

State of Maryland Board of Pharmacy 2003 Annual Report

July 1, 2002 thru June 30, 2003

Dispensing Help
In Your Community



TABLE OF CONTENTS

I. VISION	i
II. MISSION	i
III. VALUES and GUIDING PRINCIPLES.....	i
a. Trust	i
b. Quality Service	i
c. Responsibilities.....	i
IV. BOARD OF PHARMACY 5 YEAR GOALS (FY 2001-2006)	i
V. BOARD COMMISSIONERS AND BOARD COUNSEL	1
VI. PRESIDENT'S MESSAGE.....	2
VII. EXECUTIVE DIRECTOR'S REPORT	4
VIII. SECRETARY/TREASURER'S REPORT	5
IX. BOARD OPERATIONS REPORTS	6
a. Licensing Unit	6
b. Pharmacist Compliance Unit	7
c. Legislation/Regulatory Unit	9
d. Public Information and Education Unit	12
e. Technology and Automation Unit	13
f. Task Force Report – Bio-terrorism and Emergency Preparedness	15
X. PHARMACISTS' EDUCATION AND ASSISTANCE COMMITTEE (PEAC)	16
XI. STAFF MEMBERS	18
XII. PUBLIC MEETINGS	18
XIII. INTERNET SERVICE	18

VISION

Setting a standard for pharmaceutical services, which ensure safety and quality health care for the citizens of Maryland.

MISSION STATEMENT

The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality health care in the field of pharmacy, through licensing pharmacists and issuing permits to pharmacies, and distributors; setting standards for the practice of pharmacy through regulations and legislation; receiving and resolving complaints and educating consumers. The Maryland Board of Pharmacy sets standards that ensure safety and quality health care for the citizens of Maryland.

VALUES AND GUIDING PRINCIPLES

INTEGRITY – The Board selected integrity as its overarching value. It is defined through the following guiding principles:

Trust

Treating all parties served in ways that will demonstrate that the Board of Pharmacy is honest, impartial, professionally competent, consistent and ethical; that all of the Board's actions and judgments are legal and appropriately serves customers and stakeholders.

The Board respects and appropriately maintains the confidentiality of the individuals and groups that it represents and regulates.

Quality Service

The Board offers accurate, timely and appropriate services to customers and stakeholders by being responsive, accessible, respectful, attentive, consistent and tactful in accordance with its unified vision.

Responsibilities

The Board carries out disciplinary and licensing activities in an impartial, comprehensive and appropriate manner.

The Board addresses issues in accordance with established written guidelines, policies, and procedures.

Decisions are made after gathering and analyzing all pertinent information available from all parties involved.

BOARD OF PHARMACY 5 YEAR GOALS (FY2001-2006)

Goal I: Communication

The Maryland Board of Pharmacy will utilize various means of communication to maximize the efficiency and effectiveness of Board activities.

Goal II: Compliance

An efficient, fair and consistent compliant process that enhances the quality of care provided through licensed health care professionals and the regulated industry.

Goal III: Public Awareness

The Public is informed about the availability of pharmaceutical services and how appropriate medication use can enhance the quality of care and safety.

Goal IV: Political Relationship

Strong partnerships with stakeholders (to include governmental officials, consumer groups and the regulated pharmacy industry) who are educated and informed about pharmacy related issues that affect health care quality, and the safety and welfare of the citizens of Maryland.

Goal V: Addressing Change

Statutes and regulations that govern the practice of pharmacy, as well as the policies of the Board, reflect current standards of practice.

Pharmacists and permit holders have access to timely and relevant information and guidance that helps improve their practice, safely utilize new technology and remain current with the regulatory policies of the Board.

Goal VI: Staffing

The Maryland Board of Pharmacy currently has well-qualified human resources that can accomplish the Board's mission.

BOARD COMMISSIONERS

Stanton G. Ades	President; Long Term Care Representative
W. Irving Lottier, Jr.	Secretary; At-Large Representative
Melvin Rubin	Chair, Unlicensed Personnel Task Force; Independent Representative
Wayne Dyke	Chair, Licensing Committee; Chain Drug Store Representative
Jeanne Furman	Chair, Disciplinary Committee; Acute Care Hospital Representative
Barbara Faltz-Jackson	Chair, Public Relations Committee; Consumer Representative
Raymond Love	Chair, Practice Committee; Acute Care Representative
Donald Yee	Chair, Medication Error Task Force; Home Infusion/Care Representative
John Balch	Independent Pharmacy Representative
Ramona McCarthy Hawkins	At-Large Representative
Rev. William E. Johnson, Sr.	Consumer Representative

BOARD COUNSEL

Paul Ballard	Assistant Attorney General
Linda Bethman	Staff Attorney

BOARD PRESIDENT'S REPORT

Stanton G. Ades



The Board was again very active in FY 2003, successfully implementing many new initiatives and regulations. It welcomed Governor Ehrlich's appointment of Joseph DeMino (representing chain drug stores), Christiaan Blake (representing consumers) and Mark Levi (At-Large pharmacist member). Key legislation effected in 2003 allows pharmacists to engage in Drug Therapy Management arrangements with physicians and patients (HB 781) and requires permit holders to implement on-going quality assurance programs (HB 462). Also, during FY 2003, the On-line Renewal system was developed and tested for implementation. These and other significant accomplishments will be described throughout this FY 2003 Annual Report. However, the occasion of my last Board term in FY 2004 causes this to be my last Annual Report to the Governor, General Assembly, and Secretary for the Department of Health and Mental Hygiene. The remainder of my remarks will reflect upon the Board of Pharmacy accomplishments throughout my eight-year board tenure.

