

STATE OF MARYLAND
BOARD OF PHARMACY



2005 ANNUAL REPORT

SETTING STANDARDS FOR PHARMACY
SERVICES

JULY 1, 2004 THROUGH JUNE 30, 2005

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PRESIDENT'S MESSAGE



JOHN H. BALCH

Historically, fiscal year 2005 may have been one of the most positive in the annals of the Board of Pharmacy. Leadership has been demonstrated throughout the year by Executive Director, LaVerne Naesea and her staff, Board commissioners through their committee responsibilities, and consistent Executive Committee meetings to address and evaluate issues in preparation for monthly Board meetings. A well-planned and orchestrated strategic planning session allowed Board staff and commissioners to interact and develop strategies to lead the Board for the next several years.

The most significant event to occur during the last year was the passage of legislation to allow Maryland pharmacists to provide influenza immunizations as a compliment to their pharmacy practice. Cooperation by the Maryland Board of Nursing and the Maryland Board of Physicians will be essential in expediting regulations to be adopted prior to the next flu season. The School of Pharmacy has been a valuable resource in preparing pharmacists for the immunization administration by beginning to offer several training sessions for pharmacists. Multidisciplinary cooperation will be the key factor in implementing this process, and the Board of Pharmacy Practice Committee will serve as a catalyst in this effort.

Drug therapy management was initialized this past year with the receipt of the first thrombosis protocol. Once again, cooperation with the Maryland Board of Physicians will be essential as part of the Joint Committee to approve Drug Therapy Management Agreements. The Board expects more protocols to be submitted in the coming year.

The Long Term Care Task Force has been working in cooperation with the Office of Health Care Quality to bring awareness to the health facility community regarding the ongoing problems with the current discharge summary process. A joint letter between the Office of Health Care Quality and the Board of Pharmacy was mailed to health care facilities in May of 2005. Responses have been received from risk managers primarily at hospitals. Further meetings regarding this issue will be forthcoming.

The long awaited attempt to register pharmacy technicians has been delayed another year. Both the Senate and House approved bills that were amended differently, but 'sine die' prevented the reconciliation of the language in both bills. The Board is quite confident that the bill will pass during the FY 2006 session.

The Maryland Board of Pharmacy's Emergency Preparedness Committee remains active is geared up for responding to state emergencies. The Maryland contingent hosted trainings during FY 2005 in order to mobilize quickly. The Emergency Preparedness Committee was the first of its kind to be established in Maryland following the events of September 11, 2001. The committee remains active, and has become the model for other state boards to follow.

Relocation of the Board offices has been an ongoing struggle for several years. Maneuvering through the state system of checks and balances will result in new, expanded office and meeting space at the Patterson Avenue location in FY 2006. Future expanded duties and responsibilities makes this move necessary, and will result in providing better service by the pharmacy regulatory agency.

Leadership and cooperation have been the hallmarks of the last fiscal year activities. The Board continues to look for ways to improve the pharmacy inspection process, establish and tighten regulations for distributors operating in our state, and respond to legislative efforts requiring pharmacy participation, such as prescription monitoring and drug repository programs. The Board will be able to meet and move forward with the demands of future pharmacy activities by using cooperation and leadership as a means of accomplishment.

EXECUTIVE DIRECTOR'S REPORT



LAVERNE G. NAESEA

It is with pleasure that I present a summary of Board of Pharmacy's operations during a very eventful 2005 fiscal year. Three new pharmacist members were appointed during the year: Michael Souranis, Independent representative, who replaced former president, Melvin Rubin; David Chason, Hospital Pharmacy representative, who replaced Dr. Raymond Love; and Rodney Taylor, At-large representative, who replaced Ramona McCarthy-Hawkins.

Several staffing changes also occurred between July 2004 and June 2005. The Board filled six vacancies including the Pharmacist Compliance Officer, Public Information Officer, and Office Service Clerk, Health Investigator I, Administrative Officer I and Office Secretary III. Also, a new PIN position, Legislation/Regulations Manager, was assigned to the Board and three new contractual positions were approved by the legislature (Administration Specialist II and Secretary I to the Licensing Unit, and Human Resources Assistant to the APS Unit).

During FY 2005, the Board refined its disciplinary system resulting in a successful reduction in the backlog of complaints and the development of a new pre-inspection procedure. Regarding technology advancements, the Board entered into contract agreements for computer disaster recovery and a totally revamped MIS technology system.

