

STATE OF MARYLAND

# BOARD OF PHARMACY



## FISCAL YEAR 2011 ANNUAL REPORT

JULY 1, 2010  
THROUGH  
JUNE 30, 2011

Vision:

*To set a standard for pharmaceutical services, which ensures safety and quality healthcare for the citizens of Maryland.*

Mission:

*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 standard for the practice of pharmacy through regulations and legislation; receiving and resolving complaints and educating consumers.*



## FY2011 BOARD OF COMMISSIONERS

President

**Michael Souranis**

*Independent Representative*

Secretary

**Rodney Taylor**

*At Large Representative*

Treasurer

**Lenna Israbian-Jamgochian**

*Chain Drug Store Representative*

**Lynette Bradley-Baker**

*At Large Representative*

**David Chason**

*Acute Care Hospital Representative*

**Harry Finke, Jr.**

*Independent Representative*

**Mitra Gavgani**

*Home Infusion / Home Care Representative*

**Reid A. Zimmer**

*Acute Care Hospital Representative*

**Mayer Handelman**

*Long Term Representative*

**Richard W. Matens**

*Consumer Representative*

**Zeno St. Cyr, II**

*Consumer Representative*

**Donald Taylor**

*Chain Drug Store Representative*

## BOARD COUNSEL

**Linda Bethman, AAG**

**Brett Felter, Staff Attorney**

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<b>EXECUTIVE</b> 410-764-4794	
<b>LaVerne Naesea</b> , Executive Director <b>Vacant</b> , Executive Secretary	Board Operations, Board Members and Board Minutes
<b>ADMINISTRATION</b> 410-764-5929	
<b>Patricia Gaither</b> , Administration & Public Support Manager <b>Janet Seeds</b> , Public Information Officer <b>Anasha Page</b> , Office Secretary <b>Nikki Dupye</b> , Secretary/Receptionist	Fiscal, Budget, Procurement, Travel, Personnel and Public Information
<b>LEGISLATION AND REGULATIONS</b> 410-764-4794	
<b>Anna Jeffers</b> , Legislation and Regulations Manager	Legislation and Regulations and Pharmacy Practice Committee
<b>COMPLIANCE</b> 410-764-5988	
<b>YuZon Wu</b> , Pharmacist Compliance Officer <b>Emory Lin</b> , Pharmacist Inspector <b>Nancy Richard</b> , Lead Inspector <b>Jeannelle McKnight</b> , Inspector <b>Shanelle Young</b> , Inspector <b>Yin Chan</b> , Inspector <b>Vanessa Gray</b> , Compliance Investigator <b>Steven Kreindler</b> , Compliance Coordinator <b>Vacant</b> , Compliance Secretary	Complaints, Pharmacy Practice, Disciplinary, Inspections, Investigations and Pharmacists Rehabilitation
<b>LICENSING</b> 410-764-4756	
<b>Demetrius Daniels</b> , Licensing Manager <b>Doris James</b> , Licensing Specialist <b>Keisha Wise</b> , Licensing Specialist <b>Vacant</b> , Licensing Specialist <b>Lisa Woods</b> , Licensing Secretary	Licensing, Permits, and Registration, Reciprocity, and Scores
<b>MANAGEMENT INFORMATION SERVICES</b> 410-764-4685	
<b>Vacant</b> , MIS Manager <b>Michelle Hsu</b> , Database Officer	Computer, Database and Website and On-line Renewals

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## **REMARKS FROM THE BOARD PRESIDENT**

*Michael Souranis*

Fiscal Year (FY) 2011 Annual Report. This report summarizes the significant activities, accomplishments, and endeavors undertaken in fulfilling the mandate to protect the public health, safety, and welfare of Marylanders. It also reflects the Board's continued commitment for establishing and improving standards for the practice as dictated by health and population trends. As the Board continues to be faced with challenges, such as vacancies, budgetary constraints, and procedural modifications, it remains steadfast in spanning any chasm that it encounters as it awaits and plans for the implementation of its new database. This much needed operational enhancement will increase the Board's efficiency and information capability, while streamlining daily functions, and optimizing resources on both operational and administrative levels.

