

**STATE OF MARYLAND**

**BOARD OF  
PHARMACY**



Fiscal Year 2010

**ANNUAL  
REPORT**

July 1, 2009—June 20, 2010

## VISION

Setting a standard for pharmaceutical services, 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 healthcare in the field of pharmacy through licensing pharmacists and registering pharmacy technicians, issuing permits to pharmacies and distributors, setting pharmacy standards, and through developing and enforcing regulations and legislation, resolving complaints, and educating the public.

## 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 serve customers and stakeholders.

**Respect** — 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.

**FY2010 BOARD COMMISSIONERS**

President

Donald Taylor

*Chain Drug Store Representative*

Secretary

Rodney H. Taylor

*At-Large Representative*

Treasurer

Michael Souranis

*Independent Representative*

Lynette Bradley-Baker

*Chain Representative*

David Chason

*Acute Care Hospital Representative*

Harry Finke, Jr.

*Independent Representative*

Cynthia Anderson

*Home Infusion / Home Care*

Mayer Handelman

*Long Term Care Representative*

Lenna Israbian-Jamgochian

*Acute Care Hospital Representative*

Richard W. Matens

*Consumer Representative*

Reid Zimmer

*Acute Care Hospital Representative*

**FY2010 BOARD STAFF**

**EXECUTIVE**

Executive Director  
LaVerne G. Naesea

**ADMINISTRATION AND PUBLIC  
SUPPORT UNIT**

APS Manager  
Patricia Gaither

Public Information and Education Officer /  
Emergency Preparedness Coordinator  
Janet Seeds

Secretary/Receptionist  
Nikki Dupye

Office Secretary  
Anasha Page

**LEGISLATION/REGULATIONS UNIT**

Legislation/Regulations Manager  
Anna D. Jeffers

**LICENSING UNIT**

Licensing Specialist (Pharmacists)  
Doris James

Licensing Specialist (Renewals)  
Keisha Wise

Licensing Specialist (Technicians)  
Fannie Yorkman

Licensing Secretary  
Lisa Woods

**MANAGEMENT AND INFORMATION  
SYSTEMS**

MIS Manager  
Tamarra Banks

Database Officer  
Michelle Hsu

Computer Specialist  
JB Bozek

**PHARMACIST COMPLIANCE UNIT**

Compliance Coordinator  
Steven Kreindler

Compliance Secretary  
Vanessa Thomas-Grey

Lead Pharmacy Inspector  
Nancy Richard

Pharmacy Inspector  
Shanelle Young

Pharmacy Inspector  
Jeanelle McKnight

Pharmacist Inspector  
Emory Lin

**BOARD COUNSEL**

Linda Bethman  
Francessa Gibbs

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## **REMARKS FROM THE BOARD PRESIDENT**

*Michael Souranis*



On behalf of the Maryland Board of Pharmacy, I am privileged and pleased to present to you our Fiscal Year (FY) 2010 Annual Report that reflects and summarizes the significant activities, accomplishments, and endeavors undertaken in fulfilling the mandate to protect the public health, safety, and welfare of Marylanders, and to establish standards for pharmacy practice.

In deference to the enactment of laws during our fiscal period, Health Occupations 12-6C-04, Accreditation and reciprocity of the Wholesale Distributor Permitting and Prescription Drug Integrity Act, was amended by the 2010 Maryland General Assembly imparting the authority to the Board to grant deemed status to a wholesale distributor that is currently accredited by a Board-recognized accreditation organization, wherever the wholesale distributor is located; or located in a state that has requirements that are substantially equivalent to the requirements of Maryland. The Board was also imparted the authority to grant reciprocity by issuing a wholesale distributor permit to a wholesale distributor who holds a license or permit under the laws of another state if the requirements of that state meet the substantially equivalent standards of this State.

Eight years of arduous work; implementation; promulgation of regulations; approval of various protocols; a study by the University of Maryland School of Pharmacy; two reports by the Board to the Maryland Legislature; and two sets of legislation, have all led to the culmination for successful program implementation of Drug Therapy Management in Maryland, henceforth giving rise to ultimately effectuating and achieving optimal patient care outcomes for Marylanders.

The Governor of Maryland, Martin O'Malley, issued an Executive Order on November 6, 2009 that granted the Secretary of Health and Mental Hygiene the authority to authorize pharmacists to administer the 2009 H1N1 Influenza Vaccine in accordance with 10.34.32.04 of the Code of Maryland Regulations, that provide pharmacists with the requisite training and experience necessary to safely and effectively administer the 2009 H1N1 Influenza Vaccine to individuals between the ages of 13 and 17. The Board expressed its proactive commitment to increase the level of healthcare and to improve influenza immunization rates in Maryland since Maryland pharmacists are in a prime position to identify patients and educate them on their need for a flu shot. Immunization is a very effective way of preventing or ameliorating influenza, and 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 as well as herpes zoster and pneumococcal pneumonia vaccines.

With respect to an update on regulations, one regulation still awaits resolution since 2007. In accordance with the Regulatory Review and Evaluation Act, State Government Article, §§10-130—10-139, Annotated Code of Maryland, the Maryland Board of Pharmacy under the Department of Health and Mental Hygiene was charged with reviewing and evaluating the regulations codified in Title 10, Subtitle 13, Annotated Code of Maryland, of the Code of Maryland Regulations

(COMAR) 10.13.01 Dispensing of Prescription Drugs by a Licensee. The authority for other healthcare practitioners to dispense, which is a function of the practice of pharmacy, is derived from Title 12, Pharmacists and Pharmacies. The Board has unequivocally expressed its concern that allowing the dispensing of medications by licensees other than pharmacists, absent the requirements in place for pharmacists and the practice of pharmacy.

As Board functionalities continue to expand on an operational level, the upgrading of our computer system will soon be a reality. As the Board continues to be faced with challenges, such as vacancies, budgetary constraints, and procedural modifications, this operational enhancement will increase the Board's efficiency and information capability while streamlining and optimizing resources. The more daily functions of the Board, such as the registration of pharmacy technicians and wholesale distributors, the licensure of resident and non-resident pharmacist and pharmacies, reviewing and approving pharmacy technician training programs and drug repository/drop off-site applications, the monitoring of compliance with the Maryland Pharmacy Act, investigation of complaints, and the inquiries and issues related to the practice of pharmacy will continue to remain significant components of the core functionalities and activities of the Board. It is noteworthy to recognize and thank the entire diligent Board staff responsible, under the exemplary leadership of the Board's Executive Director and matriarch, LaVerne G. Naesea, for executing the priorities, policies and procedures, and administrative initiatives established by the Board. Our staff members not only provide administrative support and expertise to the Executive, Legislative, Practice, Disciplinary, Licensing, and Public Relations Committees, but have the responsibility for administering statutory and regulatory obligations such as licensing and registration, practice of pharmacy standards, inspections, compliance, processing and investigating complaints, continuing education information, public information, and emergency preparedness.

The Board continually encourages participation and welcomes comments, feedback, and support since this input is vital to the mission, vision, and values of the Board. Encouraging good communications between the Board and its stakeholders such as pharmacists, pharmacy technicians, Pharmacists' Education and Advocacy Council (PEAC), professional organizations, schools of pharmacy, sister agencies, and ultimately, consumers, is an unwavering focal point and initiative that will foster and improve the mutual understanding within the realms of the pharmacy community. While a myriad of challenges may lie ahead, it is an opportunity to discern and propose new solutions. It continues to be the desire of the Board to ensure that the practice of pharmacy in Maryland is consistent for all, resident and non-resident, pharmacists who provide pharmacy services in our State to the extent that a pharmacist shall be licensed by the Board before the individual may practice pharmacy in this State. Also, the Board seeks to include disposal of prescription drugs and medical supplies through the Prescription Drug Repository Program.

The Board participated in the 93rd Annual Flower Mart in Baltimore, Maryland. It was a successful endeavor with over 700 consumers visiting our booth, to provide general safety tips and health care services. In addition to providing consultations on prescribed medications and blood pressure monitoring, information was disseminated to the public on nutrition; diabetes; cholesterol, blood pressure, smoking cessation, substance abuse, H1N1, emergency preparedness,

safe use of acetaminophen, and other over-the-counter medications. Consumers expressed appreciation for the Board's continued outreach through the Flower Mart and many acknowledged the pharmaceutical education for consumers as a very important part of the health care process. The Board's booth won the first place ribbon for the best non-profit government and wellness booth at the Flower Mart! This was the fifth consecutive year that the Board's booth has won this honor.

In closing, special recognition must be given to my fellow Board Commissioners: Executive Director, LaVerne G. Naesea; Board Counsel, Linda Bethman and Francesca Gibbs; and Legislation and Regulations Manager, Anna Jeffers for their guidance, direction, commitment, and tireless efforts as the Board continues its mission as it embarks and progresses into the new decade.