Two new categories of pharmacists were approved for regulation under the Board's Administration of Influenza Vaccines and Drug Therapy Management (Collaborative Practice) and programs. Regulations are pending for the Influenza Vaccine program. However, recently promulgated regulations now allow pharmacists, physicians and patients to enter into time-limited treatment agreements under the Drug Therapy Management Program for treatment of specific disease states using approved protocols.

The Maryland Board of Pharmacy also assigned a Chapter <797> task force, chaired by member Donald Yee, to review the United States Pharmacopeia (USP), Chapter <797> Pharmaceutical Compounding -- Sterile Preparations standards. The task force will recommend which aspects of USP Chapter <797> the Maryland Board of Pharmacy should enforce, and what resources would be required in order for the Board to implement the resulting recommendations. .

Over 45 pharmacists enthusiastically participated in a Board planned Emergency Preparedness Drill in March 2005. Volunteer pharmacists, Board and staff members and citizen volunteers helped to work the *kinks* out of the Board's emergency response plan.

The Board was also involved in activities to strengthen relations with Maryland citizens and pharmacy associations. For example, the Board, the Maryland Pharmacist Coalition (MPS, MSHP, MPhA, MACDS and MD ASCAP) and the UMAB School of Pharmacy were again awarded the first

place ribbon for the best decorated booth at the Flower Mart's Health Village. Board members and staff participated in NABP's National and District meetings and in MPhA consumer health conference.

The Board will also be working on other possible legislation in FY 2006, such as restrictions on the sale of pseudoephedrine, legibility of prescriptions and prescription drug repositories for possible introduction during the next session. Also, on the horizon in FY 2006 will be the flu vaccine regulations that should be adopted before the next flu season and a major undertaking planned will be the Board's move to new expanded office space in the Patterson Avenue building. The move will not only accommodate staff hired for new programs and services, but will enhance the Board's ability to serve constituents better.

FY 2005 was indeed quite productive. The Board would not have been as successful in insuring the health safety of Maryland's pharmacy patients without the help of all of its constituents. Therefore, on behalf of the Board and its staff members, thanks to all of the pharmacists, legislators, agencies and Maryland citizens who provided time and support to the Board's initiatives during FY 2005.

The following pages will provide specific details about the many activities addressed by Board committees and staff. The Board looks forward to continued and new partnerships during an even more eventful year in FY 2006. Please contact the Board at **www.mdbop.org** to learn more about its activities or lend volunteer support.

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.

STATE OF MARYLAND BOARD OF PHARMACY'S 5 YEAR GOALS

5 YEAR GOALS (FY 2001-2006)

A. COMMUNICATION

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

B. COMPLIANCE

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

C. 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.

D. 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.

E. 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.

F. STAFFING

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

FY 2005 SUMMARY

REVENUE

Pharmacist Examination	\$45,020
Pharmacist Renewals	\$517,491
Reciprocity	\$20,263
Pharmacist Reinstatement	\$21,368
Establishments	\$863,603
Other	\$61,061
TOTAL REVENUE	\$1,528,806

EXPENDITURES

Salaries and Wages	\$633,142
Per Diem	\$51,991
Technical and Special	\$128,044
Operating Costs	\$378,353
Purchases	\$42,011
Fixed Costs	\$50,199
Indirect Cost	\$80,424
TOTAL EXPENDITURES	\$1,364,164

BOARD COMMISSIONERS

John H. Balch

Board President
Independent Representative

Jeanne G. Furman

Board Secretary
Acute Care Hospital Representative

Mark Levi

Board Treasurer
At Large Representative

Joseph A. DeMino

Chain Drug Store Representative

Donald Taylor

Chain Drug Store Representative

Mayer Handelman

Long Term Care Representative

Donald K. Yee

Home Infusion Representative

Margie Anne Bonnett

Consumer Representative

Consumer Position (Vacant)

Rodney H. Taylor

At-large Representative

David Chason

Hospital Pharmacy Representative

Michael N. Souranis

Independent Representative

Linda Bethman

Board Council
Office of the Attorney General

MARYLAND BOARD OF PHARMACY'S OPERATIONS REPORT

ADMINISTRATIONS AND PUBLIC SUPPORT UNIT

ADMINISTRATION AND STAFFING

In fiscal 2005 the Board was restructured from six to five units. They are the: Administration and Public Support, Compliance, Licensing and Certification, Management Information Services and Regulations and Legislative Units. The Fiscal/Personnel Officer position along with the Public Information Officer and Administrative Assistant positions were combined to form the Administration and Public Support Unit, which is assigned under the direction of the Executive Director to handle all fiscal, procurement, personnel, and public education and information functions. Fiscal 2005's staffs increase involved the addition of one employee to the Regulations Unit. Of fifteen positions, 80% were filled at all times during fiscal year 2005. Fifty percent (50%) of the Board staff members have tenures of 5 plus years.

