

STATE OF MARYLAND
BOARD OF PHARMACY



2004 ANNUAL REPORT

DISPENSING HELP IN YOUR COMMUNITY

JULY 1, 2003 THROUGH JUNE 30, 2004

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STATE OF MARYLAND BOARD OF PHARMACY AT A GLANCE

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 over-arching 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 (FY 2001-2006)

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.

FY 2004 SUMMARY

ADMINISTRATION

Budget (FY 2004)

- a. Revenue: \$1,491,969
- b. Expenditures: \$1,181,719
- c. Fund Balance \$310,250

Personnel

- a. Permanent: 12
- b. Contractual: 3
- c. Temps: 2

Public Information and Education

- a. Newsletters: 4
- b. Emergency Preparedness
 - 1. Trainings: 2 - April and October
 - 2. Drill - 1 Statewide Drill (June)
- c. Flower Mart: 2nd Prize
- d. Other Events: MPhA, ASCAP, PEAC, MPC

LICENSING UNIT

Pharmacists (FY 2004)

- a. Total: 7395
- b. New: 447 (326 exam 121 reciprocity)
- c. Growth (since 2003): +188

Pharmacies (FY 2004)

- a. Total: 1389
- b. New: 341
- c. Growth (since FY 2003): +152

Distributors (FY2004)

- a. Total: 574
- b. New: 158 (35 in-state & 123 out of state)
- d. Growth: +84

COMPLIANCE UNIT

Total Complaints Received: 145

- a. Pending Charges: 8
- b. Formal Actions: 10
- c. Informal Actions: 29

LEGISLATION/ REGULATIONS UNIT

LEGISLATION

- a. Administration of Influenza Vaccination
- b. Prescription Drug Safety Act
- c. Registration of Pharmacy Technicians (failed)

REGULATIONS

- a. Examination for Licensure & Professional Experience Programs (10.34.02)
- b. Drug Therapy Management (10.34.29.01)
- c. Long Term Care (proposed) 10.34.23
- d. Wholesale Distributor (re-proposed) 10.34.22

MANAGEMENT INFORMATION SYSTEMS UNIT

1. Annual Total for E-mails to Board Addresses: 2,278 Growth (since 2003): +195
2. Total Visitors to Web Site: 100,314 Growth (since 2003): +21,740
3. The Consumer Web Page contains more avenues for assistance with buying prescription drugs from local government and private drug companies.

WEBSITE

Through the web site, the Board provides links to assist the public in finding safe and legal methods of obtaining lower cost prescription drugs and informs the public of those companies selling counterfeit or substandard products.

ONLINE ESTABLISHMENT RENEWAL

For the second year, the Board was able to renew establishments online. The online establishment renewals usage rose 3% over last year when it was originally tested.

ONLINE PHARMACIST RENEWAL

In January 2004 the Board launched the pharmacist online renewal system. The system was design by the Maryland Health Care Commission (MHCC) utilizing user fee funds collected from pharmacist for the Commission. In it's first 6 months of operations 538 pharmacists logged on to renew, representing 30.6% of those eligible to renew during that same period.

DATABASES

The development of databases has provided the most influential contribution from MIS to Board operations. The new databases created in FY 2004 include:

- New Candidate Licensure system for examination and reciprocity applicants. New licensure candidates were previously processed through their paper files.
- Daily Online Renewal approval database that links the online system to the Licensure Unit and automatically updates the mainframe, once approved by Licensure.
- A recycled Bio-Terrorism Volunteer database has been an ongoing process which continues to improve so that the Board and Emergency Preparedness Teams can more quickly serve Marylanders. A second database was created this year that will be electronically sent to DHMH in support of the Federal governments efforts.

2004 BOARD COMMISSIONERS

Melvin N. Rubin	President
Jeanne G. Furman	Secretary, Chair Unlicensed Personnel Task Force Independent Representative
Raymond C. Love	Treasurer, Chair, Disciplinary Committee Acute Care Hospital Representative
Mayer Handelman	Long Term Care Representative
John H. Balch	Independent Pharmacy Representative
Margie Anne Bonnett	Consumer Representative
Joseph A. DeMino	Chair, Licensing Committee Chain Drug Store Representative
Donald Taylor	Chain Drug Store Representative
Mark Levi	At-Large Representative
Raymond C. Love	Chair, Practice Committee Acute Care Representative
Ramona McCarthy Hawkins	At-Large Representative
Donald K. Yee	Chair, Medication Error Task Force Home Infusion/Care Representative
Linda Bethman	Board Counsel - Staff Attorney

BOARD PRESIDENT'S REPORT

MELVIN RUBIN



FY 2004 certainly was no exception to the fast pace kept up by the Board Commissioners and staff. Following the enactment of enabling legislation for Drug Therapy Management in the previous year, the Board promulgated regulations to allow implementation of the statute and is now working with the Maryland Physician Board to finalize details to allow pharmacists to participate in this advanced practice.