## **MESSAGE FROM THE EXECUTIVE DIRECTOR**

*LaVerne Naesea*



Once again, the Maryland Board of Pharmacy proudly presents its *Annual Report* to summarize Board activities for the 2010 fiscal year. Initiatives, operations, statistical information for the period between July 1, 2009 and June 30, 2010 are detailed within, including discussion of Board achievements and challenges.

Legislation passed in FY 2010 allowed for the issuance of two-year pharmacy permits, rather than the previous one-year. This initiative set in motion Board acceptance of pharmacy renewal applications during odd years (to begin December 2011) and of wholesale distributor applications on even years. Board staff that had been receiving and processing both types of renewal applications annually will experience some relief beginning in December 2010 when wholesale distributors renew. Also in 2010, a legislative proposal was passed to require out-of-state distributors with laws less restrictive than in Maryland, to acquire national accreditation. This helped the time for inspections for renewing distributors, while also saving the Board significant dollars related to out-of-state inspections. Unfortunately, the Board did not learn until after passage of the proposal that the sole national accreditation entity approved by the Board does not inspect distributors of prescription devices and medical gases; nor does it accredit distributors that do not warehouse drugs at the locations where the sales are negotiated. The impacts of this are discussed in the Licensing and Compliance sections of this report.

A bill requiring Health Occupation Boards' (HOBs) to adopt sanctioning guidelines and to post public final order on individual Boards' web sites brought greater uniformity of certain practices among all HOBs. The Board of Pharmacy began in late FY 2010 to develop sanctioning guidelines based on previous Board decisions. It has also now posts all final public disciplinary orders on its web site.

With the H1N1 pandemic across the country and threat of a pandemic in Maryland, the Department Secretary signed a 30-day emergency order in December 2010 to allow Maryland certified pharmacists to administer vaccines to children ages 13 to 17. The Board was very supportive of this initiative. The Department of Health and Mental Hygiene (DHMH) also required all units under its umbrella to adopt a new web site face. The Board of Pharmacy saw the directive as a win-win opportunity to also review and update its web site to make it more user-friendly and aesthetically pleasing to the eye. DHMH now requires all units to use a universal web site address that incorporates the name of the department and the individual units. The Board's new site address is [www.dhmh.maryland.gov/pharmacyboard](http://www.dhmh.maryland.gov/pharmacyboard).

On the operational front, Board staff members participated in a two-day professional development retreat during the last quarter of FY 2010. Objectives met at the retreat included providing a greater understanding of: how staff may protect the Board (and State) from legal liability; State personnel requirements; State and federal confidentiality and privacy requirements;

and office protocols and team work. Most importantly, staff reviewed A – Z considerations for implementing new laws, programs and initiatives.

One outcome of the retreat was to address the shortage of staff in answering phones, filing and mail processing. The Board applied for and received two Senior Aides through the Baltimore City Health Department's Senior Aides program. The program requires the Board, in exchange, to provide training and supervision for the Aides. The placements at the Board are intended to assist the assigned Aides in obtaining paid positions. City, State and/or Federal grant funding provides stipends to the Aides, so other than providing training resources, there is no expense to the Board for this initiative. Benefits of the Senior Aides' placement at the Board were realized as soon as they were assigned.

Pharmacy technicians were most affected by operational challenges presented during FY 2010. A significant influx of first time and renewal submissions made them difficult to accommodate because of complicated and difficult to implement. Database glitches and staff processing errors occurred during the year, which created extensive delays in approving some applications. The Board is both aware and regretful that these difficulties may have negatively affected some applicants. Plans for implementing a new database system and revamping the Board organization structure will help improve customer service delivery.

The Board received approval to increase fees to meet costs related to its expanded regulatory authority. It also initiated a second overhaul of its database system, which is projected for completion by the end of calendar year 2011.

The Board celebrated the filling of two managerial vacancies in FY 2010. Former Public Information and Education (PI&E) Officer, Summar Goodman, was promoted to the Licensing Unit Manager position; and Kimberly France was appointed to the Pharmacist Compliance Manager position in the Compliance Unit. Janet Seeds was also recruited to fill Summar Goodman's former position. Former Lead Inspector, Joseph Taylor passed away suddenly during the second quarter of FY 2010. Mr. Taylor took his responsibilities very seriously, having gained the respect of fellow inspectors as well as members of the pharmacy community. Pharmacy Technician Inspectors had been averaging 100 inspections monthly; however, that number dropped significantly following the passing of Inspector Taylor. The vacancy created from this critical loss was not approved to be filled during FY 2010.

Commissioners Cynthia Anderson (Home Infusion/Home Care representative) and Alland Leandre (Consumer representative) also left the Board following the end of their first four-year terms in April 2010. Ms. Anderson provided excellent leadership and expertise, when a member and former Chair of the Licensing Committee, Chair of the Home Infusion Task Force, member of the Disciplinary Committee, and member of the Emergency Preparedness Task Force. Mr. Leandre served wisely on the Disciplinary Committee and lent his expertise to the Board's information and technology staff in reviewing and supporting MIS initiatives. Both of these Commissioners served the Board honorably and with commitment.

The first four-year term for Commissioner Harry Finke, Independent representative, also expired in FY 2010; however, he was reappointed. Commissioners Mitra Gavani, Home Infusion/Home Care representative) and Zeno St. Cyr, Consumer representative, were appointed late in FY 2010, along with Mr. Finke. The Board looks to them to continue the legacy of committed performance as Board of Pharmacy commissioners.

The Board again faced many challenges in FY 2010 related to its significant growth, but persevered under the stellar leadership of Board President Donald Taylor. Mr. Taylor began tracking all major initiatives during two one-year terms. He provided much needed support to the Department on several occasions related to public health and safety initiatives. Newly elected President, Michael Souranis, is continuing to effectively address pharmacy issues and lead Board Members and staff through the second decade of 2000.

Thanks to all of the Board members and staff for their continued support and commitment to protecting Maryland pharmacy patients. Licensees, permit holders and registrants are also thanked for their thoughtful inquires, contributions at Board and committee meetings and most importantly for their patience over the past year as the Board continued to adjust to its expansion in scope of services and pharmacy practice.

## ADMINISTRATION AND PUBLIC SUPPORT UNIT

### OVERVIEW

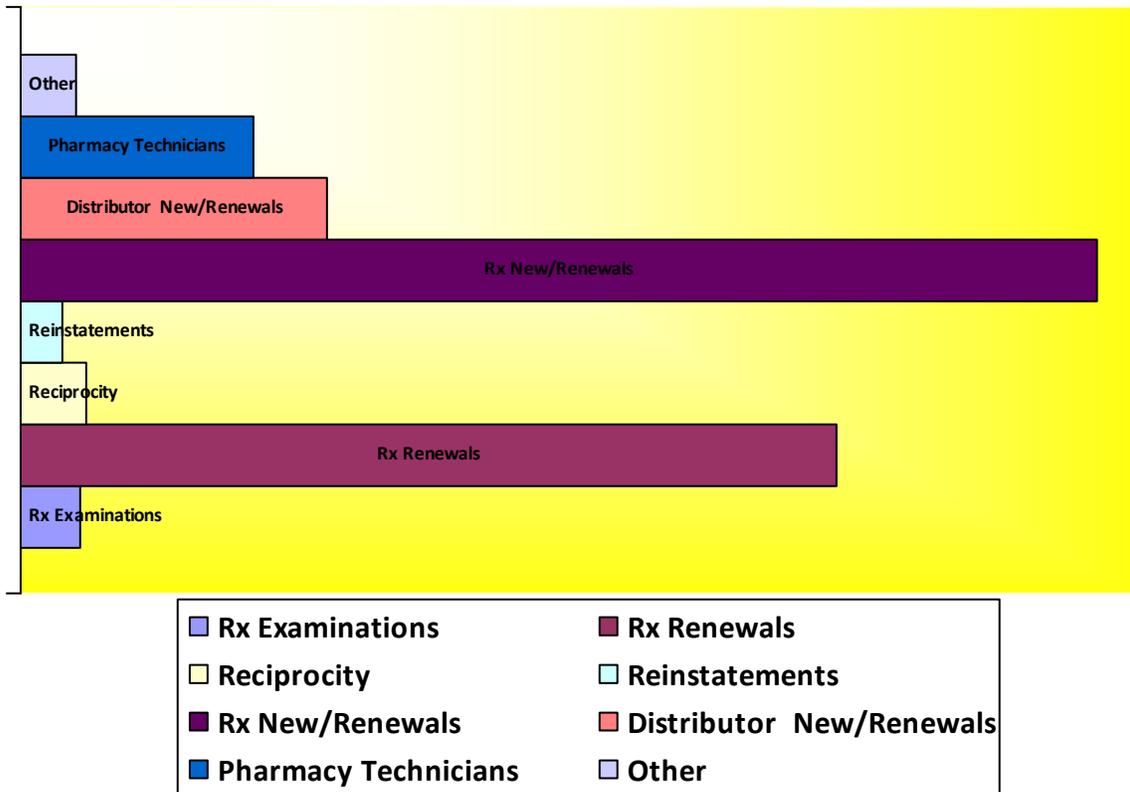
The Administration and Public Support Unit (APS) is responsible for managing the fiscal, personnel, procurement, and public information and education functions at the Board. The Board derives its revenue through payments for license, permits and other applicable fees. Expenditures are made based on submission 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. Funding for new program areas and personnel are sometimes included in the budget request. The Board's budget allocation for fiscal year 2010 was \$2,359,399. 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.