The Board requested the Maryland Legislature to approve additional staff to support the Administration and Public Support, Compliance, Licensing and Certification and Management Information Services Units in fiscal year 2006. This is necessitated because of the two new programs assumed in FY 2005 (drug therapy management and administration of influenza vaccinations) and the increase in workload related to existing programs.

FISCAL/PROCUREMENT ACTIVITIES

REVENUE AND EXPENDITURES

Total collections for the Board of Pharmacy for fiscal year 2005 were \$1,364,164. This is an 8.4 % increase over fiscal year 2004. The increase in revenue is a result of increases in the number of licensees and permit holders. Board expenditures increased by 11.8% over the previous year because of increases in the number of contracts, amounts of contracts (e.g., the PEAC more than doubled in FY 2005) and the addition of new staff members.

In fiscal year 2005 (November 2004) the Board began receiving on-line payments for pharmacists' renewals. As a result nearly 50% of all pharmacists' licenses were renewed on-line.

CONTRACTUAL AGREEMENTS

In FY 2005, The Board is negotiated new contractual agreements with Towson University for development of a Disaster Recovery system for its MIS Unit and with the University of Maryland to evaluate the outcomes of Drug Therapy Management agreements. The two

new contracts totaled more than \$142,000. These contractual agreements are expected to bring more efficiency to the Board's operations as well as enhance relationships with these agencies. The complexity of both contracts will require continuous monitoring, review and possible modification. One of the Board's largest contractual agreements was with PEAC (pharmacist rehabilitation services).

PUBLIC SUPPORT

The Board of Pharmacy offers public support by educating and increasing consumers' knowledge about pharmaceutical services and medications, keeping the public informed about the appropriate uses of medications and promoting awareness for the prevention of medication errors. Efforts by the Public Information and Education Officer (PIEO) are on-going.

CONSUMER AWARENESS

The Board's mission to increase awareness and encourage safe use of prescription and non-prescription drugs is met through the development and dissemination of brochures. Some brochures provide information about the Board regarding risks related to buying drugs from foreign countries and services available through pharmacies while other describe programs and services offer through the Board. Additionally the PIEO designed and disseminated the Board- developed Pre-Inspection booklet to all pharmacies. The booklet encourages pharmacists to conduct his or her own inspections before the formal inspection.

The Board of Pharmacy also distributed four issues of its newsletter to pharmacists and the pharmacy community during the fiscal year. Also the Unit coordinated staffing of several booths at consumer and pharmacy/association-sponsored events, such as the Flower Mart, MPhA Conference and Maryland State Fair. For example, the Board of Pharmacy in partnership with the Maryland Pharmacy Coalition (MPC) participated in the 88th Flower Mart, Mt. Vernon, Baltimore on May 18, 2005. This outreach was a huge accomplishment, at which dedicated and diligent pharmacists and interns provided consultation to hundreds of consumers who visited the booth located in the Health Village. Consultations, blood pressure screening and current informational and promotional materials relating to a variety of health topics were provided.

PUBLIC INFORMATION REQUESTS (PIA)

In fiscal year 2005 the Board responded to 16 PIA requests made to the Board relating to individual cases and various other 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. The requests made were for information regarding specific disciplinary cases that were under Board Orders as well as an assortment of general and statistical information.

EMERGENCY PREPAREDNESS COMMITTEE

At the request of the Department of Health and Mental Hygiene (DHMH), the Maryland Board of Pharmacy appointed the Emergency Preparedness Committee, which has recruited more than 1000, volunteer pharmacists and technicians. Maryland-licensed volunteer pharmacists and pharmacy technicians are trained to respond to state emergencies and catastrophic events demonstrating its commitment to ensuring that volunteers are continually available in case of emergency.

