an annual meeting with the Directors of Pharmacy Operations of chains operating in Ohio; the issuing of written warnings during compliance inspections of outpatient pharmacies; and over 70 presentations by staff to groups of pharmacists and pharmacy students throughout the state of Ohio.

### **COMPLIANCE/ENFORCEMENT ACTIVITIES**

Monitoring of compliance with the patient counseling rules has been occurring during routine inspections of pharmacies as instructed by the Board in January, 1995; when investigating complaints or allegations of violations of drug laws and rules; and when investigating reports of dispensing errors. Written warnings are issued by Board agents and specialists for not complying with the rules regarding the maintenance of patient profiles, performing prospective drug utilization review, and patient counseling. Compliance agents and specialists also issue a "written warning" during a compliance inspection or investigation of a complaint if there are certain deficiencies or violations of laws and rules governing the legal distribution of dangerous drugs.

As reported last year, three "Notices of Opportunity for a Hearing" were issued in 1996 by the Board that include allegations that the pharmacist failed to "counsel patients" and perform "prospective drug utilization review". Two were issued to the responsible pharmacist and one to a pharmacy. These charges were the result of routine inspections conducted by the Board field staff. Two of the Notices were mailed on September 4, 1996 and the adjudication hearing for both the pharmacist and pharmacy were heard on Thursday, March 6, 1997. The Board found that the pharmacist did fail to perform patient counseling as well as failed to properly document the refusal of offers to counsel. Evidence was introduced during the hearing in this matter that steps had been taken by the responsible pharmacist to insure that the deficiencies identified during the hearing would not happen again and the Board did not take any action against the pharmacy.

The third Notice was mailed on January 7, 1997 and a hearing scheduled on June 16, 1997. Following the introduction of evidence and testimony in this matter, the Board found the responsible pharmacist "continuously failed to perform prospective drug utilization review and patient counseling on three different occasions. The pharmacist's license was suspended for thirty days and placed on probation for three years following the suspension. The Board also imposed a \$1,000 monetary penalty.

#### **Failure To Counsel Patients**

**Fiscal Year 98 to date** (July 1, 1997 through December 31, 1997) - Five hundred thirty-seven (537) retail pharmacies were inspected to date during this fiscal year and 166 written warnings were issued by field staff. Fifteen (15) of the written warnings issued during this time period included a "failure to counsel patients".

**Fiscal Year 97** (July 1, 1996 through June 30, 1997) - Eight hundred forty-four (844) retail pharmacies were inspected during this fiscal year and 268 written warnings were issued by field staff. Twenty-four (24) of the written warnings issued during this time period included a "failure to counsel patients".

**Fiscal Year 96** (July 1, 1995 through June 30, 1996) - Nine hundred fifty-five (955) retail pharmacies were inspected during FY 96 and 219 written warnings were issued by field staff. Nineteen (19) written warnings issued during this time period included a "failure to counsel patients".

**Failure To Perform Prospective Drug Utilization Review**

**Fiscal Year 96** (July 1, 1995 through June 30, 1996) - Sixteen (16) investigations were assigned during FY 96 regarding failure to perform prospective DUR. The following table indicates the disposition of these investigations:

<u>Failure To Perform DUR</u> FY 96 (July 1, 1995 - June 30, 1996)	
<u>Cases Closed</u>	<u>Disposition</u>
8	no merit/unfounded*
5	no time to investigate
2	open investigation
1	written warning (Pink Sheet) issued

\* *Effective prospective drug utilization review could not be performed by the pharmacists in these eight cases due to the fact that they did not have access to the patient's records that existed in other pharmacies nor the prescriber's office.*

The eight cases that were closed as “unfounded” document a fundamental problem that exists in our health care system today - the inability of the practicing pharmacist to obtain and/or access pertinent patient information in order to effectively perform prospective drug utilization review. Board staff determined that had an integrated health care patient information system been in place and the pharmacists had had access to the same information as the State agency paying for the prescriptions, prospective DUR could have been performed with appropriate intervention on behalf of the patient. The information did, however, document possible criminal activity on the part of several of the patients and/or prescribers. Accordingly, new cases were opened by Board agents and specialists regarding the following potential violations of state law:

1. Deception to obtain dangerous drugs
2. Trafficking in controlled substances
3. Corrupting another with drugs
4. Fraud

The Board issued three “Notices of Opportunity for a Hearing” that included allegations that pharmacists dispensing prescriptions did not perform patient counseling and prospective drug utilization review. The pharmacy and both pharmacists involved in the dispensing of the patient's prescriptions were issued “Notices”.

All three of these cases were resolved through settlement agreements with the respondents. One pharmacist paid a monetary penalty of \$950 while the other pharmacist and pharmacy each paid monetary penalties of \$2,500 to the State of Ohio.

**FY 97** (July 1, 1996 through June 30, 1997) - No allegations were filed with the Board in FY 97 regarding the failure of pharmacists to perform prospective drug utilization review even though 1,320 investigations were assigned to the field staff.

**COMPLIANCE INSPECTIONS**

Ideally, each site licensed with the Board should be inspected on an annual basis. This, however, is not feasible due to the increasing number of licensees and registrants, the increasing number and complexity of investigations, and legal problems associated with the enforcement of the drug laws.

The following table illustrates the total number of dangerous drug distributors licensed by the Board for FY 83 through FY 97 and FY 98 to date, number of inspections conducted each fiscal year, and percentage of sites inspected.

Ohio Board of Pharmacy COMPLIANCE INSPECTIONS			
FY	No. of Sites (out-of-state)	No. of Inspections	%
98 td	10,393 (684)	962	9%
97	10,416 (684)	1730	17%
96	8940 (523)	1762	20%
95	8515 (565)	1823	21%
94	8630 (487)	1434	18%
93	8044 (455)	1747	23%
92	8208 (324)	2196	28%
91	7645 (338)	2421	32%
90	7701 (349)	2593	34%
89	7879 (315)	1705	22%
88	7590 (285)	2248	30%
87	6997 (287)	1983	28%
86	7013 (269)	1811	27%
85	6894 (262)	2665	40%
84	6635 (237)	2778	43%
83	6828 (250)	3078	47%

*td - as of 12/31/97*

It is expected that approximately 20% (2080) of the sites licensed with the Board and located in the state of Ohio will be inspected by the close of this fiscal year (June 30, 1998). One new field staff employee was authorized in the budget this fiscal year - a compliance specialist. It is expected that this position will be filled by the middle of May. The new compliance specialist's responsibilities cover parts of central and southeastern Ohio. The compliance specialist's position in the Dayton area became vacant as of January 4, 1997 due to the fact that the Compliance Specialist for this area - William McMillen - was appointed Licensing Administrator. Candidates are also presently being interviewed for this position.

Other factors influencing the number of inspections conducted each year include an increasing number of summary suspensions of registered pharmacists' licenses each year pursuant to the provisions of Ohio Revised Code Section 3719.12 (Am. Sub. H.B. 615 - effective March 27, 1991); and the complexity and extent of investigations involving drug trafficking or fraud by health professionals and/or employees of dangerous drug distributors. These factors, plus the increasing number of new dangerous drug distributors being licensed by the Board, result in a smaller percentage of licensed sites being inspected each fiscal year.

The following table indicates the top 18 items cited during compliance inspections conducted by the field staff for FYs 96 and 97.