Another regulation that went into effect allows pharmacists, under conditions approved by the Board, to dispense or distribute prescription drugs at a setting that does not possess a pharmacy permit. Pharmacists working with physicians in drug therapy management protocols will be able work under the authority of this regulation as well as pharmacists dispensing in community settings when called on because of bio-terrorist attacks or natural catastrophic events. The regulations require that a pharmacist obtain approval from the Board. For full information read COMAR 10.34.31.

The Board helped to put into law the authority of pharmacists to administer flu vaccines. The regulations, including required training, are being worked out now with the Board of Nursing and the Maryland Board of Physicians. This should allow pharmacists to participate in flu inoculations for the 2005 season.

The Long Term Care Task force brought the Long Term Care facility regulations up to date, although they had not been published yet at the end of the fiscal year. The Committee then went to work on expanding the regulations to make them more applicable to pharmaceutical services in assisted living homes.

A number of other regulations went into effect during the year including: eliminating the fee required of a pharmacy when it changes its name; other fee changes; and a compelling disclosure regulation.

At the end of the past fiscal year, the terms of three Board members ended including that of Stanton Ades, who had been President of the Board for several years. If the timing were different he would be writing this since he served as President during the year that this report covers. As it works out, I am doing the story of his last year and someone else will do the report of the year of my presidency since my term expires in the spring of 2005. Wayne Dyke's eight-year tenure on the Board also ended, during most of which time his primary committee responsibility was licensing.

As much as we will miss the presence of these two dedicated Commissioners, it is much sadder to think about the loss of Consumer member Rev. William E. Johnson, Sr., who passed away shortly before his term ended. Rev Johnson was an active consumer advocate in many ways, from his work as Pastor of his church to his activities with Johns Hopkins Bayview Hospital, the State of Maryland in other ways in addition to serving the Board, to his work in International matters concerning the plight of Palestinians. We will miss him.

The Board moved on and welcomed 3 new Commissioners: Chain representative Donald Taylor, Long Term Care representative Mayer Handelman and Consumer member Margie Ann Bonnett.

A great deal of time was spent trying to cope with the problem of medications being sent to Maryland residents from Canadian and other foreign sources. The law requires that the Board license all non-resident pharmacies that service consumers in Maryland. State requirements for a pharmacy permit include an inspection from the state of operation. There is no provision for pharmacies from other countries to service Marylanders. The Board has worked with the FDA and has sent cease and desist letters to pharmacies not licensed in Maryland who send prescriptions into this State. The problem is large and many sided. The U.S. Congress is considering proposals to allow importation such as this but in the meantime the Board of Pharmacy will do what it can to protect the citizens from the potential of receiving drugs that have not been approved by the FDA.

The Board has continued to do outreach to consumers and pharmacists, and during the last year participated in the Department of Health & Mental Hygiene booth at the Maryland State Fair in Timonium and the Annual Flower Mart in Baltimore City. The booth at the Flower Mart continues to be very popular and we thank the students from the school of pharmacy and the pharmacists who helped to show consumers the capabilities of pharmacists. The Board also manned a booth at the Maryland Pharmacist Association Annual Convention in Ocean City this year.

I would like to express my gratitude to those who worked so hard to see that the service level of the Board did not fall during periods of high vacancies in FY 2004. In particular, Executive Director LaVerne Naesea took command of several levels of responsibilities along with giving direction to everyone. Licensing Manager, Shirley Costly, Network Specialist Administrator Tamarra Banks, Regulations/Legislative Officer James Slade and Public Information Officer Joan Lawrence provided support well past their usual efforts both in their own duties and in support for areas where we lacked personnel. All staff members pitched in during this period and we are now working toward getting back to full strength.