During fiscal year 2005, the Board conducted its first Bio-terrorism and Emergency Preparedness Drill. On March 19, 2005 the Board offices were turned into command and communications center while other meeting rooms in the building transformed into staging, mass counseling and reception, re-packaging, supply centers, dispensing and other counseling areas. The Department of Health and Mental Hygiene and University of Maryland drill monitors tested and timed volunteer pharmacists, board members, staff and consumer volunteers on communications while they telephoned hundreds of pharmacists to determine their availability, as if it were a real emergency. Volunteer posing as patients acted out scenarios such as illiteracy, language barriers, special medical concerns, and security to strategic areas. The drill included timed repackaging of medicine, dispensing (candy) pills and mass, regular and special needs counseling. Volunteer pharmacists and other consumer participants during the closing critiqued the events of the four-hour drill. Lessons learned from constructive comments and observation will be beneficial to the Board practices for use during a real emergency event.

The Board in collaboration with DHMH, the University of Maryland School of Pharmacy, and the Maryland Poison Control Center will continue to recruit, train, and engage volunteers in drills and exercises throughout the state and looks forward to continued support from 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

FISCAL YEAR 2006 AT A GLANCE

The Board will be moving to its new location on the first floor of the 4201 Patterson Avenue facility by the end of the second quarter of FY 06, approximately December 2005/January 2006. With the adoption of the Pharmacy Technician bill and the Drug Therapy Management Project we can expect increase in revenues as well as an increase in the budget allocation for additional staffing. With the rise in pharmaceutical issues and heightening of emergency preparedness, the Board expects to participate in additional public relations and emergency preparedness activities. Training for Board,

staff and pharmacists volunteers will increase. Board and staff members will retreat early FY 06 to revisit its five-year strategic plan goals.

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 Unit’s main goal is to protect the public by ensuring that pharmacists licensed by the Board meet credentialing requirements that are then evaluated through an accurate and timely licensure process. This will ensure high quality pharmacy services to the citizens of Maryland.

The Licensing Unit’s on-line renewal system is available to all Maryland licensed pharmacists, pharmacies and distributors. Pharmacists may access the system sixty days before the license expiration date. Of the 3521 renewing pharmacists, 1194 (34%) renewed on-line in FY 2005.

The total number of pharmacists licensed at the end of FY 2005 was 7,662.

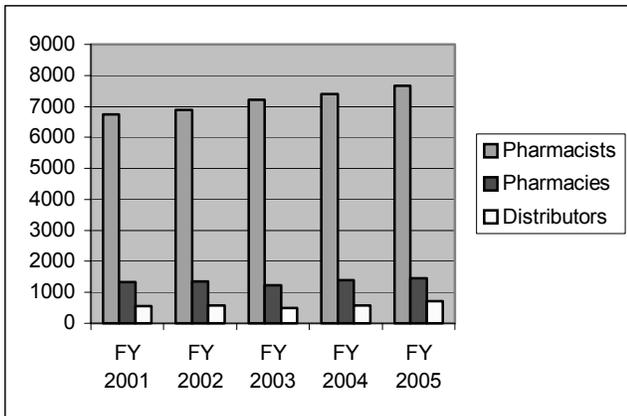
The establishments (pharmacies & distributors) on-line renewal system is available from mid October to December 26 of each year. All establishment permits expire annually on December 31st. Of the 2146 establishments that renewed, 975 took advantage of the on-line system in FY 2005.

The total number of Pharmacy permit holders at the end of FY 2005 was 1,446.

The total number of Distributor permit holders at the end of FY 2005 was 723.

The On-line renewal system has proven to be fast and effective and has reduced the average time to 4 or less working days between receipt of complete renewal applications and issuance of licenses. Electronic checks and most major credit cards are accepted. The Unit’s goal for on-line renewal is 100% participation.

Unit Statistics



The total number of licensed Pharmacists, Pharmacies, and Pharmaceutical Distributors has increased in Maryland over the last 5 years.

Pharmacists increased by 13.7% from 2001 to 2005
 Pharmacies increased by 8% from 2001 to 2005
 Pharmaceutical Distributors increased by 30% from 2001 to 2005.

The Licensing Unit and the Licensing Committee continually review and revise new and renewal applications to ensure compatibility with changes to licensing requirements and works closely with the Management Information Services and Public Information and Education staff members to ensure that current licensing information is routinely posted on the Board's web site.

