

STATE OF MARYLAND
BOARD OF PHARMACY



2007 ANNUAL REPORT
July 1, 2006 - June 30, 2007

Vision

Setting a standard for pharmaceutical services, which ensures 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, registering pharmacy technicians 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.



FY 2007 Board Commissioners

President

Donald Taylor

Chain Drug Store Representative

Secretary

David Chason

Acute Care Hospital Representative

Treasurer

Michael Souranis

Independent Representative

Cynthia Anderson

Home Infusion/ Home Care

Margie Anne Bonnett

Consumer Representative

Lynette Bradley-Baker

At Large Representative

Harry Finke, Jr.

Independent Representative

Lenna Israbian-Jamgochian

Acute Care Hospital Representative

Alland Leandre

Consumer Representative

Mayer Handelman

Long Term Care Representative

Rodney H. Taylor

At Large Representative

Reid Zimmer

Acute Care Hospital

TABLE OF CONTENTS

<u>SECTION</u>	<u>PAGE</u>
President’s Message	4
Executive Director’s Report	6
Administration and Public Support Unit Report	8
• Public Information and Education	10
Licensing Unit Report	13
Pharmacist Compliance Unit Report	16
Legislation/ Regulation Report	18
• Task Force Reports	22
Management and Information Systems Report	23

PRESIDENT'S MESSAGE



Fiscal Year 2007 was truly a year of transition for the Board of Pharmacy. The Board worked diligently to complete the many projects and regulations initiated in prior years and to fulfill legislature mandates.

First, the Board has now adapted to its new office space on the 1st floor of the Patterson Avenue building. All filing cabinets are now in their new locations, and the staff is able to work more efficiently. There were some computers issues throughout the year, but the staff was able to work around those issues until new servers and new software could be installed. The Board's contract with Towson to provide new databases for the Board's Units is in its final stages, and the Board is eagerly awaiting the first of the year and using the improved databases. The new databases will provide integration of information and will simplify operations.

Second, the Board lost a lot of experience as the three commissioners with the most Board experience ended their terms. The Board certainly wants to thank Jeanne Furman, Mark Levi, and Joe DeMino for their dedication and hard work. Their combined experience and willingness to volunteer for special assignments will certainly be missed. Their replacements, Reid Zimmer, Lynette Bradley-Baker, and Lenna Israbian-Jamgochian are well qualified, but have a high standard to follow. In terms of Board experience, this is now the youngest Board of Pharmacy, but certainly has the dedicated and qualified Commissioners and trained staff to continue the high standards set by the previous Boards of Pharmacy.

Third, the Board was able to hire a Compliance Officer to oversee the Disciplinary Unit. This is a position that is extremely important to the overall functioning of the Board's duty to protect the health and welfare of the citizens of Maryland. The position, with the exception of a few months, has been empty for approximately 3 years. This has placed a strain on the Board's staff and the entire Board welcomes the new Compliance Officer. During the last year, the Board also hired a Coordinator of Special Programs to oversee another of the Board's new initiatives, the tracking and oversight of all cases under Board Orders.

Fourth, along with the addition of those two important positions, the Board has been preparing for the transition from the Division of Drug Control doing pharmacy inspections to the Board's Pharmacy Inspection Unit. This five person units will be tasked with doing annual pharmacy inspections, as well as performing investigative inspections. In preparation for this transition, the Board has been working to finalize new inspections forms for Community, Hospital, Long-Term Care, Assisted Living, and Nuclear pharmacies. With the implementation of the new Board unit and the new inspection forms, every pharmacy in Maryland should now be inspected annually, and use of the new forms should help to streamline inspections and keep interruptions to the pharmacies to a minimum.

Fifth, the Board worked on many new laws and regulations: a.) Drug Therapy Management finally got off the ground and is working well. The Board is looking forward to the results of the program study being conducted by the University of Maryland. b.) The Drug Repository Program was also finalized and the Board has voted to provide a start-up grant of \$25,000 to help get this important program started. So far, the Board has only received one application for a Repository and one application for a Drop-Off site. With more publicity and the help of our stakeholders, the Board is hopeful that this program will be a success. c.) Pharmacist administration of the flu vaccine has been a huge success with 137 pharmacists enrolled and 10,452 flu shots administered. d.) The Wholesaler Distribution regulations are in draft form and should be approved and in effect by the first of the upcoming year.

Sixth, the long awaited Technician Registration regulations are in their final comment period, and the Board is looking forward to their implementation. Requiring pharmacy technicians to have a certain level of education and experience certainly enhances the safety of the Maryland citizenry. Registration of technicians will also allow the Board to finally have some control over previously unregulated pharmacy personnel.

Seventh, the Board has been very actively working with DHMH and the top positions in the Maryland Office of Emergency Preparedness to provide input and suggestions from the pharmacists' perspective regarding planning for protecting the citizens of Maryland and adjacent areas in the event of an emergency situation. The Board is also working on the finalization of its own COOP plan to ensure that if an emergency situation arises, the Board will have backup plans so that it will be able to continue to operate efficiently.

In closing, Fiscal Year 2007 has certainly been one of the busiest years the Board has experienced. The Board is continuing to work to make the transitions as smooth as possible, and to fulfill its mission of protecting Maryland's pharmacy patients and to ensure quality health care for all Maryland citizens.



MESSAGE FROM THE EXECUTIVE DIRECTOR



Fiscal Year 2007 was a very challenging but active period in the life of the Board. Beginning with the move from the third to the first floor in the summer of 2006, the Board and staff members took off running.

In addition to the January 2007 Open House, the Board and Division of Drug Control representatives began meeting in January to develop plans to transition annual inspection responsibilities from the Division of Drug Control to the Board. That endeavor was very successful and the Board anticipates assuming inspection responsibilities some time in FY 2008.

Various Board committees engaged in reviewing and updating the community and hospital inspection forms in FY 2007, while others developed new inspection forms for use when inspecting long-term care and sterile compounding pharmacies. Those inspection forms will be implemented in 2008 and posted on the Board web site. Development of the system for electronically recording inspection reports for all of the new and revised forms was also initiated in 2007 and is planned to implementation sometime in 2008.

Early during the 2007 Legislative Session the Board sponsored educational presentations before House and Senate subcommittees featuring Katherine Eban, author of *Dangerous Doses*. She discussed the problem of counterfeit drugs entering the legal drug distribution chain and described what other states had done to address it. Those presentations led to the passage of significantly strengthened statutory language for drug distribution by wholesale distributors in Maryland. Final regulations for that statute will be adopted in 2008.