<u>WRITTEN WARNINGS</u> (Pink Sheets)		
<u>DESCRIPTION</u>	<u>FY 96</u> <u>RANKING (#)</u>	<u>FY 97</u> <u>RANKING (#)</u>
Drug Accountability	1 (77)	1 (114)
Drug Security	2 (47)	2 (75)
Library	4 (42)	3 (65)
DEA Inventory (biennial)	5 (32)	4 (54)
Improper Dispensing	7 (24)	5 (47)
RPh Initials/Date	3 (44)	6 (43)
Improper Prescription	6 (28)	7 (35)
Drug Labels (incomplete)	10 (16)	8 (25)
Patient Counseling	9 (19)	9 (24)
Rx Information Missing	11 (15)	10 (23)
Outdated Drugs	8 (20)	11 (22)
Barricade	13 (12)	12 (19)
OTC/Syringes	18 (4)	13 (12)
Illegal Sales	12 (14)	14 (9)
Cleanliness	16 (6)	14 (9)
I.D. Cards	14 (10)	16 (8)
Rx Copies	15 (9)	17 (7)
Key Security	17 (5)	18 (0)

**ENFORCEMENT**

**INVESTIGATIONS**

The following table indicates the number of investigations assigned to the field staff for Calendar Years 1992 through 1998.

INVESTIGATIONS ASSIGNED TO FIELD STAFF						
<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>	<u>1996</u>	<u>1997</u>	<u>1998 td</u>
1052 (8%↑)	1167 (11%↑)	1085 (7%↓)	1159 (7%↑)	1198 (3%↑)	1308 (9% )	570
<i>td - December 31, 1997</i>						

Incident reports received by the Board from pharmacists, dangerous drug distributors, other health professionals, law enforcement agencies, and the public regarding alleged violations of the federal and state drug laws are classified by subject matter before they are assigned to the field staff for investigation. The following table indicates the top five classifications assigned to the incident reports for FYs 96 and 97.

INCIDENT REPORTS BY CLASSIFICATION [Investigations Assigned To Field Staff]		
	<u>FY 96 Rank</u> <u>(# of reports)</u>	<u>FY 97 Rank</u> <u>(# of reports)</u>
THEFT OF DRUGS	1 (273)	1 (392)
DECEPTION TO OBTAIN	4 (127)	2 (164)
TRAFFICKING IN DRUGS	3 (138)	3 (145)
ERROR IN DISPENSING	2 (147)	4 (125)
FORGERY OF DRUG DOCUMENTS	5 (94)	5 (114)

As indicated in this table, four of the top five classifications of incident reports received by the Board in FYs 96 and 97 allege violations of Ohio Revised Code Chapter 2925. (Drug Crimes). Investigations of these incident reports alleging violations of this chapter are presented to the appropriate prosecutors and often result in the arrest and criminal prosecution of the alleged violators. The following table provides data concerning individuals arrested following investigations conducted by Board of Pharmacy field agents during FYs 96 and 97.

ARRESTS		
Drug Law Enforcement / Criminal		
	<u>FY96</u>	<u>FY97</u>
PHARMACIST/INTERN	16	14
REGISTERED NURSE	23	17
LPN	6	12
MD/DO	7	8
DDS	0	1
Pharmacy Employee	0	3
Physician Assistant	0	0
Podiatrist	1	3
Medical Assistant	0	4
Sales Representative	0	0
Other	<u>41</u>	<u>76</u>
Total Arrests	94	138

Investigations by the Board resulted in the arrest of 55 health care professionals in FY 97. Fifty-three (53) licensed health care professionals were arrested in FY 96. The results of these investigations were presented to the appropriate prosecutors for criminal prosecution.

#### **SUMMARY SUSPENSIONS WITHOUT A PRIOR HEARING**

Division (C) of Ohio Revised Code Section 3719.121, as amended by Am. Sub. H.B. 615 effective March 27, 1991, provided that the license or registration of a practitioner, nurse, pharmacist, manufacturer, or wholesaler shall be immediately suspended without a prior hearing by the appropriate board when a prosecutor has notified the board that the registrant or licensee has:

- (1) pled guilty to, or a judicial finding [has been made] of his guilt of, a felony drug abuse offense;
- (2) a judicial finding [has been made] of eligibility for treatment in lieu of conviction;
- (3) a judicial finding [has been made] of his guilt of an offense in another jurisdiction that is essentially the same as a felony drug abuse offense; or
- (4) a judicial finding [has been made] of his eligibility for treatment in lieu of conviction in another jurisdiction.