The Licensing Unit assumed responsibilities for two new programs approved by the legislature during FY 2005: *Administration of Influenza Vaccine* and *Drug Therapy Management*. Staff members will be working closely with the Regulations/Legislative Unit to develop the application and operating procedures for both programs. The Unit will also work with representatives of both the Board of Pharmacy and Board of Physicians in evaluating treatment protocols submitted for the Drug Therapy Management Program. Procedures for both programs are forthcoming and may be accessed through the Board's website once they are finalized.

During FY 2006, the Licensing Unit will be recruiting new staff members and developing new plans to ensure that the standards established for evaluating licensees are not compromised by the addition of new program responsibilities. The Unit looks forward to a very busy but successful next year.

PHARMACIST COMPLIANCE UNIT

The Compliance Unit is comprised of a Pharmacist Compliance Officer, Compliance Specialist, and Compliance Investigator. It is responsible for: ensuring that pharmacists, pharmacies and distributors continue to meet state laws and regulations; responding to consumer complaints; providing advice and assistance to legislators, inspectors, regulations coordinators, and federal, state and non-public agencies regarding compliance with pharmacy rules; assisting the Board in taking action against pharmacists and establishments that do not meet the minimum practice standards (or who violate specific rules designed to protect the public); and monitoring pharmacists who have been placed under Board orders for various violations.

Informal actions that may be taken by the Board include informal meetings with involved pharmacists or pharmacy representatives, the issuance of Letters of Education or Letters of Admonishment and/or requiring additional continuing education training, or acceptance of voluntary surrender of licenses usually documented through letters of agreement or consent agreements. Informal actions are not subject to public review. The Board issued Sixteen (16) Letters of Education and 18 Letters of Admonishment as a result of complaints received in FY 2005.

The Compliance Unit also works closely with the Attorney General's Office prosecutors after the Board votes to issue formal charges. The Unit staff provides information gathered through interviewing witnesses and investigation findings to prosecutors who present cases before the Board. Once a referral is made to the Attorney General's office for the issuance of formal charges, the Compliance Investigator and Pharmacist Compliance Officer can no longer communicate with Board members about a particular case.

Formal actions by the Board usually involve case resolution conferences (CRC's) or formal hearings. Formal actions may include, probation, suspension, revocation of a license or permit, as well as imposition of fines. Formal actions are subject to public review. A CRC provides a charged pharmacist with an opportunity 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 him or herself or 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.

Ten of the FY 2005 complaints received resulted in formal actions taken by the Board and the issuance of 12 Board disciplinary orders (including two reinstatement orders). Specific outcomes included, four pharmacist suspensions; one (1) pharmacist revocation; three (3) pharmacists placed on probation; one (1) fined pharmacist; and the termination of probation for one pharmacist. thirty-three (33) complaint investigations were carried over into FY 2006.

The Unit receives complaints from consumers and other entities and responds to each as appropriate. It works closely with the Division of Drug Control, that is the Boards agent in performing annual inspections. The oversight committee for the Compliance Unit is the Disciplinary Committee. That committee reviews complaints received by the Unit, directs investigations of complaints and develops recommendations for Board actions based on the outcome of investigations. During FY 2005 the Unit processed 175 written or e-mailed complaints, compared to 123 in FY 2004. Of the complaints addressed, 151 were received from consumers (112 complaints received from consumers in FY 2004).

The Compliance Unit continues to struggle with staffing issues. The volume of complaints compounded by the time required to investigate each, requires additional resources as well as changes in how existing resources are utilized. Often, the workload has led to high turnover in the Unit. The Disciplinary Committee and Board are working closely with the Executive Director to develop methods to keep pace with the increase in complaints and necessity for increased regulatory oversight. Options under consideration for FY 2006 include increasing staff resources, upgrading staff positions, and redefining some positions within the Unit to enhance monitoring of persons under Board orders. The Board and Unit will continue its deliberations and anticipate positive change in FY 2006.