The Board had anticipated final adoption of the Pharmacy Technician regulations during FY 2007. However, their adoption was delayed by the Administrative, Executive and Legislative Review Committee (AELR) in order to address concerns submitted during the comment period. In addition to the planned registration of pharmacy technicians, several other initiatives that were begun in 2007 are anticipated to *take off* in 2008. They include inspection of pharmacies under the new sterile pharmaceutical compounding regulations, Drug Therapy Management, Administration of Influenza Vaccines and Prescription Drug Repositories.

The Board also began direct monitoring of pharmacists under public orders in 2007. Previously, the Pharmacist Education and Assistance Committee (PEAC) performed monitoring and rehabilitation referral services on behalf of the Board. Now that Board procedures and staff are firmly in place, the Board anticipates better assurance of patient safety as well as long-term, successful rehabilitation outcomes for involved pharmacists. The Board continues to fund PEAC to monitor, mentor and make treatment referrals for self-referred pharmacists.

After failure over the past two years to attract *and retain* appropriate pharmacist staff to lead the Compliance Unit, the Board recruited a very competent Manager in the third quarter of FY 2007. Unfortunately, the candidate resigned within three months and the Board has continued to struggle with monitoring pharmacists, pharmacies and distributors absent the on-site oversight of a pharmacist compliance officer. The Board and staff have identified working with the Department in recruiting and retaining a Pharmacist Compliance Officer as one of its key goals in FY 2008. This is an important goal because in addition to the assumption of inspection responsibilities, compliance oversight will expand to include enforcement of new, strengthened wholesale distributor requirements and the final adopted pharmacy technician regulations in FY 2008.

Despite some setbacks, FY 2007 was a fruitful year. Board members are to be congratulated for the many hours spent in Board, committee and other special meetings to develop and carry out FY 2007 initiatives. Board managers and their staffs are acknowledged and thanked for their diligent and painstaking efforts to usher in new practice requirements and for creating systems to operationalize the many Board decisions. Their efforts promise to yield successful implementation of initiatives in FY 2008. Last but not least, thanks to the community, including consumers, pharmacists, permit holders, legislators and federal and state agents all of those who made the Board's progress possible in 2007. Their input, expertise and encouragement helped the Board to continue to meet its mission to promote quality pharmacy health care while insuring patient safety for Maryland citizens.

FY 2007 BOARD STAFF MEMBERS

<p style="text-align: center;"><u>Executive</u></p> <p style="text-align: center;">Executive Director LaVerne G. Naesea</p> <p style="text-align: center;">Executive Assistant Alicia Carter</p> <p style="text-align: center;"><u>Administration and Public Support Unit (APS)</u></p> <p style="text-align: center;">APS Manager Patricia Gaither</p> <p style="text-align: center;">Public Information and Education Officer/ Emergency Preparedness Coordinator Summar J. Goodman</p> <p style="text-align: center;">Administrative Assistant Sandra Hines</p> <p style="text-align: center;">Receptionist Briget Melvin</p> <p style="text-align: center;"><u>Legislation/ Regulations Unit</u></p> <p style="text-align: center;">Legislation/Regulations Manager Anna D. Jeffers</p>	<p style="text-align: center;"><u>Licensing Unit</u></p> <p style="text-align: center;">Licensing Manager Shirley Costley</p> <p style="text-align: center;">Licensing Specialist Doris James</p> <p style="text-align: center;">Licensing Renewal Clerk Keisha Wise</p> <p style="text-align: center;">Licensing Analyst Fannie Yorkman</p> <p style="text-align: center;">Licensing Secretary Laurie Cohen</p> <p style="text-align: center;"><u>Management and Information Systems (MIS)</u></p> <p style="text-align: center;">MIS Manager Tamarra Banks</p> <p style="text-align: center;">Database Officer Michelle Hsu</p> <p style="text-align: center;">Computer Specialist Matthew Smith and Duane Truesdale</p>	<p style="text-align: center;"><u>Pharmacist Compliance Unit</u></p> <p style="text-align: center;">Compliance Manager Bonnie Rosiak</p> <p style="text-align: center;">Compliance Investigator Colin Eversley</p> <p style="text-align: center;">Compliance Specialist Vanessa Thomas-Grey</p> <p style="text-align: center;"><u>Board Counsel</u> Linda Bethman</p>
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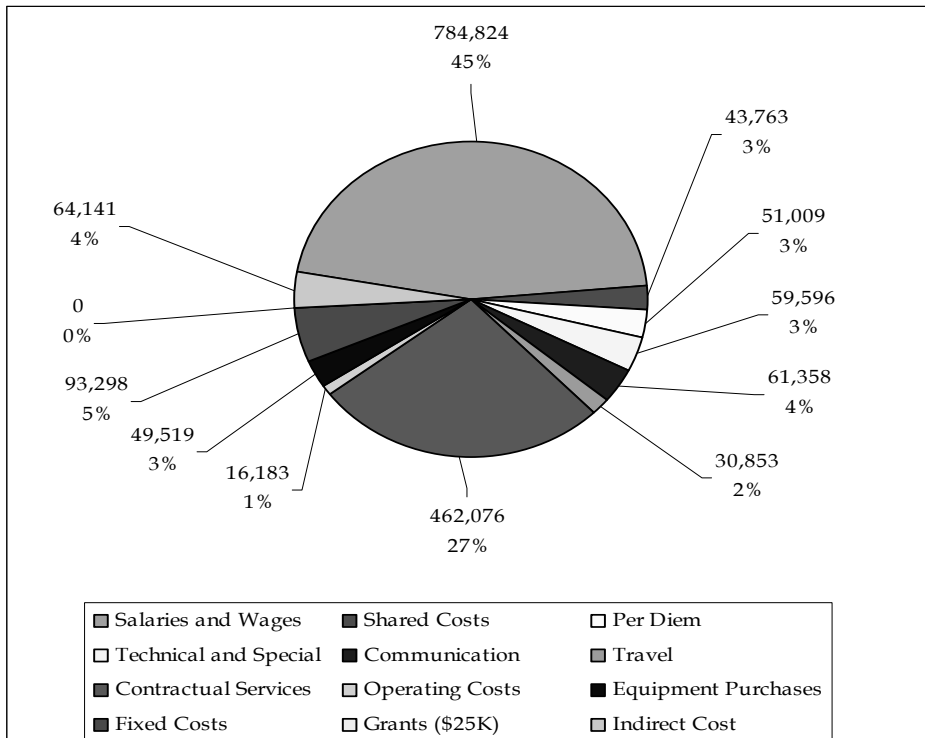
ADMINISTRATION AND PUBLIC SUPPORT UNIT

The Administration and Public Support Unit (APS) is responsible for managing the fiscal, personnel contracting and public information and education functions at the Board. The Board derives its revenue through payments for license, permits and other applicable fees. Expenditures are made based on submission of an annual budget request that must be approved by the Secretary for the Department of Health and Mental Hygiene, the Governor's office and subsequently by the State Legislature. Included in the Budget Request are requests for personnel and funding for new program areas.