The amended statute further provided that the suspension shall remain in effect until a hearing is held by the licensing board. This legislation also provided the Board of Pharmacy and the other health professional licensing boards with the authority to suspend a license without a prior hearing provided there is clear and convincing evidence that continuation of the individual's professional practice or method of distributing controlled substances presents a danger of immediate and serious harm to others.

The Board of Pharmacy has placed a high priority on those cases where the licensee or registrant presents a danger to the public. Accordingly, these cases have first priority among the duties of the field staff and are quickly and thoroughly investigated. As discussed earlier, special one-day meetings of at least five voting Board members are scheduled when the field staff has obtained substantial and probative evidence in order to issue a summary suspension order. The Board scheduled special one-day Board meetings during FY 96 and six summary suspensions were issued.

**Fiscal Year 98 to date** (July 1, 1997 through April 3, 1998) - Four registered pharmacist licenses have been summarily suspended to date this fiscal year pursuant to notification by a prosecutor of judicial findings of guilt of a felony drug abuse offense. Five registered pharmacist licenses were summarily suspended to date in FY 98 based upon clear and convincing evidence that their continued professional practice presented a danger of immediate and serious harm to others.

**Fiscal Year 97** (July 1, 1996 through June 30, 1997) - Three registered pharmacist licenses were summarily suspended in FY 97 pursuant to notification by a prosecutor of judicial findings of guilt of a felony drug abuse offense. Eight pharmacists' licenses were summarily suspended in FY 97 based upon clear and convincing evidence that their continued professional practice presented a danger of immediate and serious harm to others.

**Fiscal Year 96** (July 1, 1995 through June 30, 1996) - No registered pharmacist licenses were summarily suspended in FY 96 pursuant to notification by a prosecutor of judicial findings of guilt of a felony drug abuse offense. Nineteen (19) registered pharmacist licenses, however, were summarily suspended in FY 96 based upon clear and convincing evidence that their continued professional practice presented a danger of immediate and serious harm to others.

<b>SUMMARY SUSPENSIONS</b>				
(O.R.C. § 3719.121 effective 03/27/91)				
<u>R.Ph.</u>	<u>FY 94</u>	<u>FY 95</u>	<u>FY96</u>	<u>FY 97</u>
Felony Drug Abuse (Prosecutor's notification)	9	4	0	3
Danger To Public	19	17	19	8
TOTAL Summary Suspensions	28	21	19	11

**ADJUDICATION ORDERS**  
**(Applications Denied/Disciplinary Orders)**

**Fiscal Year 98 to date** (July 1, 1997 through April 3, 1998) - Fifty-one (51) Notices of Opportunity for Hearing letters have been issued this fiscal year as of April 3, 1998. The Board, however, has withdrawn four of the Notices. Three of the Notices withdrawn proposed to deny two applications for licensure as a terminal distributor. The applicants for licensure withdrew their applications once they received the Board's proposal to deny, consequently the Board withdrew their Notices of Proposal to Deny. Out of 40 Notices issued to pharmacists to date, there were nine summary suspensions, one proposal to deny a renewal application, and one Notice of Probation Violation.

Twenty-three (23) adjudication orders have been issued to date this fiscal year. Twenty (20) Chapter 119. hearings have been held before the full board and three were issued following consideration of evidence and testimony where the respondents did not request a hearing. Four pharmacist licenses have been revoked so far this fiscal year. The Board indefinitely suspended five pharmacist licenses, three reinstatement petitions were approved, two applications for licensure by reciprocity were denied and one was approved, and four applications to sit for the licensure examination were denied. Thirteen (13) settlement agreements have been finalized to date this fiscal year, five are pending the signature of the Board president and Assistant Attorney General, and two settlement agreements are pending.