LEGISLATIVE/REGULATIONS UNIT

LEGISLATIVE INITIATIVES

The Legislative/Regulations Unit presented 58 bills out of approximately 2,500 bills to the Board of Pharmacy's Legislative Committee for consideration. The unit drafted position papers and/or letters to legislative committees for 21 of the 58 bills. Below is provided a chart of the 21 bills and the result:

Bill Number	Bill Name	Board Action	Result achieved
SB 24	Health Occupations – Practicing Without License – Penalties	Joint position paper in support Letter to Committee suggesting necessary amendments	FAILED
HB 65	State Employees – Prescription Drugs – Canadian Mail Order Plan	Letter of Concern	FAILED
HB 113	Health Care Malpractice – Emergency Medical Care – Good Samaritan Immunity	Support with Amendments adding in Pharmacists	FAILED
HB 114	Quality Health Care Act of 2005	Support with Amendments adding in Pharmacists	FAILED
HB 115	Health Care Malpractice – Division of Lawyers' Fees – Prohibition	Support with Amendments adding in Pharmacists	WITHDRAWN
HB 203	Income Tax Credit for Services Donated by Health Care Professionals	Letter of Support with Amendments adding in Pharmacists	FAILED
HB 231	Prescription Drugs – Canadian Mail Order Plan	Letter of Concern	FAILED
HB 233	Public Health – Legibility of Prescriptions Workgroup	Letter of Information	PASSED
SB 251	Task Force to Study Electronic Health Records	Letter of Support	PASSED
HB 317	Task Force on the Establishment of a Prescription Drug Repository Program	Letter of Opposition; Taskforce created – Letter of Support	PASSED
SB 441	Task Force on the Establishment of a Prescription Drug Repository Program	Letter of Opposition; Taskforce created – Letter of Support	PASSED
SB 372	Crimes – Pseudoephedrine	Letter of Education	FAILED

	– Prohibitions		
HB 618	State Board of Pharmacy – Registration of Pharmacy Technicians	Support with Amendments	FAILED
SB 690	Medical Records – Authorized Disclosures – Compulsory Process	Joined position paper with other boards to support with amendments	FAILED
HB 735	Controlled Dangerous Substances – Schedule III and Schedule IV Substances – Prescriptions and Refills	Letter of Opposition	FAILED
SB 742	Prescription Drugs – Canadian Mail Order Plan	Letter of Concern	FAILED
HB 835	Wholesale Prescription Drug and Device Distribution Protection and licensing Act of 2005	Letter of Concern	FAILED Summer Study
HB 890	Health Care Malpractice – Claims – Physician Assistants	Joined Position paper with other boards – support with amendments adding in Pharmacists	FAILED
HB 1020	Health Care Practice and Facilities – Closure – Patient Medical Records	Letter of Concern	FAILED
HB 1058	Pharmacy Benefit Managers Regulation Act of 22005	Letter of Support	FAILED Summer Study
HB 1062	Health Insurance – Prescription Drugs Coverage – Alternative Drugs	Letter of Concern	FAILED

Summaries of major bills from the 2005 Legislative Session are provided below.

HB 233 - Public Health – Legibility of Prescriptions Workgroup

The Prescription Drug Safety Act (HB 433) passed during the 2004 legislative session resulted in a workgroup of stakeholders, staffed by the Board of Pharmacy to study prescription legibility. HB 233 continued that workgroup and required an interim and final report be submitted to the legislature (Summer 2005) outlining recommendations for improving patient safety. The July 1, 2005 report was submitted and the August 15, 2005 report will be forthcoming.

The recommendations included:

- Implement incentives for prescribers to convert to e-prescribing;
- Eliminate handwritten prescriptions in Maryland;
- Establish a phase-in period to educate prescribers and consumers concerning the required content and format of oral, typed or electronic prescriptions;
- Educate prescribers, pharmacists and consumers concerning the required content and format of prescriptions;
- Allow for continuing education credit for prescribers' training in the required content and format of prescriptions;
- Establish a phase-in period for enforcement and compliance of the required content and format of prescriptions;

SB 251 -Task Force to Study Electronic Health Records

This legislation established a task force to study electronic health records and the current and potential expansion of electronic health record utilization in MD. The bill passed and includes licensed pharmacists and stakeholders.

SB 441/HB 317 - Task Force on the Establishment of a Prescription Drug Repository Program

This bill was introduced as "Prescription Drug Repository Program" but amended into a Task Force. The Task Force will study the feasibility of designated pharmacies receiving unopened and unused prescriptions to re-dispense to qualifying individuals. The Task Force has not yet been convened.

SB 372 – Crimes – Pseudoephedrine – Prohibitions

This unsuccessful legislation restricted the sale of pseudoephedrine to 9 grams in 30 days. Recognizing the importance of restricting the sale of pseudoephedrine to protect public health, the Board is considering proposing regulations later in 2005.