### FISCAL REVENUE

Total revenue collection for fiscal year 2010 was \$2,376,799. This revenue reflects the fee increase discussed above and also changes in the renewal periods for pharmacy and distributor establishments from every year to biennial alternate years (pharmacies on even and distributors on odd years). The revenue collection for fiscal year 2010 was only 6% higher than in fiscal year 2009.

<b>FY 2010 Revenue Detail</b>	
<b>Revenue Carryover from Fiscal Year 09</b>	<b>\$926,215</b>
<b>Total Collections FY 2010</b>	<b>\$2,376,799</b>
Pharmacist Examination	\$52,650
Pharmacist Renewals	\$731,655
Reciprocity	\$59,040
Reinstatements	\$36,999
Pharmacy New/Renewals	\$964,300
Distributor New/Renewals	\$273,875
Pharmacy Technicians	\$209,244
Other	\$49,036
<b>TOTAL REVENUE</b>	<b>\$3,303,014</b>

## FY 2010 Revenue



### Fee Increases

Approval to increase fee were requested in FY 2010 to accommodate increased expenses related to the implementation of a number of new programs. Since 2003, the Board of Pharmacy has implemented without any fee increase, the: Prescription Drug Repository Program, registration of pharmacists to administer influenza vaccinations, registration of pharmacy technicians, renewal of wholesale distributors under a new law, and Board inspections of pharmacies and wholesale distributors. The Board has also hired additional staff members without fee increases.

After carefully weighing to insure that increases were limited to meeting projected expenditures, the Board's fee increases became effective February 2010. Fee increases for pharmacists, pharmacies and wholesale distributors will meet the Board's immediate fiscal needs. Increases in reinstatement and late fees were established to help defray related Board expenses and encourage licensees and permit holders to renew on time. Other minimal fee increases were for duplicate licenses, verifications of good standing, returned checks, printed rosters of labels and failure to maintain a current address with the Board will help cover associated administrative costs. The chart below shows the new and increased fee increases.

**New and Increased Fees**

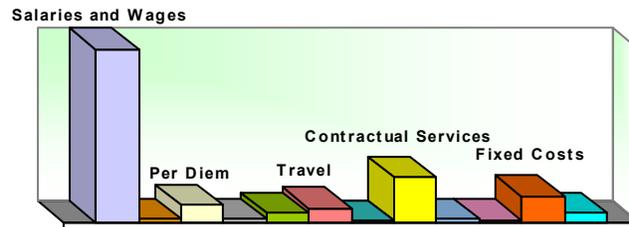
Description Of Fees	FY 09 Fees	FY 10 Fee Increases
<b>PHARMACISTS</b>		
Applications for Examination	\$100.00	\$150.00
Reciprocal Applications	\$120.00	\$300.00
Duplicate Certificates / Permits Issued	\$10.00	\$30.00
Renewals – Pharmacists	\$150.00	\$225.00
Pharmacist Reinstatements up to 2 years	\$65.00	\$300.00
Pharmacist Reinstatement more then 2 years	\$80.00	\$315.00
<b>PHARMACY ESTABLISHMENTS</b>		
New / Change Pharmacy Permits	\$300.00	\$700.00
Renewals - Pharmacy Permits	\$250.00	\$600.00
Late Fee Pharmacy Renewal	\$150.00	\$200.00
Pharmacy Reinstatement fee	\$0.00	\$550.00
<b>DISTRIBUTORS</b>		
New / Change Distributor Permits	\$1,000.00	\$1,750.00
Renewals - Distributor Permits	\$1,000.00	\$1,750.00
Distributor Reinstatement Fee	\$150.00	\$1,500.00
<b>PHARMACY TECHNICIANS</b>		
Pharmacy Technicians	\$45.00	\$45.00
Pharmacy Student	\$45.00	\$45.00
Technician Training Programs Approvals		\$200.00
<b>MISCELLANEOUS</b>		
Therapy Management Physician	\$100.00	\$100.00
Therapy Management Pharmacy	\$100.00	\$100.00
Therapy Management Student	\$50.00	\$50.00
Law Book	\$23.00	\$35.00
Written Verification of Good Standing		\$25.00
Returned Check Processing		\$35.00
Failure to Maintain Address		\$25.00
Request for Printed Rosters		\$150.00

## Expenditures

Board expenditures for FY 2010 were \$2,133,036. This seven percent decrease in expenditure activity from the previous year was a consequence of the Board terminating a vendor contract for a new Database system. A new Data Base contract is projected to be initiated in early FY 2011.

FY 2010 Expenditure Detail	
Salaries and Wages	\$1,397,888
Shared Costs	\$14,246
Per Diem	\$92,980
Technical and Special	\$18,172
Communication	\$51,925
Travel	\$77,173
Vehicle Operation	\$1300
Contractual Services	\$258,095
Operating Costs	\$17,117
Equipment Purchases	\$10,059
Fixed Costs	\$145,876
Indirect Costs	\$48,205
<b>TOTAL EXPENDITURES</b>	<b>\$2,133,036</b>

## FY 2010 Expenditures



Salaries and Wages	Shared Costs
Per Diem	Technical and Special
Communication	Travel
Vehicle Operation	Contractual Services
Operating Costs	Equipment Purchases
Fixed Costs	Indirect Costs

### PERSONNEL

The Board has 23 permanent (PIN) positions. In addition to the PIN positions the Board also had a contractual Help Desk position on staff in fiscal year 2010. Due to a retirement, a resignation and staff transfers the Board encountered six vacancies in FY 2010 - a Pharmacist Compliance Officer; a Licensing Manager; two Inspectors; and two secretaries. The Board plans to fill these positions early FY 2011.

### Contractual Agreements

The Board began research to identify a skilled database systems vendor to efficiently complete the Board's aborted data base project. The Board anticipates that a new database contract agreement will be in place by early FY 11. The Board continues its long-standing Pharmacist Rehabilitation Services contract with PEAC to support impaired practitioners under Board orders and practitioners who voluntarily (and anonymously) entered into treatment. The Board also continued and expanded its contract with the Maryland State Archives to provide service web hosting and web statistics. The Board entered new contractual agreements in fiscal year 2010 with the League for the printing of the Board's newsletter and with the National Association of Boards of Pharmacy (NABP) to perform the out of state inspections of pharmacy establishments.

## **PUBLIC INFORMATION AND EDUCATION**

Training and educational activities have included staffing the emergency preparedness task force. In carrying out this responsibility the Public Information and Education Officer (PEO) is responsible for year-round recruitment and scheduling training for volunteer pharmacists. Additionally, gathering articles and reports for the Board's quarterly newsletter, annual reports and several brochures are other functions of the PEO. These informational tools are 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 sub-unit coordinates responses to all requests made to the Board under the Public Information Act (PIA). The PIA allows certain Board information to be release regarding licensees and Board activities. The PEO is responsible for ensuring that information released does not violate state and federal confidentiality rules. This role is expanded to coordinating some 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 function in the APS Unit include monitoring pharmacy-related news media and coordinating 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 2010 Summary of Public Relations Activities

- August 2009- Maryland State Fair Exhibit Manned Booth
- August 2009 – American Society of Consultant Pharmacists (ASCP) Mid Atlantic Conference, Rocky Gap, MD Manned Booth
- October 2009 –Coordinated Pharmacist Continuing Education Brunch, Baltimore, MD
- May 2010 Flower Mart Exhibit in partnership with Maryland Pharmacy Coalition and University of Maryland School of Pharmacy
- June 2010 Maryland Pharmacist Association (MPhA) Exhibit, Ocean City, MD Manned Booth

## **NEXT YEAR AT A GLANCE**

The Board projects an increase in revenue for FY 2011. The projected revenue for FY 2011 is \$2,539,794. This projection is based on the wholesale distributor renewals fee which will be collected to cover two FY 11 and FY 12. The projected expenditures are anticipated to increase related to the new Database System which is expected to complete between the end of FY 2011 and early FY 2012.

The Board expects to heighten visibility throughout the state via its public information and education program and emergency preparedness activities.