The Board has worked hard to help educate pharmacists on ways to deal with potential errors. A form, the Error Collection Data Form (EDCF) is sent to each pharmacy/pharmacist when a consumer complaint concerns an error. Although there are times when formal disciplinary action is required, the Board's first concern is that the cause of the error is determined and corrected so that the public is not in danger. This could range from a problem of an intended dose measured in drops having a label call for teaspoons, to a pharmacist who makes repeated errors. The former can usually be corrected by stopping the computer from using 'teaspoonful' as a default, requiring manual entry of the dosage unit 'drops'. The latter may require anything from a review of workload to reassignment of personnel. The EDCF often provides both the pharmacy and the Board with enough information to show where changes in practice habits are needed.

The above gives just some idea of the areas in which the Board works in performing its duty to protect the public in all things pharmaceutical. Toward this end the Board tries support ways for the pharmacist to work more efficiently (automation regulations), to review their practices particularly in light of errors (Patient Safety Improvement regulations, EDCF form), and to expand their practices (Drug Therapy Management Regulations and Administration of flu vaccine statute).

Although a small percentage of the State's over 7000 pharmacists still need to be sanctioned, the vast majority of those with Maryland pharmacist licenses are doing their part to keep pharmacy as one of the most respected professions in the country.

EXECUTIVE DIRECTOR'S REPORT

LAVERNE G. NAESEA



The Maryland Board had a very productive FY 2004. Highlights included several Board members and staff organizational changes. Stanton G. Ades, former Board President, Wayne Dyke, Chair of the Board Licensing Committee and Reverend William Johnson, Board Consumer Representative each ended second four-year terms in April 2004. The Board mourned the death of Reverend William Johnson, shortly following the end of his term. Marjorie Ann Bonnett was appointed to the Reverend's Consumer Member position. Mayer Handelman was appointed to replace Stanton G. Ades as the Board's Long Term Care representative, and Mr. Donald Taylor was appointed to replace Wayne Dyke as the Chain representative.

The Board reorganized staff in FY 2004, creating a new Public Administration and Support Unit to house fiscal, personnel, procurement and public information Board functions. The Board also reassigned Ms. Shirley Costley from Manager of the defunct Personnel/Fiscal Unit to Manger of the Board Licensing Unit. Significant growth of this Unit over the next two years is anticipated with the addition of Pharmacy Technician registration. The Board was fortunate to acquire one new position in the Licensing Unit as well as one new position in its Compliance Unit during FY 2004. Consequently, renovations for expanded offices were completed in May 2004.

Program statistics for all Board of Pharmacy units are outlined within this Annual Report Summary. The numbers reflect continued growth and change in the world of pharmacy. One major change that continues to require attention from the Board of Pharmacy related to Emergency Preparedness. The Department of Health and Mental Hygiene conducted a statewide drill during FY 2003 to test the training plans that its units have been involved with over the past two years. We are still awaiting the outcome review of the drills, but suffice to say that our training and preparations paid off.

The Board initiated the Drug Therapy Management (DTM) joint review committee with the Board of Physicians in June 2004. This committee will develop procedures for reviewing DTM applications, pharmacist/physician agreements and medication protocols and provide recommendations to the two involved Boards. Also in FY 2004, the Board began discussions with the Office of Health Care Quality regarding Long Term Care/Assisted Living facility pharmacies.

The on-line renewal system for pharmacists was tested and subsequently initiated for pharmacists whose licenses expired at the end of calendar year 2003. On-line renewal for permit holders was implemented in FY 2002. New in FY 2004, both permit holders and pharmacists were able to charge renewal fees to major credit cards. Checks and money orders continue to be accepted through the on-line system.

All Health Occupation Board were required under a law passed during the 2004 legislative session to hold back the issuance of renewal licenses for practitioners, who have state tax liabilities. Joint regulations were developed (C.O.M.A.R.10.31.02) to provide guidance on upholding the law. The regulations specifically state that when a renewal applicant is identified as delinquent, the Boards will

be required to send written notice to the applicants. Board of Pharmacy renewal applications are usually mailed two months before expiration of the license or permit to provide ample time to resolve any tax liability problems.

The Board anticipates another challenging but fruitful FY 2005, with revisions to the Technician Bill that failed during the 2004 session and implementation of the Administration of Influenza Vaccine statute that passed during that session. Continue to logon to the Board's web site to updates on these and other changes throughout the year, and thanks to those who provided support to the Board in FY 2004.