**Fiscal Year 97** (July 1, 1996 through June 30, 1997) - Forty six (46) Notices of Opportunity for a Hearing were issued during FY 97 with 11 of these being settled by agreements between the respondent and the Board. Fifty (50) Adjudication Orders were issued by the Board in FY 97 of which 42 were the result of hearings before the full Board, and seven were issued by the Board following the consideration of evidence and testimony where the respondents did not request a hearing. The Board withdrew one of the Notices of Opportunity for a hearing.

Twelve (12) pharmacist licenses were revoked by the Board in FY 97. Three applications for licensure as a pharmacy intern were denied and one was approved by the Board following hearings before the full Board in FY 97. The Board also approved six petitions for reinstatement and denied one petition for reinstatement of a suspended pharmacist license in FY 97.

**Fiscal Year 96** (July 1, 1995 through June 30, 1996) - Sixty-seven (67) Notices of Opportunity for a Hearing were issued during FY 96. The Board issued 45 Adjudication Orders in FY 96 (34 hearings before the full Board, two before a hearing officer(s), and nine following the consideration of evidence and testimony where the respondents did not request a hearing).

The Board revoked 11 pharmacist licenses and two terminal distributor of dangerous drugs licenses in FY 96. Two applications for licensure as a pharmacy intern were approved following a hearing before the full Board, and four applications for registration as a terminal distributor of dangerous drugs were denied by the Board in FY 96. The Board approved three applications to sit for the licensure examination, of which one was a revoked pharmacist, and denied one application to sit for the licensure examination.

The Board denied two pharmacists' petitions for reinstatement of their licenses to practice and approved six pharmacists' petitions for reinstatement in FY 96. The Board also revoked two pharmacists' probation and re-instituted the suspensions following a probation violation hearing.

In FY 96, the Board also entered into five settlement agreements.

### **PROBATION - IMPAIRED PRACTITIONERS**

The license of an impaired pharmacist is immediately suspended by the Board without a prior hearing if continuation of his/her professional practice and/or method of distributing controlled substances presents a danger of immediate and serious harm to others. If requested by the pharmacist, a Chapter 119. public hearing is held to determine whether or not the pharmacist's license will be reinstated and, if so, whether or not limitations will be imposed on his/her professional practice and employment.

A license to practice is reinstated by the Board if the pharmacist has submitted satisfactory evidence at the public hearing that they are no longer impaired and that they will not present a danger of immediate and serious harm to others. Restrictions are often placed on the licenses of these individuals for a period of time as well as certain conditions that they must fulfill during the time stipulated by the Board. The restrictions vary from not being permitted to serve as a preceptor for a pharmacy intern or as the responsible pharmacist for a terminal distributor operating a pharmacy.

Often, the Board also requires that the pharmacist continue to receive counseling; attend regular meetings of support groups; submit written reports to the Board on a monthly or quarterly basis; be monitored by an approved limited treatment provider for a period of time; and submit to random, observed urine screens. The Board also stipulates that the pharmacist not violate any federal or state laws and regulations governing the legal distribution of drugs or the practice of pharmacy.

Thirty-three (33) pharmacists have had their licenses reinstated and are on probation or practicing under certain restrictions as of February 9, 1998.

### **ISSUES - TODAY & TOMORROW**

Issues that the profession and the boards will be continuing to address during the next year include the pharmacist's workload, dispensing errors, confidentiality of patient health information, informed consent, and the integrity of health care data maintained by the health care system.

Problems regarding the impact of marketing programs by prescription benefit management (PBM) firms and pharmaceutical manufacturers on patient care are also becoming an important issue and are the cause of many of the calls and complaints being received by the Board office. These calls are coming from both patients and health care professionals caring for those patients. The impact of these programs will continue to be more problematic as the health care system moves towards the goal of measuring and ensuring "positive outcomes" in patient care.

### **PHARMACIST WORKLOAD / PHARMACY STAFFING**

One of the greatest concerns of the Board continues to be the increasing workload of pharmacists in community pharmacy practice sites and the problems that result from inadequate staffing. Representative Bryan Williams introduced House Bill 532 on July 8, 1997 to amend Ohio Revised Code (ORC) Section 4729.27 as follows:

Section 4729.27.