The Maryland Board of Pharmacy celebrated its 100th anniversary in 2002. Bylaws, created in 1902 provided the Board with its framework, including: the rights to hold meetings, obtain funds, elect officers, and offer examinations. Stealing a phrase from a now politically incorrect advertising campaign. "We've come a long way, baby!"

When I was appointed to the Board in 1996, it consisted of nine (9) members and seven staff persons. I will leave the FY 2004 Board with 12 appointed members and 15 staff members (two positions were vacant as of this writing). The significant growth in Board members and staff was spurred by a need to meet identified goals (discussed later). In 1996, electronic prescribing, fax transmissions and automated dispensing were concepts that had not been addressed by Board regulations, because use of these types of systems was limited. Since then the Board has developed regulations to address new technologies used in pharmacies. In 1999, the Board launched its web site -- during FY 2003, the Board began on-line licensing.

The Board had failed several attempts to initiate legislation for collaborative practice -- it successfully ushered in the passage of the Drug Therapy Management in FY 2003, with assistance from the Board of Physicians, a consortium of interested entities and even a former Board of Pharmacy president.

The Board recruited a new Executive Director, and subsequently created three key staff positions during calendar year 2000 -- a Regulations/ Legislative Officer, Fiscal/Personnel Officer and Public Information and Education Officer. It also added a second staff position to the Compliance Unit and will hire a third part-time person to support that unit.

STATE OF MARYLAND BOARD OF PHARMACY 2003 ANNUAL REPORT

Many of the Board's accomplishments during my tenure can be attributed to adhering to a Five-Year Strategic Plan that established direction to assure that processes and systems were in place to meet the above FY 2001 – FY 2005 goals listed in this report.

With one fiscal year remaining for the current Strategic Plan, I can attest to the fact that the Board is meeting its goals. The Board now produces an in-house quarterly newsletter that reflects information of a greater significance to Maryland pharmacist practitioners; has implemented strategies for patient education, practitioner education, disciplinary actions, and medication safety; co-sponsors the Pharmacists' Education and Assistance Committee's (PEAC) annual continuing education programs; is a leader in recruitment and training methods for volunteer state licensed health practitioners engaged in emergency preparedness activities; unveiled a new website format in April 2002 that enables users to make address changes online, verify licenses and permits, and obtain reciprocity information.

Through active participation during its 10-year Sunset review and educating state legislative analysts, outgrowth legislation now requires annual inspections of pharmacies, limited discovery to facilitate pharmacies in tracking medication errors to address patient safety, and has repealed the Board's authority to regulate manufacturers. Through Board involvement with stakeholders, the State Advisory Council on Pain Management now includes a pharmacist member, and pharmacist members were also added to the Osteoporosis Prevention and Education Task Force and the State Advisory Council on Quality of Care at End of Life.

The list of regulations under C.O.M.A.R. reviewed by the Board has been extensive, including revising regulations 10.34.04-Transfer and Outsourcing of Prescriptions and Prescription Orders, 10.34.14-Closure of Pharmacies, 10.20.34-Format of Prescription Transmission, and 10.34.16-Portable Drug Kits

for Licensed Home Health Agencies and Hospice. COMAR 10.34.10.01-Pharmacist Code of Conduct was amended to require pharmacists to "maintain proper sanitation, hygiene, biohazard precautions, and infection control when performing tasks in the prescription process" and to make unprofessional conduct grounds for discipline as well as the Standards of Practice for Unlicensed Personnel regulations to require that permit holders ensure that unlicensed personnel maintain proper sanitation, hygiene, biohazard precautions, and infection control while performing tasks in the prescription process. The Delivery of Prescriptions regulations were also effected to address pharmacies' and pharmacists' responsibilities when prescription medications are sent to patients via mail or delivery system.

All Board complaints are kept on file at the Board offices and are tracked using an electronic database. The database helps with the Board's ability to identify trends among the complaints received or repeated problems that may require special attention.

The Board has come a "long way" and I can assure that it will continue efforts to achieve its mission to protect Maryland consumers and promote quality health care in the field of pharmacy through licensing pharmacists and issuing permits to pharmacies and distributors; setting standards for the practice of pharmacy through regulations and legislation, as well as receiving and resolving complaints and educating consumers. The Maryland Board of Pharmacy sets standards that ensure safety and quality health care for the citizens of Maryland and it has indeed been a pleasure and an honor to serve the Maryland Board of Pharmacy and the citizens of Maryland.

Sincerely,
Stanton G. Ades
President

EXECUTIVE DIRECTOR'S REPORT

LaVerne G. Naesea



The Maryland Board of Pharmacy continues to meet its responsibility of licensing pharmacists, issuing permits for the operation of Maryland pharmacies and distributorships, setting practice standards, monitoring pharmacists, pharmacies and distributors to insure that state requirements are appropriately met, and investigating and responding to public concerns and complaints.

The Board had difficulty in filling its vacant Compliance Officer position in FY 2003 due to a state hiring freeze as well as a limited pool of qualified applicants from which to draw. The former Compliance Officer resigned in May 2002 and a replacement was not found until late January 2003. The backlog of processing complaints that resulted from the staffing deficit will be further discussed in the Compliance section of this report. The Board strongly urges state personnel to review the State Pharmacist classification series, which requires significant updating of the job specifications and salary provisions to be more competitive with the private sector.