BOARD SECRETARY/TREASURER REPORTS

FY 2004 END OF YEAR SUMMARY

REVENUE

Pharmacist Examination.....	\$44,800
Pharmacist Renewals.....	\$525,823
Reciprocity.....	\$22,759
Pharmacist Reinstatement	\$22,919
Establishments.....	\$841,600
Other.....	\$34,068
Total Revenue.....	\$1,491,969

EXPENDITURES

Salaries and Wages.....	\$660,062
Per Diem.....	\$38,835
Technical and Special.....	\$74,281
Operating Costs.....	\$279,855
Purchases.....	\$14,795
Fixed Costs.....	\$50,314
Indirect Cost.....	\$63,577
Total Expenditures.....	\$1,181,719
FY 2004 Balance.....	\$310,250

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 FY 2003, on-line renewals were made available to pharmacists only. In FY 2004 the Board introduced an on-line pilot program for pharmacy renewals. Online renewals is planned to be available to all pharmacies and distributors in FY 2005.

The unit continues to revise 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 is routinely posted on the Board's web site for verification purposes.

PHARMACISTS STATISTICS

Pharmacists renew licenses every two years during their birth month. The total number of pharmacists licensed during any given month varies. Between July 1, 2003 and June 30, 2004 (FY 2004), a total of 3865 licenses were issued, 3435 Renewed license, 300 were licensed through Examination and 130 were licensed through Reciprocity. The total number of pharmacists licensed at the end of FY 2004 was 7395.

ESTABLISHMENT STATISTICS

All Pharmacy permits expire December 31st of each year. The total number of pharmacy permit holders at the end of FY 2004 was 1389. Of that number, 85 were issued to new pharmacies in Maryland, 98 were issued to new pharmacies located out-of-state and 19 new pharmacy waiver permits were issued. A total of 62 pharmacies did not renew in FY 2004.

Distributor permits also expire December 31st of each year. The total number of Distributor permit holders at the end of FY 2004 was 574. Of that number, 35 were issued to new distributors in Maryland and 123 were issued to new distributors located out-of-state.

The total number of establishment permit holders in Maryland at the end of FY 2004 was 1963.

PHARMACIST COMPLIANCE UNIT

The only staff member on the Board of Pharmacy who is a pharmacist is the Compliance Officer. The Board is also authorized to have a full-time Compliance Specialist and a part time investigator, neither of which position require a pharmacist. At the end of the 2004 fiscal year all three positions were vacant and while recruiting was taking place the Executive Director, other staff members and Board Commissioners filled in to keep the unit actively addressing all issues that came before it.

The Compliance Unit receives complaints from consumers and other entities and is charged with addressing each of them. Initially consumers are notified of our receipt of their complaint, and the Board sends letters to the pharmacist(s) and permit holder who were named in the complaint asking them to respond to it. Once the information is received a summary of the problem is provided to the Board's Disciplinary Committee, which usually includes a consumer Board member, to determine what action to recommend to the full Board.

The decision could be to recommend one of the following:

- Take no action
- Letter of Agreement
- Issue a letter of education
- Issue a letter of admonishment
- Bring charges which may lead to probation, suspension or revocation of license or permit.
- Emergency suspension

The first four items above are informal actions, which can be taken without hearings, and are not subject to public review. The consumer who brought the complaint can only be told that the Board considered the circumstances and has closed the case without formal action on it. Often the letter to the consumer indicates that the complaint will remain a permanent part of the record and considered again if a similar complaint is lodged. This relates to the Board philosophy that speaks first to a systems approach to errors. When an error is made the Board expects the pharmacist and permit holder to take action which is intended to prevent future errors. The Board will deal more severely with repeated or continued problems. This is not meant to imply that an initial error or other problem may not be considered severe enough to require charges or emergency suspension.

If charges are brought and the Board takes formal action, the information would become public. The hearing process starts with a Case Resolution Conference in which the accused has a chance to work out an arrangement satisfactory to the Board. If this cannot be done, then a full Board hearing is held. An emergency (or summary) suspension is one in which the license or permit may be taken away before a hearing and is done only when it appears that the accused is an imminent threat to the public. Under some circumstances the Board will hold a Show Cause hearing before a summary suspension is issued to allow the person to offer reasons that the license or permit should not have action taken against it. A person who has had a summary suspension is offered the chance to show that the license or permit should be returned at a Show Cause hearing which is usually held within 30 days of a request.