## **LICENSING UNIT**

### ***Overview***

The Licensing Unit is responsible for all activities related to the issuance of new and renewed licenses, permits and registrations for practicing in Maryland to qualified pharmacists, pharmacy technicians, pharmacy owners and pharmaceutical distributors. The Licensing Unit also processes applications for the Prescription Drug Repository Program as well as for qualified pharmacists to administer Influenza Vaccinations. The Licensing Unit consists of five professional licensing staff persons: a Manager, three (3) Licensing Specialists and a Secretary. New processes are being established to expedite and share as website resources for the following:

New and Renewal applications for: Pharmacists, Pharmacy Technicians, resident and non-resident Pharmacies, in-state and out-of-state Wholesale Distributors, Reciprocity and Reinstatement Pharmacists, Prescription Drug Repositories and the Administration of vaccines by Pharmacist Pharmacy Technician training programs, Criminal background checks for Pharmacy Technicians and Wholesale Distributors, Inquiries for Verifications, Licenses and Permits, Inspection Reports for Establishments, and Licensing Committee and Board meeting deliberations.

### ***Developments***

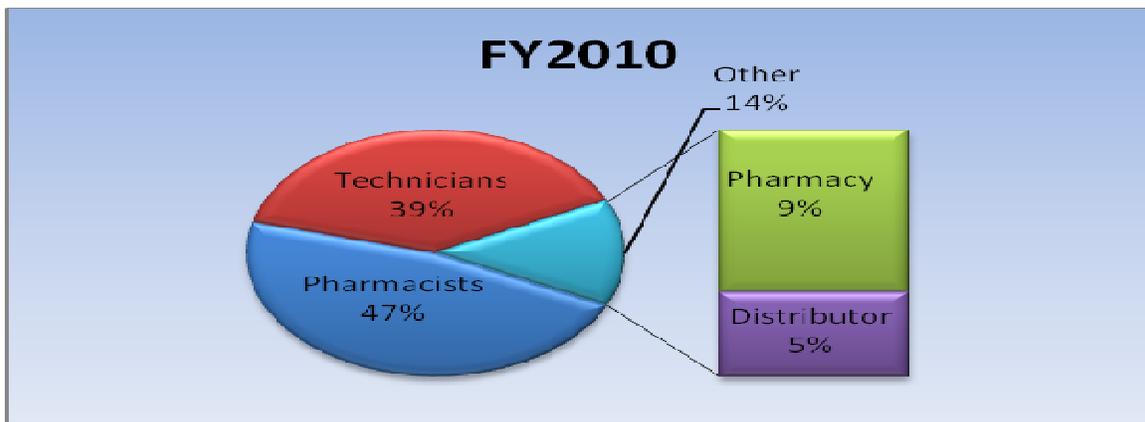
All Wholesale Prescription Drug or Device Distributors that applied to operate in Maryland in FY 2010 were required to demonstrate that they met the provisions of the new Distribution Permitting and Prescription Drug Integrity Act and revised COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device regulations. This resulted in increased numbers of nationally accredited Wholesale Distributors operating in Maryland, making it illegal to distribute prescription drugs and devices in Maryland without accreditation.

There was a high number of Pharmacy Technician applications submitted utilizing the option of obtaining certification through a nationally accredited Pharmacy Technician Certification program. This has impacted the industry by dramatically lessening alleged incidences of unlicensed / unregistered personnel working in pharmacies throughout Maryland. Currently there are two (2) national certification programs that the Board accepts: Pharmacy Technician Certification Board (PTCB) and Institute for the Certification of Pharmacy Technicians (ICPT).

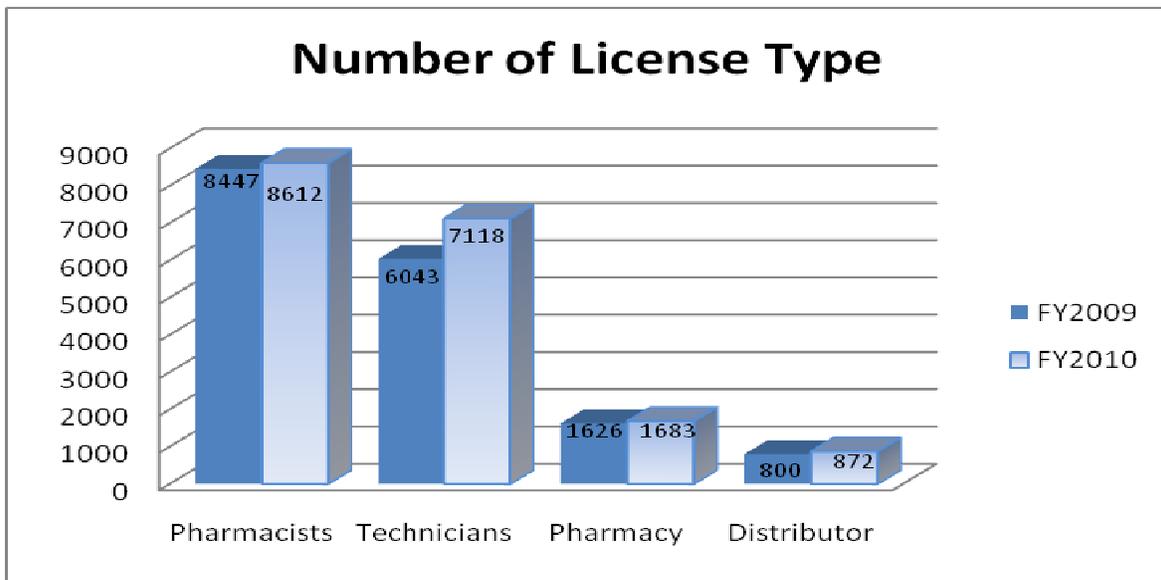
*A list of Board approved Pharmacy Technician training programs is being updated and will be available on the Board's website at <http://dbmb.maryland.gov/pharmacyboard/> at the end of June 2011.*

### ***Statistics***

The number of pharmacists licensed in Maryland increased by 2% from last year. The total number of pharmacists licensed at the end of FY 2010 was 8,612 which is 165 more than last fiscal year.



Most all Licensing Unit permits expire December 31<sup>st</sup> of each year which includes Pharmaceutical Distributors of prescription drugs and devices. The total number of licensed Distributor permit holders at the end of FY 2010 was 872, 72 more than in 2009 whereas pharmacies increased by 57 more than FY 2009. Registration for pharmacy technicians has increased by 18% whereas pharmacists show only a 2% increase for FY 2010.



Applications are being revised to capture essential applicant information upfront so as to be more readily transferred into the Board of Pharmacy database system. The Licensing Unit continues to work closely with the Legislation Manager regarding applications to implement the regulations that allow pharmacists to administer herpes zoster and pneumococcal pneumonia vaccinations in addition to the influenza vaccine. The Licensing Unit looks forward to continued public service in its responsibility for the issuance of new and renewal Maryland practice licenses, permits and registrations to qualified pharmacists, pharmacy technicians, pharmacies and wholesale distributors of prescription drugs and devices.

## PHARMACY COMPLIANCE UNIT

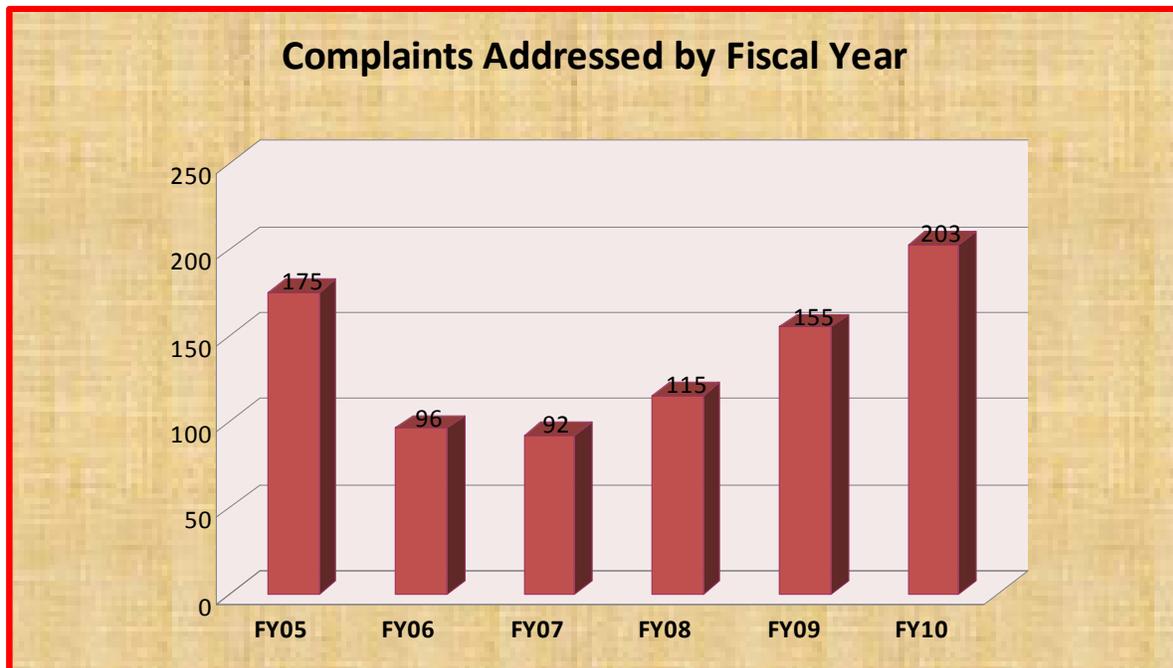
The Compliance Unit protects the public health of Maryland's citizens by ensuring compliance with state laws and regulations regarding the practice of pharmacy. Unit staff consists of a pharmacy compliance officer, coordinator, secretary, investigator and inspectors. They perform the following functions:

- ◇ receive, investigate and respond to questions and complaints
- ◇ monitor licensees and permit holders who are under order by the Board
- ◇ report disciplinary action to national databases
- ◇ inspect pharmacies and wholesale distributors

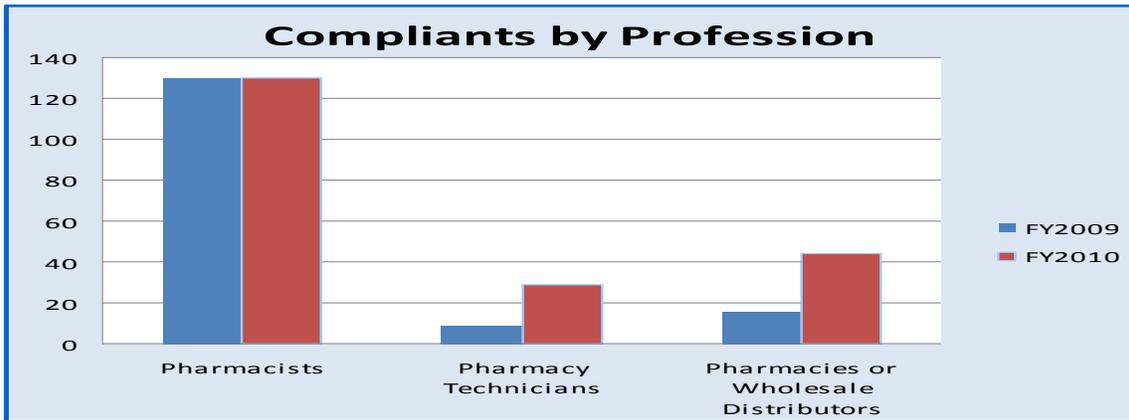
### Complaints

The compliance unit receives complaints from a variety of sources and is charged with addressing each complaint. An individual may obtain a complaint form from the Board of Pharmacy website at [www.dhmh.maryland.gov/pharmacyboard](http://www.dhmh.maryland.gov/pharmacyboard) and may file a complaint by fax, phone, mail, in person, or e-mail. All information related to the complaint is compiled and presented to the Board's disciplinary committee for review and action. The disciplinary committee makes recommendations regarding Board actions to the full Board. If the issue is outside of the Board's scope or jurisdiction, the complaint will be referred to the appropriate authority.

**Figure 1**      **Complaints Processed July 1, 2009-June 30, 2010**

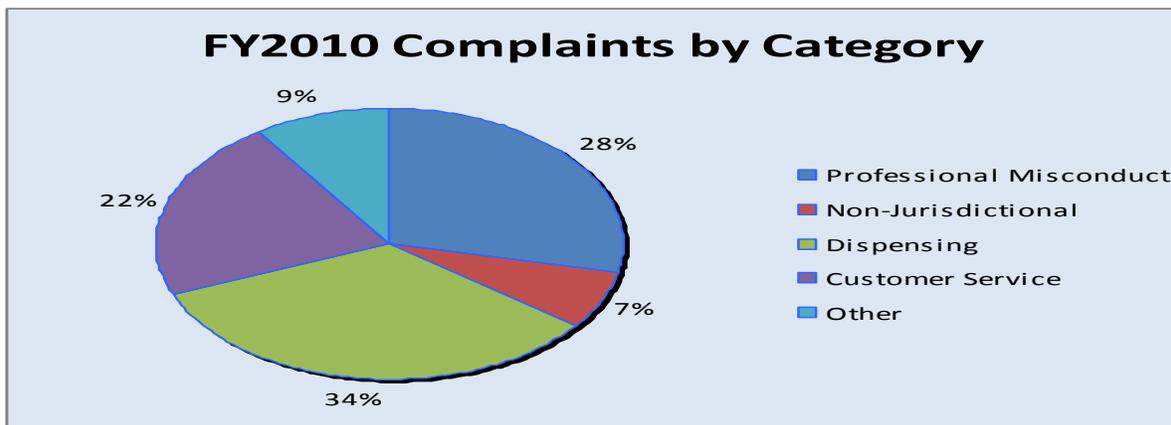


**Figure 2** Complaints against Licensees, Registrants, and Permit Holders



This is the 2<sup>nd</sup> year that the Maryland Board of Pharmacy continued registering technicians. As a result, technician compliance is also part of the Board’s purview. Figure 2 above reveals 14.3% of the complaints filed in this fiscal year were against pharmacy technicians. This is three times higher compared to that of last year.

**Figure 3** Types of Complaints July 1, 2009-June 30, 2010



**Disciplinary Cases**

All complaints are investigated by Board staff members. Approximately 45% of all complaints result in the Board taking formal or informal action. Examples of informal actions include letters of education, letters of admonishment and /or letter that require the licensee to obtain continuing education credits on a particular topic. Examples of formal actions include a license or permit being placed on probation or suspended. Approximately 41% of the complaints remained open, pending more investigation. This is due to the fact that the compliance unit was without a Compliance Officer for the first 8 months of this fiscal year as well as the loss of a Lead Inspector for the later half of Fiscal Year 2010. The Pharmacy Inspector, who would usually perform investigation in addition to inspections, had to allocate more time doing inspections due to the above mentioned loss of personnel. Figure 4 shows the number of formal and informal actions taken for Fiscal Year 2010, compared to the previous 5 years.

**Figure 4 Disciplinary Actions-Fiscal Year Comparison**

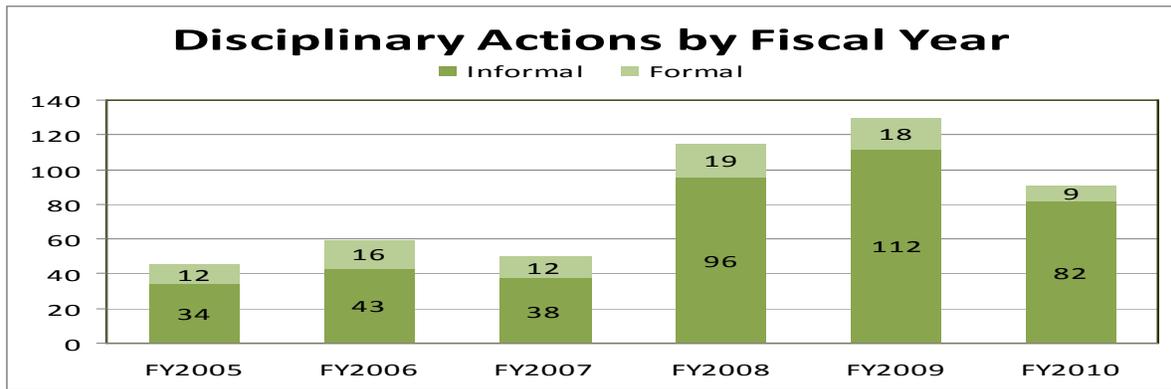
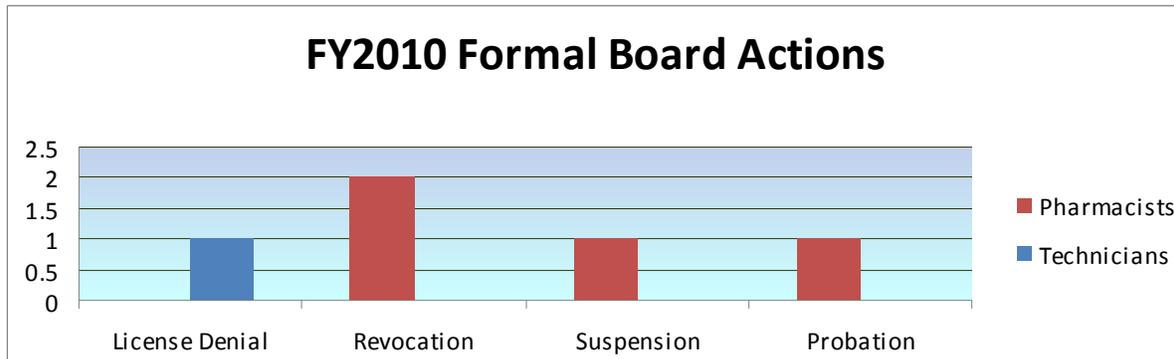


Figure 5 represents a categorical description of the various types of formal and informal actions taken against pharmacists, pharmacy technicians, and establishments in the most recent fiscal year.

**Figure 5 Board Action July 1, 2009-June 30, 2010**

Once disciplined under a public order, the licensee, registrant, or permit holder’s information is reported to the National Practitioner Data Bank and/or the Healthcare Integrity and Protection Data Bank. Figure 6 below reflects the formal actions taken against pharmacists and pharmacy technicians in Fiscal Year 2010. Some formal actions against licensees or permit holders included fines which are excluded from figure 6. Most formal actions, including fines are published in the Board of Pharmacy newsletter along with the license holder, permit holder, or applicant name.