The Board competitively solicited bids, which helped assure that customers and stakeholders received cost-effective quality services. Many of the contract fees increased during FY 2003. That led to significant increases in Board expenditures. Vendors under contract with the Board in FY 2003, included the National Association of Boards of Pharmacy (for testing and other services), the Pharmacist Education and Assistance Committee (PEAC), Sylvan Learning Center© (for test administration), the Maryland Attorney General's Office and numerous other companies for such items as rental of office space, major equipment, printing and supplies.

The Board bid farewell to Board Secretary Irving Lottier in FY 2003. He completed his second four-year term in April 2003. Mr. Lottier's oversight and guidance to the Board on fiscal and personnel matters was invaluable. This report includes the Secretary's financial report, even though Mr. Lottier departed prior to its completion. As a specially funded unit within the Department of Health and Mental Hygiene, all collected revenues support Board operations and personnel.

Best Wishes,
LaVerne G. Naesea
Executive Director

BOARD SECRETARY/TREASURER REPORTS

FY 2003 FINANCIAL SUMMARY

Revenue:

Pharmacist Examination.....	\$ 33,203
Pharmacist Renewals	\$ 491,307
Reciprocity	\$ 34,130
Pharmacist Reinstatement	\$ 19,970
Establishments	\$ 771,855
Other	\$ 15,038

Total Revenue **\$ 1,365,503**

Expenditures:

Operating Expenses:	\$ 999,346
Salaries & wages, Technical & Special, Communication, Program Expenses, Conferences, Travel, Training, and Contractual Services	
Purchases	\$ 29,530
Indirect Costs	\$ 190,981

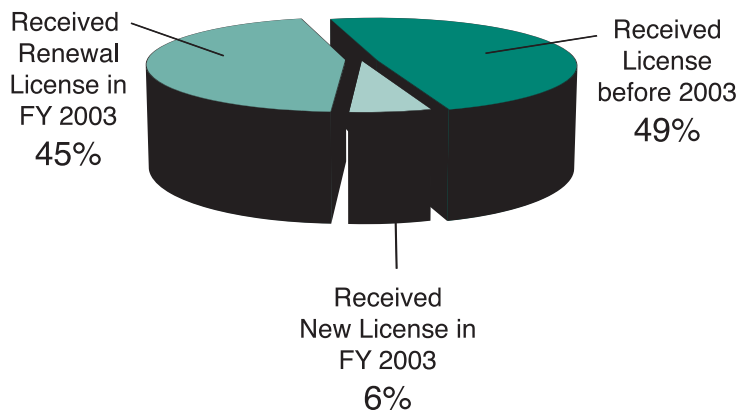
Total Expenditures **\$1,219,857**

BOARD OPERATIONS REPORTS

LICENSING UNIT

The Licensing Unit is responsible for issuing Maryland practice licenses to qualified pharmacists and issuing Maryland operating permits to qualified pharmacy owners and pharmaceutical distributors. The Maryland Division of Drug Control is responsible for inspecting all new, renovated and licensed establishments in Maryland each year. In

Total Licensed Pharmacists in FY 2003
N = 7207



addition to introducing on-line licensing in FY 2003, the Board worked closely with the Division of Drug Control to refine the inspection processes. The Licensing Unit worked jointly to update the inspection report form used by the Division of Drug Control and computerized it for better reporting of findings to the Board. They also worked together on a pre-inspection form, which will likely be implemented during FY 2004.

The Unit has continually revised new and renewal applications to ensure compatibility with changes to licensing requirements and works closely with

the Management Information Services Unit to ensure that current licensing information (including candidate scores) is routinely posted on the Board's web site.

Pharmacist Statistics

Pharmacists renew licenses every two years during their birth month. Thus, the total number of pharmacists licensed during any given month is perpetual, with 3243 (45%) having renewed between July 1, 2002 and June 30, 2003 (FY 2003); 3,531 pharmacists (49%) having been licensed in FY 2002; and 457 (6%) having been licensed for the first time in Maryland in FY 2003. Of the 457 pharmacists first-time Maryland licensees, three hundred and three (303) were licensed through examination and 154 reciprocated to Maryland from other states. The total number of pharmacists licensed at the end of FY 2003 (June 30, 2003) was 7207.

Establishment Statistics

All pharmacy permits expire December 31st of each year. The total number of pharmacy permit holders in Maryland at the end of FY 2003 was 1237. Of that number, 25 were issued to new pharmacies in Maryland, and 59 issued to new pharmacies located outside of Maryland. The Board also issued 10 new pharmacy waiver permits. In total, the Maryland Board licensed 94 new pharmacies, while only 44 pharmacies failed to renew Maryland permits (28 in state, 12 out-of-state, and 4 that owned permit waiver licenses). Thus, the Board gained fifty new pharmacies doing business in Maryland in FY 2003.

Pharmaceutical Distributor permits also expire on December 31st of each year. At the end of FY 2003, 490 distributors possessed permits. Of that number, 105 new distributor permits were issued -- 19 permits were issued to new in-state distributors and 86 permits were issued to distributors that opened new establishments outside of Maryland. Only 22 distributor permit owners did not renew in FY 2003.

Pharmacies and Distributors could renew permits on-line for the first time in FY 2003. A total of 550 did so, of which 515 were chain pharmacies (e.g., Rite Aid, NeighborCare, CVS, Giant, and Safeway pharmacies) and eleven (11) were distributors.