Most consumer complaints end in informal action when the licensee or permit holder is found not to have multiple complaints against them, no substantial harm was done and a satisfactory plan is presented to lessen the possibility of similar problems in the future. The more stringent actions listed above are most often seen after the Compliance Unit investigates a complaint about a pharmacist related to drug abuse or illegal dispensing or a permit holder when fraud is shown. Actions have also been taken against pharmacists for non-pharmacy related grievances. Although the vast majority of pharmacists are good citizens, the Board has through the years had to deal with a pyromaniac, a

child abuser, attempted murder, attempt to do bodily harm, and other issues that cause societal problems.

During FY 2004, the unit handled 123 new written or e-mailed complaints, 112 of which were from consumers. Of these 11 resulted in formal actions. The Board, acting after the Compliance Unit brought evidence to the Disciplinary Committee, which then made a recommendation to the Board, held 4 Case Resolution Conferences, 2 full evidentiary hearings and 4 show Cause Hearings. Thirteen consent orders were signed, including 9 consent orders of reinstatements. One letter of Voluntary Surrender of license was accepted. Five license suspensions and 1 Revocation of a pharmacist license took place. One non-resident pharmacy permit was revoked. Six Pharmacists were placed on Probation and probation for 2 pharmacists were terminated. Twelve pharmacist licenses were reinstated including the 6 which were placed on probationary status. Three pharmacists were fined. Nine letters of education and 5 letters of admonishment were issued. Investigations continued into the next fiscal year for 75 complaints.

The Compliance Unit also reviews inspection forms provided by the Division of Drug Control, which does the routine inspections for the Board. The ability to use these comprehensive inspection forms is being enhanced by the use of computerized reports. These can easily be reviewed for areas of deficiency and are stored electronically for use in comparing inspections over a period of years. The Inspection Form is in the process of being upgraded to include information on pharmacy and pharmacist compliance with the documentation required for several new regulations. Depending on the nature of a deficiency when reported, the Board could take immediate action, ask Drug Control to re-inspect after a period of time to allow the pharmacy to improve, or wait to review increased compliance after the next routine inspection.

The Compliance unit answers many calls daily from pharmacists, permit holders and consumers seeking information or direction.

Fortunately for the Board and in particular for the citizens of Maryland, only a small percentage of pharmacists and permit holders come to the attention of the Compliance Unit and eventually to the full Board.

REGULATORY COMPLIANCE UNIT

Bills that passed during the 2004 Maryland legislative session that affect the practice of pharmacy include the following.

House Bill 384 - Maryland Pharmacy Act – Practice of Pharmacy – Administration of Medication

This bill will authorize specified pharmacists to administer influenza vaccinations once regulations are jointly developed and adopted by the Boards of Pharmacy, Physicians and Nursing. The Boards are to establish the fee for the service of administering the influenza vaccination. The Board of Pharmacy is currently working with the Boards of Nursing and Physicians to develop the implementing regulations.

House Bill 433 - Prescription Drug Safety Act

The Prescription Drug Safety Act requires that all prescriptions written by a health care practitioner be legible. The bill also requires the Department of Health and Mental Hygiene to convene a workgroup that would include the Boards of Pharmacy and Physicians. The workgroup's objective will be to focus on issues that include: content of prescriptions and the possibility of eliminating hand-written prescriptions. A report is due to the legislature on or before November 1, 2004.

The Board of Physicians and Pharmacy are coordinating the work of the workgroup. The Board of Pharmacy has appointed Board member, Jeanne Furman, P.D., to be its representative in the workgroup. The Board expects that it will be requesting an extension from the Legislature so that it may complete its work and draft a final report that effectively addresses the issues raised in HB 433.

House Bill 519 – Pharmaceuticals – Marketing – Disclosure and Registration

This bill would have required a pharmaceutical manufacturing company to annually disclose the name and address of pharmaceutical marketers to the Board. An individual would have been required to register with the Board and pay a registration fee before practicing pharmaceutical marketing in the State of Maryland. The bill did not pass but was sent to interim study.

House Bill 998 – Board of Pharmacy- Registration of Pharmacy Technicians

House Bill 998, Board of Pharmacy- Registration of Pharmacy Technicians, would have allowed the Board to register pharmacy technicians. The Chairman of the Health and Government Operations Committee referred the bill to the Board for summer study. The Board subsequently formed a Pharmacy Technician Work Group to address issues raised during the 2004 legislative session. The Board expects the issues to be resolved and another bill to allow the Board the authority to register pharmacy technicians to be introduced during the 2005 legislative session.