**Figure 6 Formal Board Actions Taken July 1, 2009-June 30, 2010**



**Inspections**

The compliance unit continues to work closely with the Division of Drug control (DDC) in performing inspections. The Board of Pharmacy conducts opening, relocation, and annual inspections of in-state pharmacies, while DDC performs all closing inspections. The Board has a goal of inspecting all in-state pharmacies annually. The chart in Figure 7 reflects the total number of annual and opening inspections performed in Fiscal Year 2010.

**Figure 7**

Annual Inspections	1095
Opening Inspections	60
Total Inspections	1223

The Board was also required to inspect all new and renewing wholesale distributors under the Wholesale Distribution Permit and Prescription Drug Integrity Act. During Fiscal Year 2010, the Board of Pharmacy inspected 57 wholesale distributor facilities located in Maryland as well as some in neighboring states (10 in Pennsylvania and 1 in Virginia). The Compliance Department reviewed all out of state distributor's application (113 applications for Fiscal Year 2010) for a state inspection conducted by their state. Several out of state facilities required inspections, so the Board contracted with the National Association of Boards of Pharmacy (NABP), a Board-approved national wholesale distributor accreditation agency, to inspect approximately 20 facilities on the Board's behalf.

### **Pharmacist and Substance Abuse**

The prevalence of chemical dependence among health care professionals has been estimated over the years and continues to plague society. Among its many options in addressing disciplinary actions, the Maryland Board of Pharmacy may opt to mandate substance abuse treatment. If treatment is so ordered, the staff is responsible to monitor the individual to ensure compliance with the terms of the order. The Board provides direct monitoring of these licenses which include but are not limited to:

- random drug testing
- substance abuse treatment or psychotherapy
- participation in local NA/AA programs

Once disciplined, the licensee or permit holder's information is reported to the National Practitioner Data Bank and/or the Healthcare Integrity and Protection Data Bank. In Fiscal Year 2010, the Board monitored 11 pharmacists who were under orders that involved substance abuse. The Board will also monitor registered pharmacy technicians who are issued public orders for actions involving substance abuse. There is 1 public order related to substance abuse issued to the registered pharmacy technician during Fiscal Year 2010.

The Maryland Board also contracts with the pharmacist rehabilitation committee (PEAC) rehabilitation committee to provide assessments, treatment referrals, and monitoring of pharmacists and pharmacy technicians that voluntarily request substance abuse assistance. Individual assistance provided by the rehabilitation committee is confidential, with monthly aggregate reports provided to the Board. Each client served by the rehabilitation committee is required to sign a contract indicating that it understands that the Board of Pharmacy will be notified if they violate the terms of their contracts.

In Fiscal Year 2010, PEAC monitored a combined total of 23 pharmacists and pharmacy technicians.

### **Next Year at a Glance**

For Fiscal Year 2011, the Compliance Unit plans to:

- provide additional training to staff;
- implement feedback from establishments regarding their inspection experience;
- reduce number of cases carried over into the next fiscal year;
- have more uniform review and more defined categories for the different types of complaints and;
- continue to have a full cadre of compliance staff and pharmacy inspectors.

## **MANAGEMENT AND INFORMATION SYSTEMS UNIT**

### **Unit Overview**

The MIS Unit is responsible for implementing and maintaining automated systems that enhance the operation of the Board in its duty of protecting citizens through the regulation of the practice of pharmacy in the State of Maryland. The Unit is comprised of two full-time staff members; they are the MIS Unit Manager and Database Specialist.

### **New Developments**

Prior to FY 2010, a Technical Hardware Specialist was contracted to support on-going programs and new projects. As with many other state agencies, the FY2010 proposed budget for a 1 year contractual person was denied, causing a reduction in support for all Board staff, members, programs and projects.

The MIS Unit was required to respond to several new requirements put in place by the Department. Additionally the hardware and database systems were strained by the significant growth in licensees and required new types of data to be maintained (related primarily to pharmacy technicians). The Department upgraded the email system to enable retrieval of e-mails using PDA's, Blackberry's and other external devices. All Department agencies were also required to adhere to uniform branding for all web sites. The Board of Pharmacy complied by the established deadline by implementing a more versatile and sophisticated web publishing software platform. The Board was not able to implement the planned in-house database because excessive delays, cost overruns and staffing issues that resulted in the vendor's contract being terminated.

### **Accomplishments**

The MIS Unit worked hard in FY 2010 to keep pace with developments of the newer programs and mandates resulting from the legislative session. Three key related accomplishments included applying fee changes to the cash system databases, updating the online renewal system and creating a system to register pharmacists to perform vaccinations for the H1N1 virus. The word "Vaccination" is now placed on the licenses of pharmacist approved by the Board to administer vaccines. This will aid Board Inspectors in identifying those who are approved more easily.

The MIS Unit began working with the Maryland Health Care Professional Volunteer Corps to interface its volunteer database with the Board's. This allows the State to retrieve critical volunteer information in the event of an emergency. Also, a criminal background check tracking system was created in response to the growing number of submission for the technician program.

A very significant accomplishment for the MIS Unit was to deploy an in-house mobile inspection system for use by Inspectors in the Compliance Unit. The system allows Board Inspectors to perform annual and opening inspections using laptops that are synchronized with the Board's network database. When Inspectors are in the field, the system expedites the inspection process by providing each of the four Inspectors with access to ever changing data. The new system decreased the need for Inspectors to call the office to receive updated information. Inspectors can now access the Internet when necessary, to obtain information from pharmacy laws and

Inspectors may also contact other agencies for assistance when they are in field or on inspections. The system also stores complete copies of all previous inspections for referencing; eliminating the need to carry hard copies along with the equipment to each location. The MIS Unit also requisitioned and programmed mobile printers for each inspector to provide inspected pharmacies with legible copies of the inspection and all response comments before Inspectors leave each pharmacy site.

with the Board's network database. When Inspectors are in the field, the system expedites the inspection process by providing each of the four Inspectors with access to ever changing data. The new system decreased the need for Inspectors to call the office to receive updated information. Inspectors can now access the Internet when necessary, to obtain information from the Board's web site, including access to important supporting documents, licensing forms, and pharmacy laws and regulations. Inspectors may also contact other agencies for assistance when they are in field or on inspections. The system also stores complete copies of all previous inspections for referencing; eliminating the need to carry hard copies along with the equipment to each location. The MIS Unit also requisitioned and programmed mobile printers for each inspector to provide inspected pharmacies with legible copies of the inspection and all response comments before Inspectors leave each pharmacy site.

In the Spring of 2010, the MIS Unit moved the Board off the mainframe by fully enabling the in-house system created by MIS staff. This move allowed greater flexibility in the Board's capacity to meet new requirements related to program changes and additions.

#### **Next Year at a Glance**

Looking forward, the MIS Unit plans to create greater online service capabilities for all licensees regulated by the Board. The MIS Unit will explore an *off the shelf* approach to creating a modernized and centralized database system to better accommodate the needs of each unit. As had been anticipated through its previous vendor, the System is hoped to allow real time viewing of all important collected data through a completely integrated system. Unit Staff will also focus on receiving training to better support the planned MIS database project and perform additional functions related to in-house queries and generation of report.

## **LEGISLATION/REGULATION 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 and Legislative. A special task force staffed during Fiscal Year 2010 included the continuation of the Home Infusion Task Force which was convened to explore and recommend regulatory revisions.

Throughout the year the Unit responds to phone calls and e-mail inquiries from the public, applicants, licensees, permit holders, Maryland agencies, pharmaceutical companies, legislators, lobbyists, prescribers, 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 to 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 2010 the Unit responded to 1,771 phone calls and provided written responses to 566 e-mail inquiries.

### **Legislative Initiatives**

During the interim of the Maryland Legislative Session, the unit assists the Board as it determines whether or not changes to the Maryland Practice Act may be appropriate. The Unit prepares Legislative Proposals for submission to the Department’s Office of Governmental Affairs for review. Additionally, the Unit arranges for meetings in Annapolis to apprise the Senate Education, Health, and Environmental Affairs Committee’s Chairman and the House Health and Government Operations Committee Chairman of upcoming Board legislative initiatives. These meetings often lead to potential sponsors for upcoming Board legislation.

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 identified 40 bills (of approximately 2,695 bills) to present to the Board of Pharmacy’s Legislative Committee for consideration. The Unit tracked, drafted position papers and/or letters to legislative committees for 22 of the 40 bills. Below is provided a chart of the 22 bills (companion bills are counted as one bill) and the results.