Managing for Results

Regarding the Board's projections for the Licensing Unit for its FY 2003 Managing for Results plan, at least 75% are of applicants who needed to provide missing documentation were notified within three working days from receipt of their renewal applications, and approximately 79% of pharmacists'

licenses were issued within 6 working days following receipt of complete applications. The Licensing Unit will offer on-line renewal of pharmacists' licenses in FY 2004. The Licensing Unit and Licensing Committee are pleased about activities undertaken in FY 2003 and will continue to evaluate procedures in FY 2004 to ensure efficient processing of new and renewal licenses and permits.

PHARMACIST COMPLIANCE UNIT

The Pharmacist Compliance Unit interacts closely with the other units of the Board to accomplish the common goals of protecting Maryland consumers, and promoting quality health care in the field of pharmacy by monitoring and enforcing compliance with Maryland Pharmacy Laws. For example, after the Licensing Unit reviews an application for a pharmacist license or pharmacy and distributor permits, the completed paperwork may be sent to the Compliance Unit for further review where an investigation may be initiated. Twelve applications were referred for further investigation with no formal Board action resulting.

The Licensing Unit could refer a pharmacist to the Compliance Unit when information listed on the renewal form regarding continuing education (CE) credits is incomplete or invalid. Seven licensees who were unable to provide documentation of having completed required continuing education credits within the required time period were referred to the Disciplinary committee for review and recommended actions.

The Licensing Unit generates monthly reports listing permit holders and licensees who have not renewed. The permit holder or licensee is notified and the matter is referred to the Compliance Unit where an investigation is initiated. Most cases are resolved within 30 days of the expiration of the license after the licensee or permit holder reinstates the license or permit (respectively). However, approximately 13 of this type of cases were referred to the Board and resulted in informal Board actions. Also, license/permit applicants who have been identified as having been subjects of disciplinary actions in other states trigger alerts for investigations by the Compliance Unit.

Two emergency situations occurred which dislocated pharmacies, one resulting from a roof collapse from snow accumulation, and the second was due to a fire in a store. Once notified of emergency situations the Compliance Unit works with the permit holder, the Licensing Unit and the Division of Drug Control to assure that a temporarily-relocated pharmacy meets security and health safety regulations, and that customers have access to their medications.

Receiving and Resolving Complaints

The Compliance Unit processed approximately 2600 communications regarding complaints, and practice standards during FY2003. The Unit serves as an information resource for pharmacists permit holders, consumers, health care providers, legal professionals, State, Federal and private health agencies.

Important tasks performed by the Disciplinary Unit include receiving and resolving complaints from consumers and educating consumers regarding medication safety. The Board takes this responsibility very seriously and responded to 145 new complaints received in FY 2003. Some complaints were downloaded from the Board's website on complaint forms, some were e-mailed, and others were submitted by telephone or mail. The compliance staff determines if the complaint is a Pharmacy Board matter or whether it should be referred to another Board or agency (e.g., the Insurance Commissioner, Consumer Protection Agency, Medicaid, Medicare, etc.). The Board takes a systems approach in order to effectively identify and correct factors that may have contributed to dispensing errors. Unprofessional conduct, improper exercise of professional and pharmacist conduct that deviates from the standard of care ordinarily exercised, are types of complaints that are most usually investigated. Not maintaining a clean pharmacy workplace and unhygienic practices of pharmacists are included in complaints. Regulations under Chapter 10, Pharmacist Code of Conduct of the Code of Maryland Regulations (C.O.M.A.R.) are relevant to many of the issues addressed by the Compliance Unit.

After a complaint has been reviewed and determined to be a Pharmacy Board concern, the complaint is assigned a case number and entered into the complaint log that is maintained both manually and electronically. All follow-up information received from the pharmacist and permit holder during the investigation is considered confidential and will not be revealed.

Upon completion of an investigation, the case is referred to the Disciplinary Committee for review and recommendations. Eighty-seven (87) complaints pending from the previous fiscal year added to the 145 new complaints received FY2003, resulting in a total of 232 complaint cases. Cases closed without formal action, including cases transferred to other agencies, numbered 162, with formal action being taken in 11 cases for a total of 173 cases closed. Fifty-nine (59) unresolved complaints were carried into FY 2004.

Board Legal Proceedings

The Board, with staff support, held two Case Resolution Conferences, four Show Case Hearings, one Full Evidentiary Hearing, and a number of formal actions including: two Consent Orders, four Letters of Voluntary Surrender, three Orders of Emergency Suspension, one Suspension and one Revocation of pharmacists' licenses. Two pharmacists and three pharmacies were placed on Probation. Probation for two pharmacists and one pharmacy was terminated and one pharmacist was reinstated. Investigations were opened and continued into the next fiscal year for eleven pharmacists and three pharmacies.

Work with Division of Drug Control

The Division of Drug Control (DDC) interacts with the Board on a regular basis. Pharmacy inspections performed by the Division of Drug Control inspectors are reported to the Compliance Unit and reviewed to determine compliance with pharmacy laws. The Compliance Unit considers routine pharmacy inspections important in the educational process of promoting good pharmacy practice, explaining State and federal pharmacy laws, and enforcing these laws. Usually the Permit Holder immediately corrects the problem and no further action by the Board is required. At times, a routine inspection may result in further investigation, with charges being referred to the Attorney General's office for a possible formal action. Three pharmacies and three pharmacists were referred to the Compliance Unit, for further investigation. Of these, one pharmacist and one permit holder were

referred to the Attorney General's office for formal charges, resulting in the suspension of one pharmacist's license and one pharmacy permit. The Compliance Unit also interacted with other agencies, including the Drug Enforcement Administration (DEA), the Food and Drug Administration Criminal Division (FDA), Medicare and Medicaid.