REGULATORY INITIATIVES

COMAR 10.31.02 Tax Compliance Regulations

The Board, along with other health occupations boards, is prohibited from renewing a license if a licensee is identified by the Office of the Comptroller or the Department of Labor, Licensing, and Regulation as delinquent in the payment of taxes or unemployment insurance contributions. If you

have outstanding taxes or unemployment contributions, please contact the Office of the Comptroller or the Department of Labor, Licensing, and Regulation, as appropriate.

Effective date: December 11, 2003

COMAR 10.34.01 Disciplinary Proceedings

The Board of Pharmacy substantially revised its regulations relating to disciplinary proceedings. Please feel free to review this chapter of regulations on the Division of State Documents website at www.dsd.state.md.us.

Effective date: September 1, 2003

COMAR 10.34.09 Fees.

The Board created a late fee of \$100 for failing to notify the Board within 30 days of changing the name of a pharmacy or wholesale distributor. If the Board is notified within 30 days before or after a change in the name of a pharmacy or wholesale distributor, there is no charge. Please refer to the regulation below COMAR 10.34.30 Name Change – Pharmacy or Distribution Permit Holder.

Effective date: November 10, 2003

COMAR 10.34.26 Patient Safety Improvement

In 2002, records of ongoing quality assurance programs in pharmacies received the protections of a medical review committee. Protection from discoverability of ongoing quality assurance records was a recommendation of the Board's Medication Error Task Force. Based on these protections and the work of its Medication Error Task Force, the Board implemented this chapter of regulations which is divided into three concepts. The concepts are:

1. Patient education;
2. Pharmacy staff education; and
3. Ongoing quality assurance programs.

Please review this chapter of regulations in its entirety.

Effective date: October 27, 2003

COMAR 10.34.27 Compelling Public Purpose

This chapter of regulations was revised to allow the custodian of records to share certain records, as opposed to requiring the Board to vote to share certain records.

Effective date: December 11, 2003

COMAR 10.34.29 Drug Therapy Management

The Boards of Pharmacy and Physicians implemented this chapter of regulations to allow physicians and pharmacists to manage patients' drug therapy. The regulations set out the requirements that a pharmacist, physician-pharmacist agreement, protocol and therapy management contract must meet and the approval procedure.

As established in the statute, the Boards of Pharmacy and Physicians have appointed members to the requisite joint committee and the joint committee has met. The Joint Committee is currently developing documents to assist interested parties in filing drug therapy management applications. Regardless of the status of the documents that the Joint Committee is preparing, applications are being accepted from interested parties. Please mail applications to the Maryland Board of Pharmacy, 4201 Patterson Avenue, Baltimore, MD 21215.

Effective date: December 11, 2003

COMAR 10.34.30- Name Change — Pharmacy or Distribution Permit Holder

The name of an individual or entity required to possess a pharmacy or distribution permit may be changed on a permit if the permit holder notifies the Board of the name change within 30 days before or after the name change. The Board will change the name on the permit if there is no other change to the individual or entity such as a change in controlling ownership interest, type of business entity, or location. If the Board is not notified within 30 days of the name change a late fee will be charge. Please refer to COMAR 10.34.09 Fee for additional details.

Effective date: November 10, 2003

COMAR 10.34.31- Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit

The Board implemented this chapter of regulations to allow a pharmacist to dispense or distribute from a setting that does not possess a pharmacy permit and to address instances of catastrophic health emergencies and when a pharmacy is rendered inoperable. Certain approvals are required in order for a pharmacist or pharmacy permit holder to utilize this section.

Effective date: March 1, 2004

Please review the entire chapters listed above. They may be accessed on the Division of State Documents website at www.dsd.state.md.us.

PUBLIC INFORMATION & EDUCATION UNIT

PUBLIC AWARENESS

The purpose of the Public Information & Education Unit is to play 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. Unit staff also informs the public about how appropriate medication use can enhance the quality of care and safety.

The Unit developed and continued to disseminate three consumer brochures. They provided information about the Board, buying drugs from foreign countries and on services available through pharmacies with the intent of increasing consumer's awareness and encouraging safety relating to the use of prescription and non-prescription drugs. The Public Information and Education Unit also staffed booths at four consumer and pharmacy/association-sponsored events.

The Board of Pharmacy encouraged all Maryland pharmacies and pharmacists to participate in National Pharmacy Week, with suggestions for activities that will attract patients and raise awareness of the need for consumers to practice safe prescription and over-the-counter drug use.