<b>Bill #</b>	<b>Bill Name</b>	<b>Result</b>
SB 86	Correctional Services - Medication for Chronic or Acute Medical Condition - Waiver of Liability	FAILED
HB 114	Health Occupations Boards - Revisions	<b>PASSED</b>
SB 291	Health Occupations Boards - Revisions	<b>PASSED</b>
SB 163	State Board of Pharmacy - Wholesale Distributors - Accreditation and Reciprocity	<b>PASSED</b>
HB 868	State Board of Pharmacy - Wholesale Distributors - Accreditation and Reciprocity	<b>PASSED</b>
SB 165	Health Occupations - Therapy Management Contracts - Repeal of Sunset	<b>PASSED</b>
HB 600	Health Occupations - Therapy Management Contracts - Repeal of Sunset	<b>PASSED</b>
SB 370	Pharmacies - Delivery of Controlled Dangerous Substances	WITHDRAWN
HB 431	Medical Review Committees - Subpoenas - Medical Records for Mental Health Services	FAILED
HB 411	Statewide Advisory Commission on Immunizations - Membership, Sunset Extension, and Study of HPV Vaccine	<b>PASSED</b>
HB 713	Drug Schedules – Marijuana	FAILED
HB 712	Public Health – Medical Marijuana	FAILED
SB 627	Public Health – Medical Marijuana	FAILED
HB 627	Health Occupations Boards and Committees - Consumer Member Requirements	WITHDRAWN
HB 649	Environment - Pharmaceutical Disposal Act	FAILED
SB 662	Prescription Drugs - Controlled Dangerous Substances - Certification of Information on Delivery	FAILED
HB 862	Statewide Advisory Commission on Immunizations - Membership and Sunset Repeal	FAILED
SB 932	Civil Actions - Immunity from Civil Liability - Health Care Providers	FAILED
HB 1068	Criminal Law - Distributing a Controlled Dangerous Substance to a Minor Causing Death	FAILED
HB 1089	Health Occupations - Pharmacists - Laboratory Tests	WITHDRAWN
SB 1053	Health Occupations - Pharmacists - Laboratory Tests	WITHDRAWN
HB 1180	Prescription Confidentiality Act	WITHDRAWN

HB 1180	Prescription Confidentiality Act	WITHDRAWN
SB 1040	Prescription Confidentiality Act	FAILED
HB 1353	Veterans Affairs – Military Health Care Provider Transition Plan	<b>PASSED</b>
SB 1033	Veterans Affairs – Military Health Care Provider Transition Plan	<b>PASSED</b>
HB 1357	Professional Boards - Transfer of Funds - Repayment	FAILED
HB 1381	Prescription Drugs - Controlled Dangerous Substances - Certification of Information on Delivery	FAILED
HB 1387	Health Occupations - Pharmacists - Disposal of Unused Prescription Drugs ("Operation Take-back")	WITHDRAWN
HB 1445	Vehicle Laws - Controlled Dangerous Substances - Per Se Driving Offenses	FAILED
SB 698	Vehicle Laws - Controlled Dangerous Substances - Per Se Driving Offenses	FAILED

**Summaries of major bills from the 2010 Legislative Session are provided below.**

**SB 163 - State Board of Pharmacy - Wholesale Distributors - Accreditation and Reciprocity**

This legislation revised the Wholesale Distribution Permitting and Prescription Drug Integrity Act by requiring that an out of state wholesale distributor may reciprocate into Maryland without an inspection if 1) accredited by an accreditation organization recognized by the Board; or 2) located in a state with laws that are substantially equivalent to Maryland's laws. Before this statutory change, a few wholesale distributors were accredited to operate in only the three states that require accreditation; and only a dozen or so states have laws that are substantially equivalent to Maryland's laws. Thus, the Board, or its designee, was required to inspect facilities in the remaining states, causing considerable unbudgeted expense and delay in processing the applications. The legislation passed and all other application requirements remained the same.

**SB 165 - Health Occupations - Therapy Management Contracts - Repeal of Sunset**

This bill proposed to repeal the Sunset date for the Drug Therapy Management Program, making it a permanent program in Maryland. Drug therapy management is a course of treatment predetermined by a licensed physician and licensed pharmacist through an approved protocol according to generally accepted medical practice for the proper completion of a particular therapeutic or diagnostic intervention. Drug therapy management is allowed under very restrictive management is allowed under very restrictive protocols, agreements and contracts that are voluntary, include the consent of the patient, and are pre-approved by both the Board of Pharmacy and the Board of Physicians. Examples are the management of anticoagulation disorders, diabetes and smoking cessation. The legislation passed and the Sunset date was repealed making the Drug Therapy Management Program a permanent program in Maryland.

### **HB649—Environment-Pharmaceutical Disposal Act**

This legislation prohibited a health care facility and any individual acting on behalf of or under the direction or supervision of a health care facility from discharging, disposing of, flushing, pouring, or emptying an unused medication into a wastewater system. Home health agencies, home-based hospice care programs, or hospice facilities did not have to comply if the medications were controlled dangerous substance (CDS) items unless the U.S. Drug Enforcement Administration adopted regulations to dispose of CDS in a manner consistent with HB 649. The Board noted in its position paper the importance of the proper disposal of prescription medications to protect the environment and to keep prescription medications from individuals for whom the prescription medications were not prescribed. It was also noted that this legislation did not include intravenous fluids, syringes or transdermal patches from those items that may not be flushed, poured or emptied into a wastewater system. Many of these produce are biological or chemotherapy medications and the Board maintained that these items are just as injurious, if not worse, to the water supply as pills, tablets, capsules and caplets and requested that section be stricken from the legislation. Additionally, the Board suggested in its position paper that a section be added to the legislation that required, where practicable, a health care facility to take advantage of the existing Prescription Drug Repository Program. This legislation failed.

### **HB 1387 - Health Occupations - Pharmacists - Disposal of Unused Prescription Drugs ("Operation Take-back")**

This legislation placed the burden on the pharmacy to dispose of unwanted or expired prescription medications. It required labels on prescription drug containers to include a notice advising the retail consumer of the proper disposal of any unused prescription drugs in the containers. It required that an information sheet be included with each prescription drug dispensed that provides the current Federal Drug Administration (FDA) Guidelines for drug disposal that is available from the FDA internet website. Each pharmacy would also have been required to develop a program for the disposal of unused prescription drugs which would have had to include a secure container for the deposit of unused prescription drugs. The pharmacy would have had to display a written notice notifying consumers of the availability of the prescription disposal program and the positive effect on water quality derived from the proper disposal of unused prescription drugs. The Board opposed this legislation because the requirements outlined in HB 1387 were an unfunded mandate and placed an immense burden on Maryland retail pharmacies. The Board suggested instead, that pharmacies be provided with incentives to apply to be a Drop-off Site or a Repository under the existing voluntary Prescription Drug Repository Program and dispose of medications through that program. This legislation failed.

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 - .34, revisions effective during Fiscal Year 2010:

<b>COMAR Citation</b>	<b>Title</b>	<b>Effective Date</b>
10.34.09	Fees	February 1, 2010
10.34.17	Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties	October 19, 2009
10.34.22	Licensing of Wholesale Prescription Drug or Device Distributors	October 5, 2009
10.34.32	Pharmacist Administration of Vaccinations	August 1, 2009

Pursuant to the **Regulatory Review and Evaluation Act**, throughout Fiscal Year 2010, Board subcommittees continued to revise COMAR 10.34.03 Inpatient Institutional Pharmacy and COMAR 10.34.23 Pharmaceutical Services to Residents in Long-Term Care Facilities. COMAR 10.34.23 was published in the Maryland Register on June 4, 2009.

Maryland Board of Pharmacy Regulations, COMAR 10.34.01 - .34 and other COMAR chapters, currently in the revision or promulgation process:

<b>COMAR Citation</b>	<b>Title</b>	<b>Proposal status</b>
10.13.01	Dispensing of Prescription Drugs by a Licensee	Revisions under consideration pursuant to the Regulatory Review and Evaluation Act Report dated February 28, 2008. Board of Pharmacy in correspondence with Board of Physicians concerning revisions. Various meetings occurred during FY 2010.
10.34.03	Inpatient Institutional Pharmacy	Released for informal comment in June 2009
10.34.20	Format of Prescription Transmission	Released for informal comment in August and November 2009. Published in the Maryland Register June 4, 2010.
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. Released for informal comment in November 2009. Published in the Maryland Register June 4, 2010.
10.34.25	Delivery of Prescriptions	Proposal submitted to the Department for sign-off June 21, 2010.
10.34.28	Automated Medication Systems	Regulatory revisions pursuant to HB 1387/SB 767 Health Occupations - Board of Pharmacy - Remote Automated Medication Systems, 2008. Published in the Maryland Register December 4, 2009. Comments received. Re-proposal approved by the Board March 17, 2010. Returned to Practice Committee in June 2010 for further revisions.
10.34.35	Infusion Pharmacy Services in an Alternate Site Care Environment	Task Force meeting regularly to draft regulations.