Carryover from Fiscal Year 06	1,090,370
Collections FY 2007	1,614,939
Pharmacist Examination	36,500
Pharmacist Renewals	536,758
Reciprocity	20,880
Reinstatement	25,979
Pharmacy New/Renewals	468,550
Distributor New/Renewals	475,050
Other	51,222
TOTAL REVENUE	2,705,309

FY 2007 Revenue

➤ Total revenue collection of \$1,614,939 was 3.7 % higher than in fiscal year 2006, largely due to increased numbers of pharmacist renewals and permit holders.



FY 2007 Expenditures

➤ Board expenditures were 31% more than FY 2006 due to increases in permanent employee positions and contractual services.

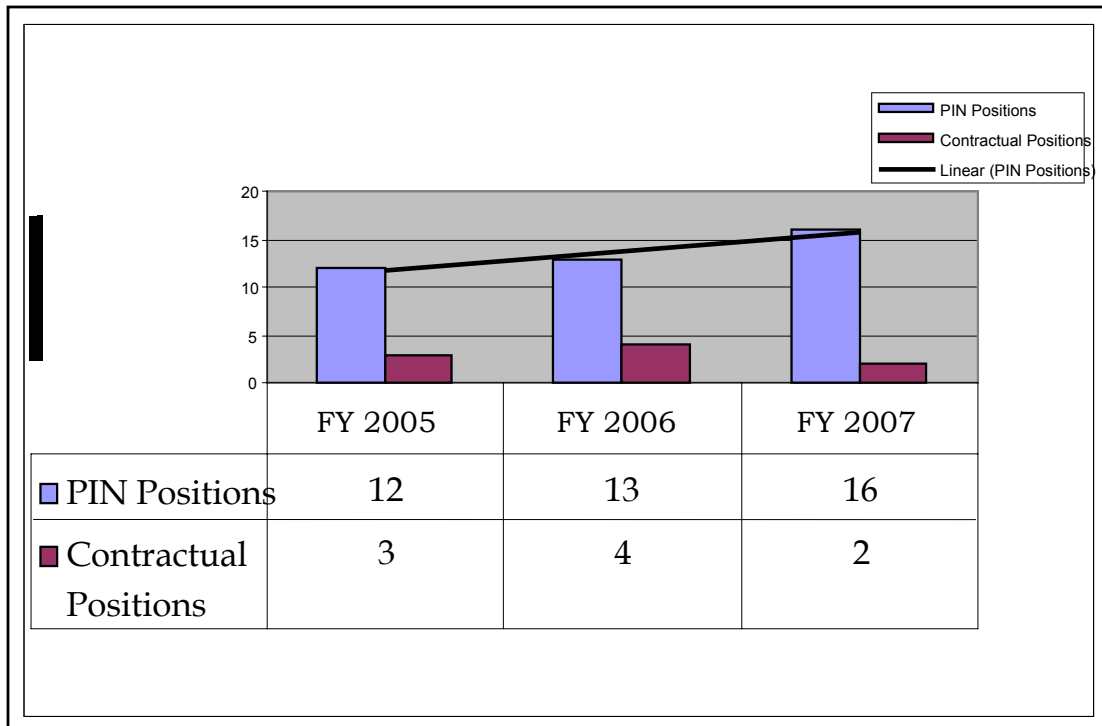
Expenses for additional furniture and equipment related to the Board's renovation and expansion in FY 2006 also increased FY 2007 expenditures.

Expenditure Detail

Salaries and Wages	\$784,824
Shared Costs	43,763
Per Diem	51,009
Technical and Special	59,596
Communication	61,358
Travel	30,853
Contractual Services	462,076
Operating Costs	16,183
Equipment Purchases	49,519
Fixed Costs	93,298
Grants (\$25K)	0
Indirect Cost	64,141
TOTAL EXPENDITURES	\$1,716,620

Personnel

In fiscal 2007 the Maryland Legislature approved three contractual staff positions for conversion to permanent (PIN) positions.



The three PIN positions, Administrative Specialist II (Licensing Specialist), Administrative Specialist III and Office Secretary III (Executive Secretary), were added to support the new Pharmacy Technician program and expected increase in compliance issues related to that program. At the end of FY 2007, the Board had sixteen (16) PIN positions and two (2) contractual positions. Ninety (90) percent of the positions were filled at all times during fiscal year 2007.

Contractual Agreements

The Board continued its contractual agreement with Towson University for development of a new Database and Disaster Recovery during some of FY 2007. The agreement is expected to bring more efficiency to the Board's data collection and sharing operations. A continuation contract with the University of Maryland to evaluation the outcomes of Drug Therapy Management agreement was also initiated in FY 2007 in order to measure the success of the Drug Therapy Management project. The Board also modified the long-standing Pharmacist Rehabilitation Services contract in FY 2007. The change reduced services provided by the contractor from support to impair practitioners under Board orders and practitioners who voluntarily (and anonymously) entered into treatment, to the provision of services to voluntary practitioners only.

Public Information and Education

The Board's Public Information and Education component of the APS Unit is responsible for providing information and education about the Board to the Public and Pharmacist Community. Training and educational activities have included coordinating emergency preparedness activities. In carrying out this responsibility the Public Information and Education Officer is responsible for year-round recruitment and training of volunteer pharmacists. Additionally, the Board's quarterly newsletter, annual reports and several brochures are other informational tools produced and disseminated to ensure that practitioners and consumers are informed of changes in legal requirements and board procedures and recommended safety measures.

The Public Information and Education component coordinates responses to all requests made to the Board under the Public Information Act. The Public Information Act allows certain Board information to be release regarding licensees and Board activities. The Public Information and Education Officer is responsible for ensuring that the information that is released does not violate state and federal confidentiality rules. This role is extended to coordinating responses to pharmacy related inquiries made to the Governor and Secretary for the Department of Health and Mental Hygiene. The Board is frequently asked to prepare written responses (controlled correspondence) on their behalf to constituents.

Two other, as important responsibilities for this component of the APS Unit include monitoring pharmacy-related news and coordinating media responses; and, planning and staffing events to ensure the Board of Pharmacy's presence around the state. Both of these functions are necessary to encourage patient safety, keep the communities informed of how the Board works to protect Maryland's consumers, and ensure continuous communications between the Board, its licensees, other governmental agencies, and the public.