2004 FLOWER MART – BALTIMORE, MD

The Maryland Board of Pharmacy and the Maryland Pharmacy Coalition [consisting of the Maryland Pharmacists Association (MPhA), Maryland Society of Health System Pharmacists (MSHP), Maryland Chapter of Consultant Pharmacists (MD-ASCP), Maryland Pharmaceutical Society (MPhS), and the Maryland School of Pharmacy Student Government Alliance (SGA)], participated in the City of Baltimore's 87th Flower Mart, on Mt. Vernon Street, Washington Monument, Mount Vernon Square, Wednesday, May 12, 2004. It was a successful endeavor thanks to the joint efforts of the Board of Pharmacy and the Maryland Pharmacy Coalition.

Health concerns were addressed with products and literature received from various pharmaceutical companies. Consumers appreciated the outreach project, and agreed that education is a very important part of the health care process.

Volunteer pharmacists and pharmacy technicians worked tirelessly from 7:00 a.m. to 6:00 p.m. and provided more than 1,000 consumers visiting the booth with general safety tips and health care services. In addition to providing information, blood pressure monitoring, diabetes screening, and consultation on medications, information was given to the public on nutrition, diabetes, cholesterol, high blood pressure, smoking cessation, osteoporosis, and over-the-counter prescriptions.

BIOTERRORISM RESPONSE ACTIVITY

The Board again targeted its Public Information and Education efforts in response to bio-terrorist and other threats to the state. At the request of the Secretary the Board's Public Information & Education Unit, in conjunction with a Board appointed Bio-terrorism and Emergency Preparedness Committee, recruited more than 1000 volunteer pharmacists and technicians, conducted 8 training sessions to over five hundred of those volunteers, established a 800 emergency telephone system and issued volunteer badges to those who were trained throughout the state.

Limited time and fiscal resources made development of a major consumer campaign prohibitive in FY 2004. 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 2004 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 250 requests were responded to in FY 2004.

TASK FORCE REPORT

BOARD OF PHARMACY BIO-TERRORISM AND EMERGENCY PREPAREDNESS

A MUST FOR THOSE WILLING TO PROVIDE PHARMACEUTICAL SERVICES DURING A CATASTROPHIC EVENT!

At the request of the Department of Health and Mental Hygiene (DHMH), the Maryland Board of Pharmacy appointed a Bio-terrorism and Emergency Preparedness Task Force to develop plans for recruiting and training Maryland-licensed volunteer pharmacists and pharmacy technicians to respond to state emergencies and catastrophic events. Demonstrating its commitment to ensuring that volunteers are continually available and supported, the board subsequently made the Task Force one of its permanent standing committees.

During the first training held September 2002, Arlene Stephenson, former Deputy Secretary for Public Health Services, thanked volunteers for answering the state's request for assistance and officially designated the more than 250 volunteers as members of the "Maryland Pharmacist Volunteer Corps (MPVC)." The Board designated 35 liaisons from among the MPVC to work closely with local health departments (LHD) to develop emergency plans. In addition, more than 160 team leaders have also been selected from the MPVC to assist the LHD designees in the operation of local treatment centers during an actual event.

Training is a must for those willing to provide pharmaceutical services during an emergency or catastrophic event. To date, the board, in collaboration with DHMH, the University Of Maryland School Of Pharmacy, and the Maryland Poison Control Center, has recruited 1,030 volunteers, of which more than 500 have been trained during eight training programs offered throughout Maryland. The board has also participated in three statewide drills.

The board continues to recruit, train, and engage volunteers in drills and exercises throughout the state and looks forward to continued support from MPVC volunteers. Trained pharmacists and pharmacy technicians will insure preparedness to provide state and local support when called upon. Volunteers are encouraged to keep current contact information on file with the board. For more information on how to join or to train for the Maryland Pharmacist Volunteer Corps, or to update contact information, e-mail: RxEmergency@dhmh.state.md.us.