A person not a registered pharmacist, who owns, manages, or conducts a pharmacy ~~as defined in section 4729.02 of the Revised Code,~~ shall have in ~~his~~ THE PERSON'S employ, in full and actual charge of such pharmacy, a pharmacist registered under ~~the laws of this state~~ THIS CHAPTER. Any registered pharmacist who owns, manages, or conducts a pharmacy shall be personally in full and actual charge of such pharmacy, or shall have in ~~his~~ THE PHARMACIST'S employ in full and actual charge of such pharmacy, a pharmacist registered under ~~the laws of this state~~ THIS CHAPTER.

EACH PHARMACY SHALL BE STAFFED AND EQUIPPED IN A MANNER THAT IS APPROPRIATE TO PROVIDE ITS PHARMACISTS WITH THE ABILITY TO PRACTICE PHARMACY IN A SAFE AND EFFECTIVE MANNER.

The legislation has had two hearings in the house to date.

Inadequate staffing and increasing workloads not only prevent or make it difficult, if not impossible, to counsel patients and perform prospective drug utilization review but also results in an increasing number of dispensing errors. The proposed legislation will provide the Board of Pharmacy with the ability to address these issues when inspecting pharmacies, investigating complaints, and in taking disciplinary action against the pharmacy and its owners when appropriate.

### **CONFIDENTIALITY OF PATIENT HEALTH INFORMATION** **(Patient Compliance Programs and Therapeutic Switch Programs)**

The confidentiality of patients' health care records continues to be a major concern at both the state and federal level. The topic has been receiving considerable publicity with the implementation of bogus "patient compliance programs". A person's health is a "personal" matter and many patients are outraged when they have reason to believe that their prescription data is being shared with individuals that they do not know and do not have any legitimate need to know what drugs they are taking or medical problems that they may be experiencing.

These programs are also increasing the administrative workload of practicing health care professionals and interfering with their ability to care for patients. Three cease and desists regarding prescription records and patient confidentiality were issued by the Board to date this fiscal year - Wholesale Alliance, L.L.C., Neucare, and Kmart.

The following text has been excerpted from the Cease and Desist Order that was issued by the Board this past week to the headquarters of Kmart in Troy, Michigan. This Cease and Desist Order documents the problems being created by these marketing programs. The full text of cease and desist orders issued by the Board may be found in the Board Minutes [may be viewed on the Board's Internet HomePage site (click on "Board Minutes")].

RE: Compliance Programs/Patient Records

Ohio Board of Pharmacy records indicate that you are the Executive Vice-President and Chief Administrative Officer of Kmart which owns and operates several pharmacies throughout the state of Ohio.

It has come to the attention of the Board that Kmart's corporate headquarters has implemented a computer-based marketing program regarding patients' compliance with their prescribed drug therapy. Ensuring that a patient complies with this drug therapy is an important goal that can only be accomplished by a practicing pharmacist whose intent is to improve the patient's quality of life and ensure positive drug therapy outcomes.

Kmart's program as it is structured, however, is problematic in several areas – not the least of which is that the program appears to be designed primarily to increase drug sales rather than placing the primary concern on the welfare of the patient. The system automatically targets a patient based on the prescription refill records maintained in Kmart pharmacies only and does not involve the professional judgment of a pharmacist who directly interacts with the patient.

Whether or not a patient should have a prescription refilled is a personal decision based on professional advice given by the pharmacist and the prescriber when appropriate. The decision needs to be based on personal information obtained by a pharmacist who has the opportunity to discuss the matter confidentially with the patient. Once the pharmacist has determined the reasons why the prescription has not been refilled, the reasons should be documented and an appropriate intervention carried out by the pharmacist communicating personally with the patient.