Work with PEAC

The Compliance Unit works closely with the Pharmacist Educational Assistance Committee (PEAC) in the monitoring of Board-referred impaired pharmacists. Conditions for reinstatements and petitions for modifications of terms of probation of pharmacists under contract with PEAC are reviewed by the Disciplinary Committee, which submits recommended actions to the Board.

LEGISLATION/REGULATORY UNIT

LEGISLATIVE INITIATIVES

The Regulations/Legislative Unit is responsible for providing support to the Board and its committees in the areas of legislative review, monitoring proposed regulations of other federal, state and local agencies, and providing assistance with research and preparation of information and documents related to regulating services and programs offered by the Board.

The Board supported with amendment a bill that passed the Maryland General Assembly during the 2003 legislative session relating to the provision of certain information to consumers.

- Consumer Information- Information on Generic Drug Option
- Notice of Availability of Generically Equivalent Drug and Approximate Cost Difference.

Effective October 1, 2003, if a prescription is written for a brand name drug, the pharmacist or the pharmacist's designee must inform retail consumers to the best of the pharmacist or pharmacist designee's knowledge:

1. Whether there is a generically equivalent drug available, and

2. If there is a generically equivalent drug available, what the approximate cost difference is between the cost of the brand name drug and the generic drug.

Exceptions

The information is only required to be given to retail consumers. The pharmacist or the person working with the pharmacist is not required to relay the availability and cost-difference information to the consumer under the following circumstances:

1. When a prescription is specifically written for a generic drug;
2. When the authorized prescriber writes that the prescription should be dispensed as written;
3. When the pharmacist works in a pharmacy that primarily serves institutionalized or hospitalized patients; or
4. When the prescription is reimbursed by insurance.

REGULATORY INITIATIVES

Examination for Licensure and Professional Experience Programs

Effective February 17, 2003, the laboratory examination is no longer required for licensure. Other changes were made during this regulatory proposal as well.

Fees

The Pharmacist Reciprocity Fee was reduced from \$250 to \$120. The emergency regulation went into effect October 1, 2002 and the standard regulation was effective March 3, 2003.

Monetary Penalties

Changes to this chapter were effective January 20, 2003. The maximum limit for a monetary penalty against a pharmacy permit holder or pharmacist was increased from \$5,000 to \$10,000. This change was required to bring the regulations into compliance with the statute. Two factors for consideration in assessing penalties were added. The regulations were otherwise simplified and certain clerical changes were made.

Reinstatement of Expired Licenses for Pharmacists

Several revisions of this regulation occurred during this fiscal year. The first revision to the reinstatement regulations became effective October 14, 2002. The revision allows pharmacists who fail to renew on time and have practiced on an expired license, to reinstate the license provided certain requirements are met. The Board may initiate charges against the pharmacist who actively engages in pharmacy on an expired license but must consider certain aspects when determining a sanction. The Board must consider the length of time during which the pharmacist practiced without a license and any other violations by the pharmacist during the period when the pharmacist practiced without a license.

A pharmacist who does not actively engage in the practice of pharmacy while his or her license is expired and the license has been expired for less

than 2 years before applying for reinstatement, the pharmacist will only have to:

- (1) Complete the amount of approved continuing education required by the Board,
- (2) Provide evidence of good standing in any other state in which the pharmacist has been licensed, and
- (3) Pay to the Board a reinstatement fee.

A pharmacist not actively engaged in the practice of pharmacy in another state, but whose license has been expired for more than 2 years and less than 5 years in Maryland, will no longer be required to obtain the continuing education during the time that their license is expired. Additionally, a pharmacist who is not practicing pharmacy in another state but whose Maryland license is expired for more than 5 years is no longer required to obtain continuing education for the time during which the license is lapsed. The examination requirements will satisfy the knowledge-base requirements.

The second revision, which was effective February 17, 2003, repealed the requirement that certain pharmacists complete the laboratory examination in order to reinstate a license. Please see COMAR 10.34.13.

Automated Medication Systems

Regulations relating to automated medication systems became effective August 2, 2002. The regulations address the use of centralized, decentralized and remote automated medication systems. Please see COMAR 10.34.28. The regulations establish:

- (1) The conditions under which an automated system may be used;
- (2) The requirements for a multidisciplinary committee when remote and decentralized automated medication systems are used;
- (3) The rules for filling the system;
- (4) The parameters for return of medication to a system;

- (5) The rules relating to final check of medication in centralized automated medication systems;
- (6) The required education and training necessary for personnel working with an automated medication system;
- (7) The need for a quality assurance program; and
- (8) Record keeping requirements.

This is only an abbreviated list of issues addressed in the regulations. Please review the entire regulation for further guidance.

Accessing Regulations on the Internet

To view these regulations on the Internet, please log on to www.dsd.state.md.us. Go to the "COMAR Online" link. There are several ways to access the regulations. One way is to click option number 1 to search the codification number. Be sure to type an * after the codification number, otherwise only the title of the regulation will appear. Another way to search for regulations is to click option number 3, then click Title 10, Department of Health and Mental Hygiene. Once the subtitles show, click Subtitle 34. This will pull up a list of the Board of Pharmacy's regulations. Open each chapter of regulations individually.

FY 2003 Significant Regulatory Changes

10.34.11- Monetary Penalties

Effective January 20, 2003.

10.34.13 Reinstatement

Effective February 17, 2003.

10.34.02 Examination for Licensure and Professional Experience Programs

Effective February 17, 2003.

10.34.09 Fees. (Reciprocity fee).

Effective March 3, 2003. Reduced fee.