TECHNOLOGY & AUTOMATION

MANAGEMENT INFORMATION SYSTEMS (MIS) UNIT

- Annual Total for E-mails to Board Addresses: 2,278 Growth (since 2003): +195
- Total Visitors to Web Site: 100,314 Growth (since 2003): +21,740
- The Consumer Web Page contains more avenues for assistance with buying prescription drugs from local government and private drug companies.
- Through the web site, the Board provides links to assist the public in finding safe and legal methods of obtaining lower cost prescription drugs and informs the public of those companies selling counterfeit or substandard products.
- Online Establishment Renewal: For the second year, the Board was able to renew establishments online. The online establishment renewals usage rose 3% over last year when it was originally tested.
- Online Pharmacist Renewal: In January 2004 the Board launched the pharmacist online renewal system. The system was design by the Maryland Health Care Commission (MHCC) utilizing user fee funds collected from pharmacist for the Commission. In it's first 6 months of operations 538 pharmacists logged on to renew, representing 30.6% of those eligible to renew during that same period.
 - Databases: The development of databases has provided the most influential contribution from MIS to Board operations. The new databases created in FY2004 include:
 - New Candidate Licensure system for examination and reciprocity applicants. New licensure candidates were previously processed through their paper files.
 - Daily Online Renewal approval database that links the online system to the Licensure Unit and automatically updates the mainframe, once approved by Licensure.
 - A recycled Bio-Terrorism Volunteer database has been an ongoing process which continues to improve so that the Board and Emergency Preparedness Teams can more quickly serve Marylanders. A second database was created this year that will be electronically sent to DHMH in support of the Federal governments efforts.

PHARMACISTS' EDUCATION AND ASSISTANCE (PEAC) 2004 ANNUAL REPORT

BACKGROUND

Established in 1983, the Pharmacists' Education and Assistance Committee (PEAC) is charged with advocating for and providing assistance to members of the pharmacy community who are impaired by substance abuse or mental illness. The existence of a Pharmacist Rehabilitation Committee is recognized in the Pharmacy Practice act, which authorizes the actions of the committee, provides protections for confidentiality of client information and good faith activities of committee members. Pharmacy regulations now require that pharmacists have a duty to report members of the profession who are impaired and practicing. These reports must be made directly to the committee rather than the Board of Pharmacy. PEAC is a 501(C) tax-exempt organization, which is contracted by the board to provide services to the Pharmacists of the State of Maryland. Maryland law authorizes the board to provide funding to support the activities of the committee.

COMMITTEE ACTIVITY 2004

1. During FY 2004 PEAC monitored 26 cases. Board of Pharmacy referred 12 of these cases. The Board of Pharmacy has extended the contract with PEAC for committee services. Pursuant to this new contract PEAC has hired an Executive Director. The role of the Executive Director is to develop a strategic plan, which will build on the organizational structure of PEAC and further the objectives of the organization in serving the public and the pharmacy community. Specifically the he is charged with:
 - a. Developing written standards and training material for client monitors
 - b. Upgrading the data collection and record keeping systems including faster communication of information to and from the Board of Pharmacy.
 - c. Broadening the support base of the committee through enhanced services and alternate funding sources.
 - d. Increasing awareness of the availability and value of PEAC intervention in the pharmacy employer community.
 - e. Expansion of continuing education programs and academics studies
2. PEAC has continued to support the Students Promoting Awareness (SPA) group by sponsoring training of a first year pharmacy student at the University of Utah Summer School on Alcoholism and Other Chemical Dependencies. This student and others who have attended the program form a cadre of leaders who have committed to lead the SPA in providing peer assistance to pharmacy students who are challenged by drugs or alcohol. PEAC involvement in this program serves to provide early intervention to protect the public and the pharmacy student but also acts as an avenue for developing potential monitors and committee leaders. PEAC continued to offer students in need of recovery support the same services available to practicing pharmacists and the School of Pharmacy policies identify PEAC as the avenue for reporting drug or alcohol abuse to the dean's office as required by campus regulations.
3. The Annual October continuing education program for pharmacists and allied health professionals is scheduled for October 21. The program is entitled "Crossing the line: when prescription drug use becomes abuse and addiction "to be held at Ten Oaks Ballroom in Clarksville, MD.

BOARD STAFF

LaVerne Naesea	Executive Director
Catherine Putz	Pharmacist Compliance Officer
Tamarra Banks	Network Specialist Administrator
Marianne Pindell	Administration and Public Support Manager
Joan Lawrence	Public Information Officer/Bioterrorism Coordinator
James Slade	Regulations/Legislative Officer
Shirley Costley	Licensing Manager
Doris James	Licensing Officer
Deitra M. Gale	Compliance Specialist
Jacqueline Higgins	Compliance Investigator
Vladimir Konstantinov	Database Specialist
Latonya Dickerson	Executive Secretary
Sandra Hines	Secretary
Lakeya Davis	Licensing Clerk

PUBLIC MEETING

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.

INFORMATION SERVICE

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

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.

**Maryland Department of
Health and Mental Hygiene**



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LaVerne Naesea – Executive Director