**Summaries of regulatory changes that became effective in FY 2010 are provided below.**

**10.34.09 Fees**

The purpose of this regulatory proposal was to increase fees for pharmacists, pharmacies, and wholesale distributors to meet the current and future fiscal operational needs of the Board of Pharmacy. The proposal increased reinstatement and late fees that would help defray some Board expenses and encourage licensees and permit holders to renew on time. It also added or increased minimal fees for duplicate licenses, verifications of good standing, returned checks, printed rosters of labels, and failure to maintain a current address with the Board, to cover associated administrative costs.

**10.34.17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties**

The purpose of this regulatory proposal was to clarify terms and provide more detailed explanations of: (1) what constitutes a pharmaceutical specialty; (2) evaluation criteria for the Board to consider when approving an application for a waiver permit; and (3) the restrictions placed on a waiver pharmacy. Pharmaceutical specialty was defined to mean a limited pharmaceutical service provided by a pharmacy that is in or makes use of a specialized setting by virtue of certain equipment, systems, location, or physical structure; and restricts or limits its services to a group or groups of individuals requiring such specialty services. Pharmaceutical specialty includes assisted living facilities; comprehensive care facilities; developmental disabilities facilities; home infusion; inpatient hospital; nonsterile compounding; nuclear pharmaceutical; research; sterile compounding; veterinary care; and other services approved by the Board.

**10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors**

The purpose of this regulatory proposal was to revise the regulations to comply with Emergency Bill, HB 1195 (2009) Prescription Drugs—Wholesale Drug Distribution—Surety Bond Requirements, which altered the surety bond requirement for applicants for a wholesale distributor permit to \$50,000 for those applicants with annual gross receipts under \$10,000,000 from sales of prescription drugs and devices in Maryland. The surety bond remains \$100,000 for those applicants with annual gross receipts of \$10,000,000 or more from sales of prescription drugs and devices in Maryland.

**10.34.32 Pharmacist Administration of Vaccinations**

The purpose of this regulatory proposal was to revise the regulations to comply with SB 717/HB 551 (2008) Pharmacists—Administration of Vaccinations—Expanded Authority, which allowed pharmacists to administer two additional vaccinations: herpes zoster and pneumococcal pneumonia. Pharmacists must now comply with additional requirements for pneumococcal pneumonia and herpes zoster that include: the requirement of a prescription before administration; notification to the prescribing physician within 7 days of the: identity of the patient, vaccination administered, route and site of the administration, dose administered, and date of administration. If the prescribing physician is not the patient's primary care physician, the pharmacist is required to make a reasonable effort to make the same notifications to the primary care physician as would be made to the prescribing physician. Additional record-keeping requirements include documenting the nature and outcome of adverse reactions and reporting

those adverse reactions to the primary care physician and the Vaccine Adverse Event Reporting System. Finally the regulations include record-keeping requirements for pharmacists administering vaccines at locations other than a pharmacy. If on behalf of the permit holder, the pharmacist maintains records with the permit holder. If acting as an independent contractor, the pharmacist maintains the records.

### **Legislative Reports**

The Unit is also responsible for drafting and obtaining Board approval for legislative reports including the following:

- Annual Report on the Implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act
- Annual Report on the Operation of the Prescription Drug Repository Program

Other legislative reports as required.

### **New Year at a Glance (Projections for FY 2011)**

At the end of FY 2010, the Unit began the process of revising the Maryland Pharmacy Laws Book. The expectation is that the review and proofing process will be completed in the late summer of 2010 with a shipment date in the fall. As with the other Maryland Pharmacy Laws books, it will be distributed to all pharmacy permit holders and will be offered for sale to pharmacists and the public on the Board's website.

The Unit will be busy in the beginning of Fiscal Year 2011, preparing two legislative reports due January 1, 2011. Those reports include:

- Annual Report on the Implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act
- Annual Report on the Operation of the Prescription Drug Repository Program. The Unit will continue to coordinate, review, format, and process the regulatory chapters reviewed under the Regulatory Review and Evaluation Act throughout Fiscal Year 2011.

## **PHARMACIST'S EDUCATION AND ADVOCACY COUNCIL**

*Submitted by Tony Tommasello, Pharmacist, PhD., Executive Director*

### **New BOP contract:**

The Pharmacists' Education and Advocacy Council (PEAC) provides services to the State of Maryland Board of Pharmacy (the Board) under the provisions of the Maryland Department of Health and Mental Hygiene Standard Service Contract (DHMH form 3883 & 3982). Although the terms of the contract have varied over time, the Board has provided continuous support for a portion of the PEAC operations budget for over twenty years. This contract was renewed on May 24, 2010 for a period of 2 years from April 21, 2010 to April 20, 2012. The contract provides limited financial support for PEAC to offer a therapeutic alternative for substance abusing or impaired pharmacists. PEAC's therapeutic alternative helps pharmacists address the immediate needs associated with substance abuse/impairment while appropriately keeping them indirectly under the Board's supervision through an anonymous and confidential process without the stigma or restriction of disciplinary action. The contract also funds PEAC as the "Pharmacists Rehabilitation Committee" defined in HO 12-317.

### **Treatment Contract extension – 5 year**

In order to ensure comprehensive therapeutic oversight, PEAC extended the term of monitoring under the "Treatment Contract" from 3 to 5 years. This modification was implemented to incorporate new clinical research findings that correlate reduced relapse rates associated with the extended monitoring period. It is likely that some elements of monitoring will ease throughout the 5 year period as the client's recovery commitment matures and s/he demonstrates secure abstinence. By retaining the authority under the contract to conduct random urine tests at any time throughout the 5 year period PEAC ensures that clients can be brought back into more closely supervised monitoring and potentially re-entry into treatment if the need is identified.

### **Budget**

The Board's funding of PEAC, although not adequate to address annual expenses, reimburses a portion of incurrent operational costs. Monthly invoices and expenditure reports are submitted for review to Board of Pharmacy Fiscal Officer by the PEAC Treasurer, Mr. Gil Cohen. The State of Maryland issues payment following the Board's approval of the invoice.

### **Case summaries**

From July 1, 2009 through June 30, 2010 PEAC provided services for 24 pharmacists, technicians and students in a therapeutic process with a treatment contract (see table below). The number of clients in a given calendar month ranged from 22 to 12. The number rises as new Board of Directors cases either complete treatment and exit our monitoring system or are brought into the Board's disciplinary procedure under a consent order after being convicted of a violation

convicted of a violation of the Maryland Pharmacy Practice Act. In some of these latter instances PEAC continues to offer monitoring and support outside of, and separate from what the Board provides for pharmacists and technicians. PEAC submits a monthly tally of cases to Mr. Steve Kreindler in the Board’s compliance office. These figures are presented to the Board at the Board’s monthly public meeting.

At the request of the Board PEAC added a new element titled “unique clients” to the monthly report. This item recognizes that while our monthly total client count fluctuates the report should capture the number of pharmacists, technicians and students brought into the system over the course of the year. The table below summarizes PEAC’s client service activities from July 1, 2009 to June 30, 2010.

		Jun-09	July	August	Sept	Oct	Nov	Dec	Jan-10	Feb	Mar	Apr	May	Jn
total clients		21	20	21	22	22	20	17	16	15	14	13	13	12
pharmacists		13	12	13	14	14	13	11	10	9	8	8	8	8
technicians		3	3	3	3	2	1	1	1	1	1	1	1	0
students		1	1	1	1	1	1	1	1	1	1	1	1	1
# drug tests		54	52	56	57	58	54	52	56	52	52	52	56	54
# positive		2	0	2	0	1	1	2	0	0	0	1	0	0
# clients positive		1	0	2	0	1	1	1	0	0	0	1	0	0
# discharged			2	0	0	0	2	2	1	1	2	1	0	1
cases referred to BOP			0	0	0	1	0	0	0	0	0	0	0	0
new cases			1	1	1	0	0	0	0	0	0	0	0	0
unique clients		21	22	23	24	24	24	24	24	24	24	24	24	24
	pharmacists													
	technicians													
	students													
consent order cases followed		4	4	4	5	5	5	4	4	4	4	3	3	3

**Monitor meetings**

PEAC holds meetings of its monitors along with others who are involved in the functions of PEAC and the implementation of our initiatives, for example planning and executing the annual PEAC seminar. Monitor meetings were held on March 21, 2009, August 24, 2009, February 27, 2010, and May 6, 2010. Monitors are provided a meager stipend for client services. Others provide volunteer, uncompensated time to implement PEAC activities.

**CE program**

PEAC offered a 6.5 hour live CE event on September 26, 2009 at the Maritime Institute in Linthicum Heights, MD. The program entitled Ethical Perspectives in Addiction Intervention and Pharmacy Practice examined policy and clinical practice related to impaired pharmacists from an ethical perspective.

# STATE OF MARYLAND

# BOARD OF PHARMACY



4201 Patterson Avenue

Baltimore, MD 21215

410-764-4755

410-358-9512 FAX

<http://dhmh.maryland.gov/pharmacyboard>

[mdbop@dhmh.state.md.us](mailto:mdbop@dhmh.state.md.us)