Accessing Board of Pharmacy Regulations on the web

The regulations listed above, as well as all Board of Pharmacy regulations, may be viewed in entirety on the Internet through the following:

1. Logon to www.dsd.state.md.us
2. Click the "COMAR Online" link
3. Click search option 3 "Access through Table of Contents Structure"
4. Click Title 10 Department of Health and Mental Hygiene
5. Click subtitle 34 (Board of Pharmacy regulations)
6. Click whichever chapter of regulations you are interested in reviewing. Each regulation is brought up individually so each must be opened individually.

PUBLIC INFORMATION AND EDUCATION UNIT

The Public Information & Education Unit plays an active role in educating and increasing consumers' knowledge about pharmaceutical services and medications, by promoting awareness for the prevention of medication errors, and maintaining on-going activities to protect the public. The Unit is also responsible for keeping the public informed about appropriate uses of medications and the positive effect it may have on their health quality and safety.

The Unit developed and continued to disseminate three consumer brochures, two printed in FY 2002, and one in 2003. The brochures provide information about the Board, regarding risks related to buying drugs from foreign countries, and on services available through pharmacies. The content is intended to increase consumer's awareness and encourage safe use of prescription and non-prescription drugs. The Public Information Unit also staffed booths at four consumer and pharmacy/association-sponsored events.

The Board of Pharmacy also encouraged all Maryland pharmacies and pharmacists to participate in National Pharmacy Week, with suggestions for activities to attract patients and raise awareness of the need for consumers to practice safe prescription and over-the-counter drug use. Six pharmacies participated in Pharmacy Week using some of the Board's suggestions. The Board acknowledged participating pharmacies and pharmacists in the Board's newsletter and provided each a certificate of appreciation.

Emergency Response Activity

The Board again targeted Public Information and Education efforts to developing response plans for potential bio-terrorist and other catastrophic emergencies in the state. At the request of the Secretary for the Department of Health and Mental Hygiene, the Board appointed a Bioterrorism and Emergency Preparedness Task Force and recruited over 900 volunteer pharmacists and pharmacy technicians. A summary of the Task Force activities is provided in a later section of this report.

As a consequence of limited time and fiscal resources due to the Emergency Response activities the Unit did not develop a major consumer campaign as projected for FY 2003. Thus, the objective of conducting a subsequent survey in response to such a campaign was not met.

Public Information Requests (PIA)

A third primary activity in which the Public Information & Education Unit was involved in FY 2003 was responding to requests from consumers, governmental agencies and other entities for public information retained by the Board. The Public Information Act, State Government Article 10-611 thru 10-628 requires the Board to provide public information as requested. A total of 150 requests were responded to in FY 2003.

TECHNOLOGY AND AUTOMATION

MANAGEMENT INFORMATION SERVICES UNIT

The Board of Pharmacy's customers (consumers, licensees and permit holders) are accustomed to relying on computers as a resource for information through the Internet, to access databases, and to pay bills. The Board changed the name of its Information and Technology unit to the Management Information Services (MIS) unit to better describe the types of services available through the unit. The Unit has worked closely with the Board's other units, committees and task forces to continually enhance information services for licensees and the public. The development of an Emergency Preparedness Database is an example of a recent set of information stored and maintained to enhance program services.

The Internet

When the Board of Pharmacy launched its web site in December 1999, a yearly goal of 100,000 or more visitors was projected by December 2004 (first half of FY 2004). Based on the number of visits to the site in FY 2003, the Board is on track achieving the goal of 100,000 visitors.

Total number of visitors to the Board web sites:

FY2003 Total: 78,574
FY2002 Total: 34,874
FY2001 Total: 21,436

MIS plans to accomplish the goal of 100,000 visitors by providing valuable information and links to other relevant sites, working with the Public Education Unit to promote the site at consumer and licensee events, regularly updating information and providing more on-line access to services provided by the Board's Public Education, Licensing, Executive and Legislative Units.

Establishment Services

Online Renewals: In November 2002, the Maryland Health Care Commission (MHCC) developed an online licensing system for the Board of Pharmacy's permit holders. The Board solicited volunteers to test the system, and on December 16, 2002,

with only 16 days to renew permits, 27% of the Board's 2,046 eligible permit holders renewed online. Positive feedback was received from the volunteers, despite the lack of an online method of payment. The Board looks forward to making the online system available to all permit holders in FY 2004 and to obtaining State approval to accept electronic payments.

Computerized Inspection Form: In February 2003, in conjunction with the DHMH Laboratory Administration, Division of Drug Control (DDC), the Board developed a database and data entry screen for DDC Inspectors to enter the particulars of each pharmacy and distributor inspection performed in Maryland. The system replaces the tri-copy paper forms previously used by DDC inspectors. The DDC is now required by the 2002 Sunset review and audit to perform an annual inspection of all establishments located in Maryland and licensed by the Board. The data entry screen, which is loaded on DDC Inspector laptops, provides reports to DDC and the Board's Compliance Unit on inspections that contain discrepancies. It also allows for more efficient tracking of compliance with Board safety and legal requirements. The Compliance Unit can now review all the details of any inspection without physically needing to obtain the establishment file.

E-mail

Recognizing that the use of e-mail is no longer an option, but a necessity. The Board's E-mail address, mdbop@dhhm.state.md.us, receives approximately 200 requests and questions each month regarding licensure, pending regulations, pharmacy compliance, complaints, public information (PIA) requests, and forms.