FY 2007 Public Information and Education Activities

Open House	Board's Open House in new headquarters January 2007.
Annual Report	Coordinated production and design of 2007 Annual Report.
Consumer Brochures	Updated Board's consumer brochures.
Consumer Best Buy Drugs	Coordinated partnership with Consumer Best Buy Drugs to market and promote both the Board's services and the Consumer Reports website www.crbestbuydrugs.org to consumers.
Donation Drives	Coordinated with partners in collection of donations for consumer and pharmacist events.
2007 Flower Mart	The Board's and its partners was awarded 1 st place in the booth decorating contest for the Wellness Village. The Board partnered with the Maryland Pharmacy Coalition and University of Maryland Pharmacy School Students in handing out health brochures and promotional items at and testing consumer's blood pressure. Surveys related to consumers risk for diabetes were also taken. Over 950 consumers were greeted at the booth from 9 a.m. until 5 p.m.
Maryland State Fair	Disseminated health brochures and promotional items at the Department of Mental Health and Hygiene booth.
Public Information Requests	Responded to 200 requests from the public for copies of Public Orders issued for specific pharmacists/ pharmacies following the Board's decision on various disciplinary issues.
Board of Pharmacy Newsletter	Designed and published 4 quarterly newsletters. The Board's newsletter is considered an official method of notification to pharmacists and pharmacies.
Website	Consumer Information pertinent to Maryland community was routinely updated on the Board of Pharmacy's website.
Mailing Campaigns	Coordinated mass mailing campaigns to promote new programs at the Board.
Maryland Professional Volunteer Corp Committee	Represented Board at monthly meetings with the Maryland Professional Volunteer Corps Committee to plan and execute a collaborative drills and trainings for all medical professional volunteers.
Maryland Health Professional Volunteer Corps Newsletter	Prepared articles on the Pharmacy Board's Emergency Preparedness activities.
NABP Annual Meeting	Provided planning support for the National Association of Boards of Pharmacy's 104 th Annual Meeting scheduled for May 2008 at the Marriott Waterfront Hotel in Baltimore, MD.

Control Letters	Coordinated Board responses to constituent letters on behalf of the Governor and DHMH Secretary (Control Letters).
Press Kit	Created and disseminated Maryland Board of Pharmacy Press Kits
Volunteers	Perpetual Recruitment of pharmacist volunteers for the Emergency Preparedness Program
Staff Recognition	Coordinate internal recognition activities (e.g., staff /board member birthdays, family losses, births, etc.).
Maryland Pharmacists Association	Staffed booth at the Maryland Pharmacists Association in Ocean City.
American Society of Consultant Pharmacists	Staffed booth at the 15th Annual MD-ASCP Mid-Atlantic Conference in August of 2007.
Media	Responded to television and print media interviews to include: <ul style="list-style-type: none"> ➤ Channel 11: Safety of Expired Medications, November 2007. ➤ Capital News Service: Article “Pharmacy Board Asks for More Control to Beef Up Inspections” December 2006; and Article “MD. Pharmacy Inspections Lag; Board Blames Bureaucracy, Lack of Funds” December 2007 ➤ ABC 20/20 - News Report “Medication Errors” March 2007

Next Year At A Glance

The Board projects \$1,790,590 in revenue for FY 2008 as a result of the new Pharmacy Technician registration. This amount represents approximately an 11% increase over FY 2007. While anticipating the increase in revenue the Board also projects increase spending related to the Board’s assumption of responsibility for performing annual inspections of pharmacies (this responsibility was previously performed by the Labs Administration’s Division of Drug Control). The new responsibility requires the recruitment of six additional staff persons.

The Board expects to heighten visibility throughout the state via its public information and education program and emergency preparedness activities. The Board of Pharmacy will also support the National Association of Boards of Pharmacy in hosting its Annual Meeting in Baltimore, Maryland in mid-Spring 2008.

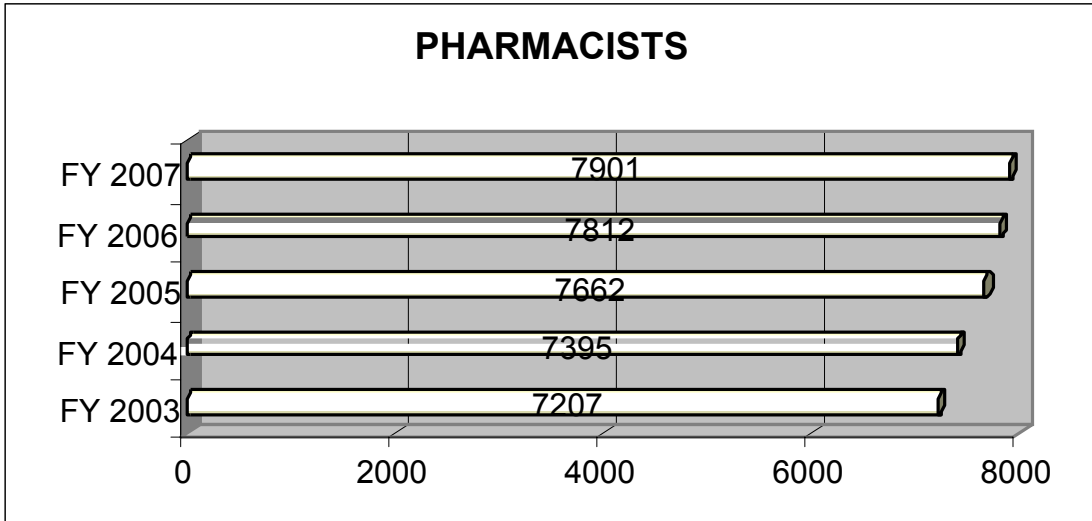
LICENSING UNIT

The Licensing Unit plays a major role in the Board's mission to provide safe, high quality patient services by ensuring that all required standards of practice, education and continuing education have been met before licenses and permits are issued. The Licensing Unit is responsible for all activities related to the issuance of new and renewal Maryland practice licenses to qualified pharmacists and issuing Maryland operating permits to qualified pharmacy owners and pharmaceutical distributors. In addition to processing and issuing licenses and permits to pharmacists, pharmacy owners and pharmaceutical distributors, the Licensing Unit processes applications for the Drug Therapy Management Program, The Drug Repository Program and registers qualified pharmacists to administer Influenza Vaccinations. Also, with the re-introduction and passing of the bill in 2006 requiring the Certification of Pharmacy Technicians, the Licensing Unit will operationalize registration of pharmacy technicians once the regulations for the program are promulgated. The Unit is required to operate at a very fast pace, usually responding to the highest volume of calls and processing the greatest number of correspondences daily at the Board.

Pharmacists Activities

Maryland pharmacists renew licenses every two years during their birth month. This year the Board changed the way that pharmacists are notified of time to renew. The old process of stuffing envelopes with notices and an application was eliminated, instead a pharmacist now receives a brightly colored yellow postcard as a reminder that his or her current license will soon expire. The postcard lists the license expiration date and a choice of renewal options. The pharmacists may choose to renew online, or download an application from the Boards' website, or request by phone, fax or email a paper application be mailed to them via US postal service. The On-line renewal system has proven to be fast, effective, and the number one choice for renewing pharmacists. The Board has seen an increase in the usage of the online renewal system for pharmacist renewals from 34% in FY 2005 to 70 % in FY 2007.