HB 618 – State Board of Pharmacy – Registration of Pharmacy Technicians

This bill authorized the Board of Pharmacy to regulate pharmacy technicians. The legislation was well received and amended in both the House and the Senate. Due to time constraints, it did not pass before the last day of session (Sine Die). This legislation will be introduced again in both houses in 2006.

HB 835 -Wholesale Prescription Drug and Device Distribution Protection and Licensing Act of 2005

The purpose of this legislation was to deter diversion and drug counterfeiting. The Board supported that goal, however, HB 835 was problematic for the Board for a number of reasons. Since the majority of the wholesale drug and device distribution business is by interstate commerce, the proposed law would have placed an undue burden on the Board in regulating wholesale distributors beyond the current scope of the Board's regulation.

At the time the Board suggested to the Committee that they allow the FDA to provide guidance regarding protection of drugs and devices so that there is a uniform standard applied across the country. Additionally there were some technical problems with some of the text of the bill. The bill went to summer study for further consideration.

HB 1058 - Pharmacy Benefit Managers Regulation Act of 2005

The purpose of this legislation was to set up a system of regulations for Pharmacy Benefit Managers (PBMs) in Maryland. It would have regulated PBMs in 4 different ways: 1) It established a regulatory system for PBMs, primarily through the Maryland Insurance Administration; 2) It required PBMs to disclose information about rebates and other arrangements; 3) It required that PBMs follow certain procedures when substituting a different prescription drug for a prescribed drug, and 4) It made certain insurance benefit requirements applicable to PBMs. The bill went to summer study for further consideration.

REGULATORY INITIATIVES

The Legislative/Regulations Unit assists in revising the Board's regulations. Below is provided a chart of the regulatory revisions and accomplishments.

Maryland Board of Pharmacy Regulations, COMAR 10.34.01 - .31, revisions effective since July 1, 2004.

COMAR Citation	Title	Effective Date
10.34.02	Examination for Licensure and Professional Experience Programs	June 20, 2005
10.34.07	Pharmacy Equipment	August 30, 2004
10.34.22	Licensing of Wholesale Prescription Drug or Device Distributors	March 28, 2005

Maryland Board of Pharmacy Regulations, COMAR 10.34.01 - .31, currently in the amendment process

COMAR Citation	Title	Proposal Status
10.34.23	Pharmaceutical Services to Residents in Long-Term Care Facilities	Published August 6, 2004 Proposal revisions under consideration
10.34.32	Pharmacist Administration of Influenza Vaccinations	Promulgation of proposal under consideration by the Board of Pharmacy, Board of Physicians and Board of Nursing
10.34.19	Parenteral/Sterile Enteral Compounding	Taskforce working on recommendations for revisions to comply with USP 797
10.34.28	Automated Medication Systems	Promulgation of Proposal under consideration
10.34	Conscience Clause	Promulgation of Proposal under consideration
10.34	Registration of Pharmacy Technicians	Promulgation Pursuant to Passage of Registration of Pharmacy Technician Legislation

Summaries of regulatory changes that became effective in 2005 are provided below.

10.34.02 Examination for Licensure and Professional Experience Programs

This amendment set forth in regulations that an applicant may take Exam I upon satisfactory proof that the applicant has graduated, or is expected to graduate from a school of pharmacy at the completion of the immediate semester. Traditionally the applicant had to wait until they had graduated.

10.34.22 Licensing of Wholesale Prescription Drug or Device Distribution

The purpose of this revision was to ensure compliance with 21 CFR 205. This regulation was also revised to comply with the Maryland Pharmacy Act with respect to the regulation of wholesale prescription device distributors and the repeal of the Board's authority to regulate manufacturers.

10.34.07 Pharmacy Equipment

This revision updated the description of a Class A prescription balance to include a prescription balance with equivalent or superior sensitivity to a Class A prescription balance.

TECHNOLOGY & AUTOMATION

MANAGEMENT INFORMATION SYSTEMS (MIS) UNIT

Annual total for E-mails to the Board's general E-mail addresses: 2,274.

In FY01 the Board introduced MDBOP@dhhm.state.md.us , it received 604 E-Mail that year. The Board had 40 E-Mails to the newly created RxEmergency@dhhm.state.md.us address. RxEmergency receives requests from the Board's Emergency Preparedness Volunteers.