A major advantage of e-mail over regular mail is immediacy. Even with special couriers, physically moving paper from one place to another, limits still exist on how quickly it can be accomplished. E-mail is very economical because messages do not need to be printed. It is also better for our environment for the same reason; e-mail cuts down the use of paper, toner and disposal costs. Before

FY 2003, the Board responded to requests for lists of licensee's names and addresses by printing the information on gummed labels and mailing them. This cost in supplies and postage for one mailing was approximately \$40. As businesses became more computerized, the Board began placing the name and address files on floppy diskette and mailing them to requestors at an approximate cost of \$12 in supplies and postage. At the end of FY 2003 the Board began electronically mailing this type of information; thus, saving the Board the cost of postage, supplies, wear and tear on the printer, and reducing the amount of time required by staff to prepare the data for shipping.

Total number of E-mail requests processed in the Board's general E-mail account:

FY03 Total:	2,083
FY02 Total:	1,088
FY01 Total:	604

The Future

The Board's more appropriately named Management Information Services Unit will continue in its commitment to providing better tools for Board Staff and more services for licensees and the public. In November 2002, the Board experimented with the idea of dedicating an Information Services Staff person to the Licensing Unit as a means of providing more of the day-to-day coverage necessary to improve and/or implement quality assurance, reporting, forms management, problem tracking and resolution processes and other internal functions to better serve the licensees and permit holders. This proved to be a success and may be considered again as other Units prepare to implement new services, or improve existing processes.

TASK FORCE REPORT

BOARD OF PHARMACY BIO-TERRORISM AND EMERGENCY PREPAREDNESS

The Maryland Board of Pharmacy is leading the State's effort to develop and implement an Emergency Preparedness Response Plan for volunteer health care practitioners to assist during a terrorist or other catastrophic event. FY2003, the Board recruited nearly 900 volunteer pharmacists and pharmacy technicians, of which approximately 500 have been trained. In the event of a State emergency, the Maryland Department of Health and Mental Hygiene would direct the Board to deploy volunteers to assist local health departments with the receipt and breakdown of the National Pharmaceutical Stockpile (NPS). Volunteers would also provide counseling and dispense medications to affected persons based on levels of illness and special considerations (i.e., pregnancy, drug interaction, allergies etc.), and assist with other activities as authorized. Volunteer recruitment, coordination and training sessions are ongoing.

Phase I Training

During September and October 2002, the Department of Health and Mental Hygiene (DHMH), in collaboration with the Maryland Board of Pharmacy, the University of Maryland School of Pharmacy, and Maryland Poison Center, hosted Phase I of a training program for volunteer pharmacists and pharmacy technicians to insure their preparation to provide support to the State and local jurisdictions during catastrophic events. The program entitled, "The Pharmacist's Response to Bio-terrorism," offered three ACPE continuing education credits. Four sessions were offered of which the first two were held on September 14, 2002, at the University of Maryland, School of Pharmacy, Baltimore Campus. Over 200 volunteers participated at those sessions and received picture identification badges to signify official registration as members of the *Maryland Pharmacist Volunteer Corps (MPVC)*. Also in attendance were a number of local health department officers and representatives from other Boards.

Board Chairman and program moderator, Stanton G. Ades introduced Gary Hollenbeck, Associate Dean for Academic Affairs, who welcomed attendees to the School of Pharmacy. Arlene Stephenson, Deputy Secretary for DHMH, relayed greetings from Secretary Georges Benjamin and Governor Parris Glendening. She praised the Board for leading plans for developing a model for emergency response by health care practitioners. Ms. Stephenson also thanked volunteers for answering the State's request for assistance. The program included a review of biologic agents, a summary of the National Pharmaceutical Stockpile (NPS) plan to transport and set-up medication and supplies during emergencies, and the Board's volunteer deployment plan. Paul Ballard, Assistant Attorney General with the State Attorney General's Office, provided a lively presentation on the State's plans to address relevant liability issues. Phase I seminars also took place in Western Maryland and on the Eastern Shore. Additional Phase I training is planned. To become a member of the Maryland Pharmacist Volunteer Corps, pharmacists and pharmacy technicians must register with the Board, have participated in mandatory Phase 1 training and possess a photo ID badge.

Bio-terrorism Task Force Members include: Board President and Chair, Stanton G. Ades; Co-Chair, Bart Regan; Board Members: Dr. Raymond Love, John Balch, Melvin Rubin, Laura Schneider; Board Staff: LaVerne Naesea and Joan Lawrence; Bruce Anderson (Presenter), Maryland Poison Center; Joey Scaletta (Presenter), DHMH; Dr. Cynthia Boyle, University of Maryland School of Pharmacy; Phil Cogan, Maryland Pharmacist Association (MPhA); Bob Feroli, Johns Hopkins Hospital/Maryland Society of Hospital Pharmacists.

PHARMACISTS' EDUCATION AND ASSISTANCE COMMITTEE (PEAC)

Background:

The Pharmacists' Education and Assistance Committee (PEAC) was established in 1983 for the purpose of providing advocacy and assistance to members of the pharmacy community who had become impaired by the use of alcohol and other substances. The Maryland Pharmacy Practice Act recognizes the concept of a Pharmacist Rehabilitation Committee and provides protections under the Act regarding the confidentiality of records and client identities. Maryland law enables the Board of Pharmacy to provide funding to a pharmacists' rehabilitation committee. PEAC continues to work with the Board of Pharmacy to provide services to the Pharmacists of the State of Maryland under a contract with the Board. PEAC is a 501 (C) 3 tax-exempt independent organization.

During FY 2003 PEAC monitored 28 cases of which 11 were referred by the Board of Pharmacy.