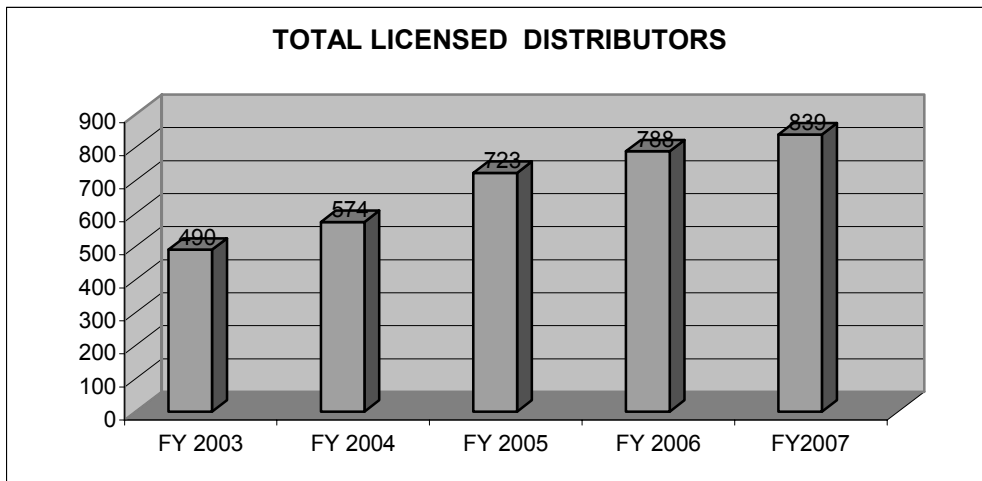
The number of Maryland licensed pharmacists has increased approximately 10% over the last 5 years. There were 401 new licenses issued this fiscal year bringing the total number of pharmacists licensed at the end of FY 2007 to 7901. Of this number, 5,437 pharmacists are located in state and 2,464 out of state.



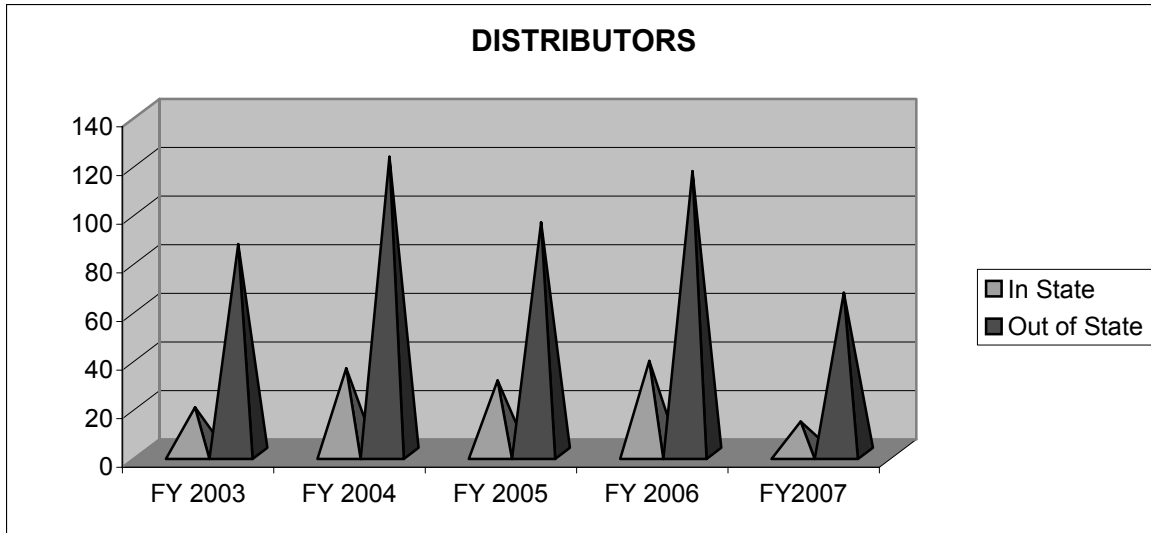
Establishment Activities

All establishment (pharmacies & distributors) permits expire annually on December 31st. The establishment on-line renewal system is available from mid October to December 31 each year. Of 2,315 renewing establishments, 1,235 renewed on-line in FY 2007. The Unit's goal for on-line renewal is 100% participation.

The Board has seen an increase in licensure of new establishments especially within the last three years. The most noticeable increase has been with pharmaceutical distributors.

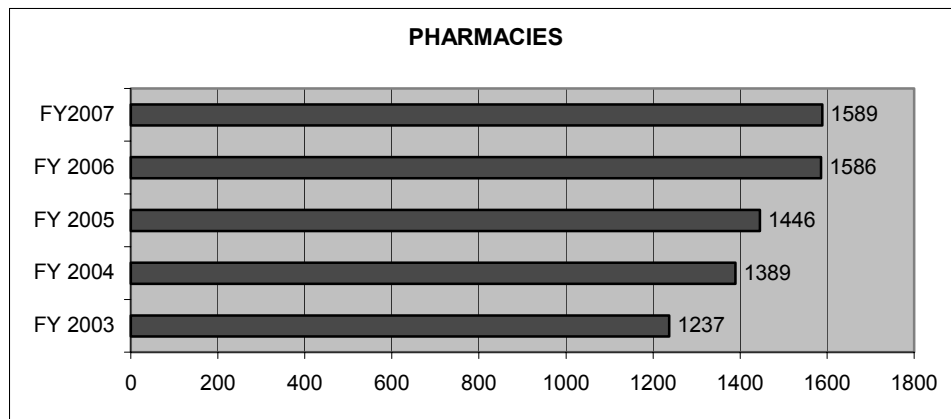


The greatest increase occurred between fiscal years 2004 and 2005, changing the total number of licensed distributors from 574 to 723.



The total number of new licensed distributors at the end of FY 2007 was 839; of that number, 640 are located out of state.

The number of new pharmacies this year was slightly less than in previous year. The total number of pharmacy permit holders at the end of FY 2007 was 1,589.



Other Certification & Registration Activities

The Administration of Influenza Vaccination program allows qualified pharmacists to administer the influenza vaccine (intramuscularly and intranasally) to adults, eighteen years or older, within the scope of a Maryland physician-established protocol. Increasing awareness and offering tailored immunization programs in more convenient and accessible pharmacy settings have led to the successful provision and administration of the influenza vaccine by pharmacists in Maryland. The Board recently conducted a survey of the total 137 pharmacists certified to administer influenza vaccines in Maryland. Of the 87 numbered responses received 60 pharmacists indicated that they had administered a total of 10,452 vaccinations

The Board received and approved three Drug Therapy Management physicians-pharmacist agreements and protocols in FY 2007. Two of the protocols (Tobacco Use and

Dependence; and Metabolic Syndrome) were submitted by a Baltimore Medical Center. The third protocol, Metabolic Syndrome was submitted by an independent pharmacy.