Total Visitors to Web Site: 125,623

Up +25,305 over FY04 total of 100,314. MIS plans to redesign the Board's web site within the next 2 fiscal years reflect changing in the way people utilize the Internet and the information that can be found there. New to the we site this fiscal year:

Online Pharmacist Renewal:

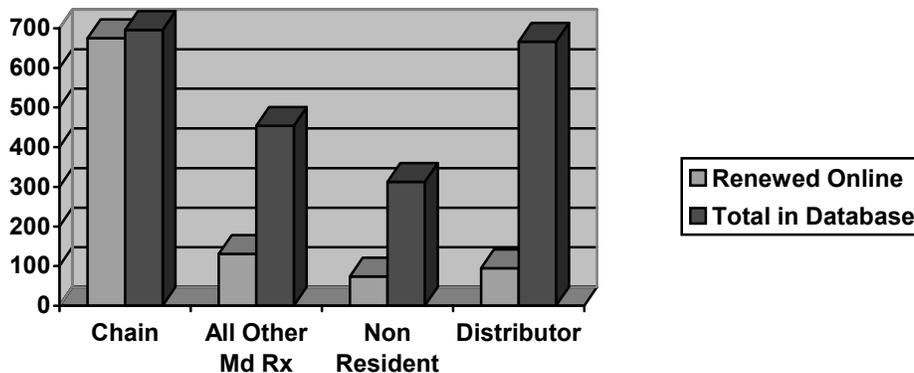
In it's second year, the Pharmacist Online Renewal System, designed by the Maryland Health Care Commission (MHCC), saw an increase of 44%.

Total Applications Mailed	3,769
# Logged On to System	1,221

Online Establishment Renewal:

For the third year, the Board was able to renew establishments online. The following chart represents the breakdown for establishment online usage.

Total Applications Mailed	2,129
# Logged On to System	975



At the end of FY2004 the MIS Unit provided to the Board a list of MIS plans for FY2005. Despite new legislative initiatives, requests to provide information in support of compliance and licensing matters, the following actions occurred in FY2005.

In May 2005 the Board of Pharmacy signed an agreement with Towson University / RESI to design and implement an In-House database. This system would take the Board off the mainframe system and provide greater flexibility for storing and reporting on licensee, disciplinary and other information collected by the Board. The system would also tie in stakeholder data, and provide a cross reference of the information that is collected by the Division of Drug Control, the FDA and other entities. The system would also ensure Medicaid has access to the information necessary for claims processing by pharmacies.

Promotion of online renewal systems to achieve 50% participation

As indicated above, the Pharmacist Online system saw an increase of 44% and the Establishment Online system increased by 5%. Due to the lack of staffing, the increase came without the aid of a promotional campaign to be developed between the Board's MIS and PR Units.

Additional Support for the Board's Automated Services

The agreement with Towson University also included several hours of hardware/software support for all systems affected by the implementation of the In-House database system, as well as knowledge transfer between the Board's Database programmer and the Towson's programming staff assigned to work on the project.

Expand web services by providing more interactive and online forms and verification systems. New web services have been rescheduled to begin with the next 2 fiscal years.

MARYLAND BOARD OF PHARMACY STAFF

LaVerne Naesea	Executive Director
Chandra Mouli	Pharmacist Compliance Officer
Tamarra Banks	Network Specialist Administrator
Patricia Gaither	Administration and Public Support Manager
Summar Goodman	Public Information Officer/Emergency Preparedness Coordinator
Christina Harvin	Regulations/Legislative Officer
Anna Jeffers	Regulations Officer
Shirley Costley	Licensing Manager
Doris James	Licensing Officer
Colin Eversley	Compliance Investigator
Vladimir Konstantinov	Database Specialist
Jessica Acevedo	Compliance Secretary
Sandra Hines	Human Resources Assistant
Stacy Wallace	Licensing Clerk
Keisha Wise	Receptionist

INFORMATION SERVICE AND PUBLIC MEETINGS

INFORMATION SERVICES

Log on to the Board's website 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.

PUBLIC MEETINGS

Public meetings are held at The Board of Pharmacy, 4201 Patterson Avenue, Baltimore, Maryland 21215, on the 3rd Wednesday of each month, from 9:00 a.m. until 12:00 noon. 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 e-mail the Board at mdbop@dhhm.state.md.us to request a copy via e-mail.

Maryland Department of
Health and Mental Hygiene



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LaVerne Naesea – Executive Director