The Board has received information that a pharmacist practicing in Kmart's pharmacy where the patient's prescriptions are dispensed is not involved in the decision about whether or not a letter under that pharmacist's name will be sent to a patient encouraging the patient to have a particular prescription refilled. This raises several questions:

- (1) What information does corporate headquarters have that indicates that the patient should be continuing a particular drug therapy?
- (2) Is corporate headquarters encouraging a patient to have prescriptions refilled for drugs that have been discontinued by the physician or are no longer needed by the patient?
- (3) Does the patient have another prescription on file for a different drug to treat the same condition at the pharmacy or at another pharmacy in the community?

The problems with Kmart's program are exacerbated in that it appears that confidential prescription information that is patient-specific may have been compromised by being disclosed to individuals who are not responsible for providing professional care to the patient. According to information received by the Board, Kmart pharmacists do not know who has generated the letters under their name and how confidential patient information has been obtained by the persons preparing and mailing the letters.

If confidential patient information has been released pursuant to a written authorization from the patient in accordance with paragraph (A)(8) of Ohio Administrative Code Rule 4729-5-29 (copy enclosed), the Board is concerned that the authorization on the part of the affected patient was not "an informed consent". "Informed consent" connotes the fact that the patient understood that their prescription information would be provided to other entities by the corporate office of Kmart for marketing purposes. The signing of a third party log when picking up a prescription does not meet the Board's requirement for "written authorization" as used in Ohio Administrative Code Rule 4729-5-29.

YOU ARE HEREBY ADVISED that, pursuant to Section 4729.25(B) of the Ohio Revised Code, the Board of Pharmacy may issue notice or warning to an alleged offender of any of the provisions of Chapter 4729. of the Ohio Revised Code; thus, you are hereby notified to immediately cease distributing patient prescription information to any person in violation of Rule 4729-5-29 of the Ohio Administrative Code.

Another marketing program causing considerable controversy regarding the confidentiality of patients' prescription records, the workload of health care professionals, and quality patient care are referred to in the pharmaceutical trade literature as "therapeutic switch" or "preferred drug programs". The following text appears in the May 1998 issue of the State Board Newsletter and is published in this report to illustrate the problems resulting from these marketing programs.

#### **PBM's AND THERAPEUTIC SWITCH PROGRAMS**

Prescription Benefit Management (PBM) firms are actively engaged in programs to switch patients' medications from centralized calling centers. Pharmacists or other employees located at these call centers are calling physician offices to obtain their permission to dispense a different medication than that originally prescribed. Once authorization is obtained, one of the prescription benefit companies forwards a "prescription change authorization" form to the patient with the instructions that they are to give the form to their pharmacist when they go to a pharmacy to obtain a refill of the previously-prescribed medication.

THE BOARD ADVISES PHARMACISTS PRACTICING IN OHIO THAT THIS FORM MAY ONLY BE USED FOR INFORMATION PURPOSES. IT IS NOT A NEW PRESCRIPTION. Pharmacists receiving these forms must contact the prescriber in order to obtain a new prescription order for the patient. Any refills remaining on the original prescription order should also be cancelled and comments recorded in the patient's drug therapy profile regarding the date the patient's therapy was changed following receipt of a new oral or written prescription from the prescriber. The PBM firm's pharmacist or other employee is not an agent of the prescriber and cannot legally transmit a prescription order for the prescriber as his/her agent.

The Board has also received a report that another PBM company had one of their pharmacists or employees call in a new prescription to an Ohio pharmacy following contact with the prescriber to change the drug originally prescribed and dispensed to the pharmacy's patient. THIS IS NOT A NEW ORAL PRESCRIPTION AND THE NEW DRUG MAY NOT BE LEGALLY DISPENSED WITHOUT THE DISPENSING PHARMACIST CONTACTING THE PRESCRIBER AND OBTAINING A NEW PRESCRIPTION DIRECTLY FROM THE PRESCRIBER OR THE PRESCRIBER'S AGENT.