Registration of Pharmacy Technicians did not begin in FY 2007 as anticipated. The proposed regulations for the Pharmacy Technician Registration were published in May 2007. Due to comments received, the Board is considering re-proposing the regulations. This will be discussed at a public meeting during the beginning of FY 2008. Draft policies, procedures and applications have been developed in preparation for implementation of the program.

The Licensing Unit assumed another new program in FY 2007-- The Maryland Prescription Drug Repository Program. The Program was established to allow Board approved repositories and/or drop-off sites to accept donated prescription drugs and medical supplies for the purpose of dispensing the donated drugs to needy individuals. The Board received five applications, all of which are pending approval.

Next Year At A Glance

The Maryland Board of Pharmacy anticipates that the proposed Pharmacy Technician program will be well underway in fiscal year 2008 and anticipates that all pharmacy technicians will become registered or grandfathered as of July 2008. The wholesale Distributor program is expected to follow depending on legislation.

PHARMACY COMPLIANCE UNIT

The Compliance Officer is the only pharmacist staff member at the Board. The unit consists of three other members including two Compliance Investigators and a Compliance Coordinator. One investigator handles complaints regarding pharmacists, and the other handles complaints and inspection infractions regarding establishments. The Compliance Coordinator tracks and monitors all cases under Board orders.

The Compliance Unit receives and investigates all complaints from consumers and other entities, e.g. F.D.A., D.E.A. and various law enforcement agencies.

Written Complaints

Compliance investigators process all complaints received on a Board created form. Complaints can be submitted through four methods: mailed-in hard copy, telephoned interview, walk in drop off or from the Board's on-line system.

Once a complaint is received, the investigators determine the appropriateness of the Board to receive the complaint. If the complaint is appropriate for the Board to address rather than another agency or entity, all pertinent information is entered into the Board's compliance database. The investigators notify the complainants of receipt of the complaint, and request the pharmacist or pharmacy to respond to complaint in writing. All information is collected, summarized, and then presented to the Board's Disciplinary Committee which

reviews and makes recommended action to the full Board. The Board then votes on the actions to be pursued.

The Board may dismiss the complaints if it is not substantiated. It may also take informal actions that could include, sending letters of education or admonishment to the involved parties (pharmacists and/or pharmacies), and/or requiring a pharmacist to sign an agreement to take continuing education credits related to the charges in the complaint. If the Board votes to issue formal charges, the Compliance Unit may interview witnesses and collect additional investigational information before referring to the Office of the Attorney General for prosecution. Formal actions, if supported following a hearing or settlement agreement may result in dismissal of cases, orders of probation, suspension or revocation, and or imposing of fines.

FY 2007-129 Complaints

<i>Complaint Submission Method</i>	<i>Number</i>
Walk-in	12
Mail	44
Phone Interview	17
On-line	45
Not Identified	
Total Complaints	129

Professional Incompetence	22
Dispensing Errors	56
Non-jurisdiction	17
Customer Service	27
Other/No Defined	7
Total Complaints	129

Verbal Inquiries/Questions

The pharmacy Compliance Unit processed 2,800 calls in 2007 related to pharmacy complaints (verbal), technical or regulatory questions, and pharmacy technician certification. These questions originate from many sources: from federal agencies such as the Food and Drug Administration, to local Police Departments, as well as private agencies. When appropriate some calls are referred to other State Boards.

Our Regulator Manager works in conjunction with the Pharmacy Compliance Unit to provide expertise regarding Maryland law, and to educate the consumer on their rights. However, the majority of the verbal complaints are from consumers regarding many topics, including cost or billing issues, generic drugs, medication errors, and unclear directions. Complaints concerning the prices of prescriptions are referred to the Consumer Protection Division of the Office of Attorney General.

Next Year At A Glance

The Board of Pharmacy will begin steps to implement the compliance procedures for registered pharmacy technicians. It will conclude discussions with the Labs Administration and Division of Drug Control in order to assume responsibility for establishment inspections, including revision of all pharmacy inspection forms. Also the Board will begin

developing plans for inspecting wholesale distributors under the recently passed statute. These new areas of responsibility will require a fully staffed unit, including additional staff members to perform inspection and investigate the anticipated significant increase in complaints, related to pharmacy technicians.

The unit's growth will be addressed through a planned reorganization process, including installation of a new disciplinary database, recruitment of four pharmacy inspectors and a dedicated unit secretary, and a pharmacist inspector. Future planned initiatives evidence the Board of Pharmacy's continued effort to meet its mission of protecting Maryland consumers by encouraging the delivery of high quality services throughout the profession of pharmacy.

LEGISLATIVE/REGULATIONS UNIT

Legislative/Regulations Unit Overview

The Legislative and Regulations Unit (the "Unit") plays an active role in supporting the Board by evaluating, developing and drafting Board-directed legislative and regulatory proposals that protect the public and promote quality health care in the pharmaceutical profession. The Unit is also responsible for supporting the Board and its various committees in the areas of legislative review, health policy research, regulatory evaluation and a variety of special assignments. The committees staffed by this Unit are Pharmacy Practice, Long-Term Care, and Legislative. Special sub-committee and task forces staffed during 2007 included the Pharmacy Technician Regulatory Subcommittee, Wholesale Distributor's Regulatory Subcommittee and the Wholesale Distributor SB 759 Workgroup.

Throughout the year the Unit responds to phone calls and email inquiries from the public, applicants, licensees, permit holders, Maryland agencies, pharmaceutical companies, legislators, other state agencies, other state boards, attorneys throughout the country and students. The Unit makes every effort to respond in detail, addressing all the issues, in the order in which the inquiries were received. Questions posed to the Unit that require Board interpretation or involve controversial issues are presented at the monthly Practice Committee Meeting. Depending on the Practice Committee's recommendations, some of the responses are brought to the public Board Meetings for approval. During Fiscal Year 2007 the Unit responded to 1,133 phone calls and provided written responses to 398 email inquiries.

Legislative Initiatives

During the Maryland Legislative Session, the Unit reviews and tracks legislation, prepares written position papers, determines fiscal impacts of bills, testifies before legislative committees and meets with legislators, stakeholders and subcommittees regularly to insure that the Board's legislative initiatives are successful in Annapolis. The Unit is most visible during the session as it strives to effectively communicate Board policies to health professional boards, local and national health associations and the regulated industry.