Achievements of PEAC:

1. PEAC submitted a bid for the new contract with the Board of Pharmacy.
2. PEAC members have developed various ideas for support of an executive director. One of these was to build "part-time" support for this position into the Board of Pharmacy contract. With the award of this contract PEAC will hire an executive director and give him/her the task of garnering additional support for the position. Ideas that emerged from PEAC retreat meetings have been developed but in the absence of an executive director have not been vigorously pursued.
3. Over the course of the past ten years PEAC has made inroads into student life by fostering the development of the group Students Promoting Awareness (SPA). These pharmacy students are trained at the University of Utah Summer School on Alcoholism

and Other Chemical Dependencies. PEAC supports one of 4 to 6 students each year who receive this training. Each of these 1st year students understands that upon returning to the Pharmacy School he/she will commit to a leadership role in the SPA program. This group acts as a peer assistance program for pharmacy students having trouble with alcohol or other drugs. Through an informal referral process SPA members can identify students about whom they have concerns. This leads to execution of several response possibilities ranging from providing information on treatment options to launching a formal intervention.

4. Students in need of recovery support are offered entry into the PEAC program and are given the same level of monitoring support as is provided to pharmacists. The influence of PEAC in the pharmacy school is visible not only in the form of curricular content but also in the policies of the school. Every student gets an overview of the problem of substance abuse among pharmacists, specific information about referrals to PEAC and the elements of the Pharmacy Practice Act that relate to impaired practice. The school policies specifically identify PEAC as the group to which students can go to satisfy a campus requirement that drug or alcohol abuse convictions be reported to the dean's office.
5. Publication of PEAC events is carried on our website at <http://www.peacmaryland.org/> as well as in the Board of Pharmacy newsletter.
6. October's continuing education program began early with the procurement of Pharmacy Association Management, Inc. to coordinate speakers, prepare and distribute advertising materials, secure a program site, arrange for catering services, and to complete the paperwork requirements for national ACPE accreditation of the program.

STATE OF MARYLAND BOARD OF PHARMACY 2003 ANNUAL REPORT

The program was entitled "New Opportunities for Addiction Treatment: Solve a Problem, Save a Life" and was held at the Handelman Learning Center at the Beacon Institute in Columbia, Maryland.

Financial report:

PEAC completed its contract with the Maryland Board of Pharmacy and bid on the new contract for the coming year. A financial statement is provided at the end of each year. Most funds are spent on a) staffing, b) annual CE conferences, and c) telephone and internet communications. PEAC sponsored one pharmacy student to attend the Utah Summer School on Alcohol and Other Drug Dependencies.

The committee receives tax-deductible contributions into the "Moskowitz Fund" set up to assist pharmacists in recovery that have financial needs. Information on making a tax-deductible contribution is available by calling PEAC at (410) 452-8683, through its website <http://www.peacmaryland.org/>, or by e-mail to PEAC@verizon.net. A new arrangement has been made that allows PEAC to process credit card charges for PEAC C.E. programs and to receive tax-deductible donations.

Financial Summary July 1 2002 thru June 30, 2003

Income:

State of Maryland	\$30,312
Donations	400
CE Program	<u>11,394</u>

Total Income: **\$42,106**

Expenditures:

Coordinator	\$12,824
CE Program	12,179
Advertising	1,267
Evaluations	932
Meeting Expense	423
Per diem/members	2,320
Mileage	606
Office Expenses	362
Computer	914
Telephone	860
Internet	302
Accountant	75
Travel/Ed/Utah	<u>1,022</u>

Total Expenses **\$34,086**

BOARD STAFF

LaVerne G. Naesea	Executive Director
Vacant	Pharmacist Compliance Officer
Tamarra Banks	Network Specialist Administrator
Shirley Costley	Fiscal/Personnel Officer
Joan Lawrence	Public Information Officer/BT Coordinator
James Slade	Regulations/Legislative Officer
Doris James	Licensing Supervisor
Deitra M. Gale	Compliance Specialist
Vladimir Konstantinov	Database Specialist
Vacant	Executive Secretary
Sandra Hines	Secretary
Devin Cunningham	Licensing Secretary
Lakeya Davis	Licensing Clerk
Vacant	Data Entry Clerk

PUBLIC MEETINGS

Public meetings are held at The Board of Pharmacy, 4201 Patterson Avenue, Baltimore, Maryland 21215, on the 3rd Wednesday of each month, at 9:00 a.m. Anyone may attend the public session, which begins at 9:00 a.m.

All records of Board public proceedings are available and may be reviewed Monday through Friday from 8:30 a.m. to 5:00 p.m.

To view the Board's monthly agenda and public meeting dates, log on to: www.mdbop.org or www.dhmh.state.md.us/pharmacyboard.

INTERNET SERVICE

Nothing will replace the customer services provided when the Board is visited in person, or is called on the telephone. However, as new opportunities in Internet services arise, online services offered by the Board for the convenience of the consumer, the Board's licensees and permit holders will also expand.

Log on the Board's web site at: www.dhmh.state.md.us/pharmacyboard or www.mdbop.org. The Board provides information on a wide variety of activities it conducts, including:

- Pharmacists, pharmacies, and distributors licensed by the State of Maryland
- Board meeting schedules, minutes and newsletter
- Pharmacy Board applications (some may be submitted on-line)
- Links to pharmacy assistance and other health organizations
- Pharmacy store openings and closings
- Summaries of committee activity
- Consumer educational information
- Proposed regulations and legislation
- Forms to file complaints, and
- Opportunities to e-mail the Board

**MARYLAND DEPARTMENT OF
HEALTH AND MENTAL HYGIENE**



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