The Ohio pharmacist receiving the telephone call from a pharmacist employed by the PBM company questioned whether or not the prescription that he was calling in was a legitimate prescription in Ohio. The pharmacist calling from the PBM located in another state was reported to "stammer" and quickly state that the call is for information purposes only and that the Ohio pharmacist may want to call the prescriber. The pharmacist did call the prescriber and discovered that the prescriber had completed a form sent to him by the PBM firm and mailed it back to the PBM over a month ago. The prescriber completed the form and authorized that Zestril 5mg be dispensed in place of the previously prescribed and dispensed Vasotec 5mg. The prescriber also noted however that he had seen the patient since the authorization form had been completed and returned to the PBM over a month ago and reported that he had issued a new written prescription for Zestril 10mg since authorizing the change in drugs. The pharmacist was told that the lower dose should not be dispensed since the information on the form was out of date and did not reflect his most recent decision to increase the dose.

### **INTEGRATED HEALTH CARE DATA SYSTEMS & DATA INTEGRITY**

One of the assumptions regarding health care reform and the pursuit of positive outcomes is that the development and implementation of integrated patient care data systems is necessary for success. This assumption is based on the belief that access to and the use of the integrated patient health care information by health professionals will result in good decisions and positive outcomes.

The Board's limited experience with integrated data in systems capturing and maintaining patient prescription data exposes a major problem - the integrity and trustworthiness of the patient data in the system. This is a major problem that will become more important as more patient data systems are integrated and unreliable information is used by health care professionals using such data to make patient care decisions. The following text has been excerpted from the May 1998 State Board Newsletter and is included in this report to document two problems that resulted in complaints being filed with the Board by both a patient's caregiver and a prescriber.

### **INTEGRATED HEALTH CARE DATA SYSTEMS AND DATA INTEGRITY**

Several complaints have been received within the last month by the Board from prescribers and patients regarding problems they have experienced with PBM programs. An investigation of the complaints documents the fact that there is a real problem with the integrity and reliability of prescription information being entered into the systems by dispensing pharmacies.

The first complaint was from a prescriber who received a "DUR" letter from the PBM questioning her prescribing of drugs for a patient that the PBM considered to be over-utilizing controlled substances. The "DUR" letter further stated that the PBM's program "is an information sharing tool intended to help you (the prescriber) assess your patient's drug therapy requirements". Following receipt of the DUR letter, the prescriber was furious and following a telephone call to the Board office on the advice of a local pharmacist, the prescriber's office manager faxed copies of the FAX cover sheet, the DUR letter, and the so-called "Patient Profile".

The prescriber was extremely upset and rightly so due to the fact that she had not prescribed any of the drugs for the alleged "patient" who was "over-utilizing" controlled substances. The prescriber wanted her name removed from the records indicating that she was the responsible prescriber. A careful review of the so-called "Patient Profile" by Board staff also indicated that one controlled substance prescription had been filled six times on the same day, two times with the brand name drug and four times with a generic by the same pharmacy. How the PBM generated such a report and from what information has not yet been determined. It is obvious, however, that the information is not reliable and should not have been used in judging the prescribing practices of the prescriber or possible "over-utilization" of controlled substances by the patient.

Another example of the questionable integrity and reliability of prescription data submitted to third-party payers and used by or accessed by a PBM to perform a "therapeutic switch" is the complaint received by the Board from an irate patient. The patient's spouse called the Board office to complain about the fact that they had received a "prescription change authorization form" indicating that a prescriber had authorized a new drug for her husband's blood pressure. The problem was that the prescriber authorizing the change was not the prescriber providing her husband's medical care. In fact, the prescriber authorizing the change had not even seen her husband for at least six years and they had changed to a new doctor because they were dissatisfied with the care provided by this prescriber.

The problems illustrated by the complaints described above provide the reasoning behind the Ohio Board of Pharmacy's warning that an authorization to dispense a different medication than that originally prescribed should be obtained directly from the prescriber and no one else. Relying on a third-party source for information that will result in an action being taken regarding a patient's drug therapy can cause serious problems if the information is not correct or current.

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