The Unit presented 43 bills out of approximately 2,480 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 43 bills. Below is provided a chart of the 21 bills and the results:

Bill #	Bill Name	Result
SB 47	State Government – Administrative Procedure Act – Scope of Judicial Review	FAILED
HB 237	State Government – Administrative Procedure Act – Scope of Judicial Review	FAILED
HB 100	Health Occupations – Cultural Competency Workgroup	WITHDRAWN
HB 123	Consumer Protection – Personal Information Protection Act	FAILED
SB 904	Consumer Protection – Personal Information Protection Act	FAILED
HB 141	State Board of Pharmacy - Sending Renewal Notices by Electronic Means	PASSED
HB 210	Consumer Protection - Sale or Distribution of Personal Information – Limitations	WITHDRAWN
HB 236	Health Occupations - Registered Nurses – Dispensing Methadone	PASSED
SB 266	Prescription Privacy Act	FAILED
SB 349	Disease Prevention - Sexually Transmitted Diseases - Expedited Partner Therapy	PASSED
HB 769	Disease Prevention - Sexually Transmitted Diseases - Expedited Partner Therapy	PASSED
SB 670	Prescription Drugs – Canadian Mail Order Plan	FAILED
SB 677	Pharmacy Benefit Managers Regulation Act	FAILED
HB 734	Pharmacy Benefit Managers Regulation Act	FAILED
HB 736	State Board of Pharmacy - Job Classifications and Grades for Staff	FAILED
SB 1013	State Board of Pharmacy - Job Classifications and Grades for Staff	FAILED
HB 820	Health Occupation Boards - Determination of Job Classifications and Grades for Staff	FAILED
SB 939	Controlled Dangerous Substances – Dextromethorphan Products	FAILED
HB 1030	Wholesale Distributor Permitting and Prescription Drug Integrity Act	PASSED
SB 759	Wholesale Distributor Permitting and Prescription Drug Integrity Act	PASSED
HB 1169	Health Programs - Diabetes - The Maryland P3 Program	WITHDRAWN

Summaries of major bills from the 2007 Legislative Session are provided below.

HB 100 Health Occupations – Cultural Competency Workgroup

This bill required the Department of Health and Mental Hygiene (DHMH) to convene a workgroup on cultural competency to make recommendations and to review certain curriculum modules. The legislation also required each health occupations board to develop recommendations for requiring individuals licensed by the health occupations boards to receive instruction in cultural competency. Recognizing the importance of encouraging cultural competency the Board voted at its January 2007 Public Board meeting to approve the following motions:

- 1) That up to 3 CEU credits in cultural competency and/or health care disparity provided by entities recognized by the Office of Minority Health and Health

Disparities is accepted if submitted by renewing pharmacists and pharmacy technicians.

- 2) That at least twice annually, articles received from the Office of Minority Health and Health Disparities are published in the Board of Pharmacy Newsletter.

The Board submitted a Letter of Information providing an update on the measures being taken by the Board to encourage and facilitate cultural competency education. This legislation was withdrawn.

HB 141 State Board of Pharmacy - Sending Renewal Notices by Electronic Means

This bill allows the Board to send renewal notices by electronic means to licensed pharmacists, pharmacy and distribution permit holders, and registered pharmacy technicians. Notification by electronic means will be an optional election by pharmacists, pharmacy and distribution permit holders, and registered pharmacy technicians on their initial applications or on their renewal applications. The bill passed.

HB 236 Health Occupations - Registered Nurses – Dispensing Methadone

This bill authorizes registered nurses to dispense methadone in a methadone clinic licensed by DHMH in accordance with regulations developed and adopted by the Board of Nursing and the Board. The Board of Nursing and the Board are in agreement that both registered nurses and licensed practical nurses should be able to dispense methadone at methadone clinics licensed by the DHMH. The bill passed.

HB 1030/SB 759 Wholesale Distributor Permitting and Prescription Drug Integrity Act

This bill as originally written provided the Board the authority to adopt regulations that addressed three (3) additional requirements to obtain a wholesale distributor's permit in Maryland. Those three requirements are: 1) the posting of a surety bond; 2) routine inspections by the Board or its agent; and 3) pedigrees for each distribution of a prescription drug distributed outside the normal distribution chain. During the session this legislation was revised through numerous meetings, negotiations and hearings to encompass detailed requirements for the licensure of wholesale distributors. The bill passed.

Regulatory Initiatives

The 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 - .33, revisions effective since July 1, 2006:

COMAR Citation	Title	Effective Date
Special Notice	Negative Formulary - The Department eliminated the policy that prohibits substitution of certain drugs, thereby removing six drugs from the Maryland Drug Formulary of Equivalent Drug Products.	November 1, 2006
10.34.33	Prescription Drug Repository Program	January 29, 2007

Maryland Board of Pharmacy Regulations, COMAR 10.34.01 - .34, currently in the amendment process:

COMAR Citation	Title	Proposal status
10.34.01	Reinstatement	Published May 11, 2007. Included in the Pharmacy Technician Proposal. Board anticipated to approve responses to pharmacy technician comments and to repropose at July 2007 Board Meeting
10.34.19	Parenteral/Sterile Enteral Compounding	Published January 19, 2007. Reproposed June 22, 2007. Notice of Final Action pending.
10.34.22	Licensing of Wholesale Prescription Drug or Device Distributors	The Wholesale Distributor SB 759 Workgroup is drafting and making recommendations for revisions to 10.34.22 pursuant to the Wholesale Distributor Permitting and Prescription Drug Integrity Act passed in 2007.
10.34.23	Pharmaceutical Services to Residents in Long-Term Care Facilities	Published August 6, 2004 and withdrawn December 23, 2005 by operation of law. Proposal revisions under consideration.
10.34.32	Pharmacist Administration of Influenza Vaccinations	Amendment to add fee for pharmacist administration and "live" CPR instruction. Published October 13, 2006; Reproposed March 30, 2007. Notice of Final Action published June 22, 2007.
10.34.34	Pharmacy Technicians	Published May 11, 2007. 11 comments received. Board anticipated to approve responses to the 11 comments and to repropose at July 2007 Board Meeting.

Summaries of regulatory changes that became effective in 2007 are provided below.

Special Notice: Maryland Drug Formulary of Equivalent Drug Products

The FDA has declared the following drugs to have generic equivalents. Therefore, they no longer need to continue as nonsubstitutable narrow therapeutic index drugs in Maryland. The drugs are Carbamazepine Oral Tablets 200 mg; Phenytoin Sodium Extended Oral Capsules 100 mg; Valproic acid; Theophylline extended release; Warfarin sodium; and Primidone.

10.34.33 Prescription Drug Repository Program

A Task Force of stakeholders, who made recommendations to the General Assembly regarding the Prescription Drug Repository Program, remained together to make recommendations for the proposed regulations. The Task Force made recommendations concerning the nature and functions of a Repository and Drop-Off site. Under the Task Force plan, only those drugs donated in original unopened packaging would be accepted at designated Repositories or Drop-off sites and would be eligible for re-dispensing. The standards and procedures for dispensing, shipping, disposing and safely storing donated items shall be in accordance with State and federal laws and regulations. Repositories shall maintain separate inventories for donated items; store donated items in a secure location; maintain separate prescription files for patients receiving donated items; and submit annual reports on its activities to the Board. Patient eligibility will be determined by the patient's health care practitioner with prescribing authority based on the financial need of the patient and Maryland residency. Recipients will be required to sign a Board approved recipient form

to confirm that the recipient understands the donated items have been donated and that entities involved in the program are immune from liability.

Task Force Reports

Prescription Drug Repository Program Task Force

SB 441 – Task Force on the Establishment of a Prescription Drug Repository Program was passed to study and make recommendations regarding the establishment of a Prescription Drug Repository Program in Maryland. The Maryland Board of Pharmacy staffed the Task Force for the Department of Health and Mental Hygiene (the “Department”). The Task Force submitted a First Interim Report, for January 1, 2006 to comply with SB 441. The Task Force then submitted a Second Interim Report on February 28, 2006 that included recommendations that could be considered for use in related proposals for legislation during the 2006 Legislative Session. The Second Interim Report was used as a basis for HB 1689 and SB 1059, Prescription Drug Repository Program. Both bills passed and SB 1059 was signed into law on May 6, 2006 as Chapter 287.

The Task Force met several times during and after the 2006 Legislative Session to draft regulations for promulgation by the Maryland Board of Pharmacy. The proposed regulations were based on the recommendations set forth in the First and Second Interim Reports. The intent of the regulations recommended by the Task Force was to set forth the structure of the Drug Repository Program and add details as required by SB 1059, Prescription Drug Repository Program. The Maryland Board of Pharmacy reviewed the recommendations and voted to begin the promulgation process for the proposed regulations in July 2006. The regulations became effective January 29, 2007. The Prescription Drug Repository Program Task Force completed its tasks and no longer meets.

Wholesale Distributor SB 759 Workgroup

The Wholesale Distributor Permitting and Prescription Drug Integrity Act passed during the 2007 Maryland Legislative Session. The Act requires that the Board of Pharmacy adopt regulations to implement the Act by January 1, 2008. Additionally the Act requires that the Board convene a workgroup to recommend a target date for implementation of electronic track and trace pedigree technology. The Workgroup shall: (1) survey the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain; (2) determine when electronic track and trace pedigree technology will be universally available across the entire prescription pharmaceutical supply chain; and (3) based on its determination of the universal availability of electronic track and trace pedigree technology, make recommendations to the Board for a target date, no sooner than July 1, 2010, for implementation of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain.

Next Year At A Glance

The Board of Pharmacy will begin steps to implement the extension of the Drug Therapy Management Program for two additional years so that the study to assess the outcomes achieved by drug therapy management agreements could be completed. The Board also plans to complete the promulgation of the Pharmacy Technician Regulations.

Additional goals include staffing and following through with the SB 759 Wholesale Distributor Workgroup pursuant to SB 759, completing the promulgation of the Wholesale Distributor Regulations, continued monitoring of the Drug Therapy Management study and completion of the promulgation of sterile compounding regulations.

In summary, projected goals in FY 2008 include the revisions of the following regulations:

1. 10.34.25 Delivery of Prescriptions
3. 10.34.09 Fees
4. 10.34.32 Influenza Vaccinations
5. 10.34.28 Automated Medication Systems
6. 10.13.01 Dispensing of Prescription Drugs by a Licensee
7. Format of Prescription Transmission 10.34.20
8. Long Term Care
 - 1) Repackaging
 - 2) Prescription Writing
 - 3) Central processing or remote hosting
 - 4) Non-Sterile Compounding
 - 5) Expiration of drugs

Management and Information Services Unit

The 2007 Fiscal Year began with the Management & Information Services Unit operating without a Database Specialist. Through a Governor's Internship Program, MIS obtained a Help Desk Specialist for 3 months to work along side the MIS Unit manager to provide support for all the Board's information technology needs. The Help Desk position was invaluable to the continued operations of the Board without a Database Specialist. In February 2007, MIS welcomed a new Database Specialist, whose several years experience working with databases and online system software helped the MIS Unit keep pace with the many database upgrades required to keep pace with new program and unit initiatives. Specifically, the continued development of the Board's new in-house database system, which will feature real-time licensure verifications accessible by the public, and development of plans to combine some of the Board's existing 27 databases into one system to address the Board's licensure and compliance units' needs.

Online systems and the Internet are the wave of the future. Over two thirds of pharmacist licensees renewed on-line in FY07. The Board's pharmacist online renewal system has been in operation since 2003. The ease in accessibility for renewing on-line has save licensees time in receiving licenses.

During FY07 the Board web site had 100% "up time." Despite power outages at the Board or within the office building, the web site remained up and available to the public. The Board received 3,530 e-mails in FY 2007, which were generally responded to within 24 hours. All Board applications, including Emergency Preparedness volunteer forms are downloadable from the Board's web site. Also the MIS Unit continues to add links and features to the site to provide convenience to consumers and the pharmacy profession alike.

Next Year At A Glance

New legislative initiatives have created a greater need for the use of technology to accomplish each newly mandated task. With the regulation of Pharmacy Technicians, databases and tracking systems will need to be created. Nationwide, more emphasis is being placed upon verification of drug pedigrees that document the legitimate transfer of drugs from the manufacturer through the distribution chain to the pharmacy for final patient dispensing. MIS will need to incorporate new technology for use by Board staff to help verify drug pedigrees. Also, with the Board's assumption of direct responsibility for the pharmacy and distributor inspection processes, MIS plans to explore and implement use of the latest available technology for collecting inspection data and creating deficiency reports found during the inspection process.

MIS focus for FY 2008 will be on implementing these new process and to complete and the implement the Board's new in-house database system that will integrate licensee and permit holder data with disciplinary and fiscal data. Design and staffing challenges over the past year have complicated and delayed completion of this project which is now slated to be completed by the end of FY 2008.

In summary, projected goals in FY 2008 include:

- 1) Developing and incorporating a new pharmacy technician system into the existing licensure and compliance systems;
- 2) Developing an Internet-based inspection system for different pharmacy and distributor practice settings;
- 3) Continuing design and implementation of the new in-house, integrated database system; and
- 4) Reviewing and developing new approaches for tracking and verifying drug pedigrees.

Information Services at www.mdbop.org
<p>The Board provides information on a wide variety of activities it conducts, including:</p> <ul style="list-style-type: none">• 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• Report and review information on missing or stolen prescription pads• 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