Legislatively, the Maryland Board of Pharmacy supported a proposal that would have addressed its concern about non-pharmacist practitioners dispensing medications absent meeting the requirements in place for pharmacists and the practice of pharmacy. This practice continues to pose a significant risk to the safety of the patient; particularly when pharmacists and pharmacy services are readily available and duly sanctioned and regulated by the State of Maryland. The Maryland General Assembly has statutorily mandated the Maryland Board of Pharmacy as the appropriate and primary authority to regulate prescription drugs and devices in the State and the Board will continue to support legislation that restricts the ability of non-pharmacists to dispensed prescription drugs and devices under the current unsafe system. The Board was successful however, in supporting HB460/SB770 Prescription Drug Repository Program – Disposal of Prescription Drugs and Medical Supplies, HB986 Pharmacists – Administration of Vaccines – Children, and HB1229/SB883 Prescription Drug Monitoring Program that are discussed in the Legislation/Regulations Unit section of this report. The Maryland Board of Pharmacy has existed since 1902 protecting Maryland consumers and regulating the practice of pharmacy. 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 pharmacies and pharmacists who provide services in our State. Maryland residents who are serviced by nonresident pharmacies are not afforded the same level of protection as Maryland residents whose prescriptions are filled by pharmacies located in Maryland. The Board plans to pursue legislation during FY 2012 to also address this consumer-oriented issue.

Throughout this past year, I have been impressed with the untiring efforts of the Commissioners of the Maryland Board of Pharmacy that give their utmost in the name of service to Marylanders. I am truly pleased and proud to enunciate and commend their myriad deeds and their important contributions that continually stimulate participation, offer constructive dialogue, and create the forum to effectuate the practice of pharmacy in such a manner that help makes the difference in the lives of many people.

In closing, special recognition must be given to Executive Director LaVerne Naesea; Board Counsel Linda Bethman; Staff Attorney Brett Felter; Legislation and Regulations Manager Anna Jeffers and to our dedicated staff for their professionalism, guidance, commitment, and tireless efforts. Let us commence the new fiscal year with an auspicious beginning to yield a productive year.



## **MESSAGE FROM THE EXECUTIVE DIRECTOR**

*LaVerne Naesea*

It is with pleasure that I present the FY 2011 Annual Report on behalf of the Maryland Board of Pharmacy (Board). This report reflects the Board's initiatives and involvements between July 1, 2010 and June 30, 2011. One very important involvement by the Board was its 10-year Sunset Evaluation which began in April 2011. The final report is due in October 2011, and will be presented to the State legislature for review and subsequent action during the 2012 Legislative Session. A Sunset Review is performed for each of the state health occupation boards and commissions every ten years to determine if the board should be re-authorized to regulate the health occupations and industries under their purviews. Prepared by the Maryland Department of Legislative Services (DLS), the final evaluation report will discuss the Board's regulatory, statutory, operational and program involvements since the last review in 2001.

Those of you who have observed or worked with the Board as a licensee, task force member, agency representative, State legislator, or perhaps, as a former Board member or employee, have witnessed the Board's efforts and challenges over the past ten years. You've seen the Board address societal and industry trends that posed risks to the safety net established to protect Maryland's pharmacy patients. Such initiatives have included steps to: address potential pharmacist shortages, monitor the growth in the sale of prescription drugs, decrease medication and prescribing errors, and avert diversion, counterfeiting and illegal prescriptions drug sales. You may have commented on proposed regulations related to sterile compounding, electronic prescribing, pharmaceutical specialties, home infusion, prescription drug repositories, patient safety and quality assurance; or supported Board efforts in planning, implementing and/or expanding key programs (including: registration of pharmacy technicians, tightening requirements for wholesale prescription distribution into and out of Maryland, establishing collaborative practice, and the Board's assumption of direct responsibility for inspections of pharmacies and wholesale distributors).

Securing the operational infrastructure to sustain these initiatives became one of the Board's most complicated and greatest challenges in FY 2011. Adequate staffing, enhanced data management systems and Board and staff training and development for addressing aspects of the many new program areas, were needed to meet the growing demand for patient protection. A key effort in 2011 was to improve the Board's efficiency and accountability for processing applications – particularly related to pharmacy technicians and wholesale distributors. The Board had anticipated that its new database system would have been fully implemented before assuming responsibility for registering pharmacy technicians and expanding authority for wholesale distribution in Maryland. The system would have also helped streamline the Board's inspection processes. Due to a series of unfortunate events, implementation of the system was not completed in FY 2011; thus staff members continue manually process information collected and received at the Board.



The Board's Practice, Disciplinary and other committees also began tackling several new initiatives begun in FY 2011, specifically related to: developing sanctioning guidelines for disciplinary actions; revising regulations to better address recent trends; developing statutory proposals to close loop holes and ensure better monitoring of drug dispensing and distribution in Maryland; updating the Board's web-site to accommodate the Department's planned transition to an agency encompassing SharePoint portal; reviewing and enhancing the Board's contractual relationships (e.g., pharmacist rehabilitation, network support, etc.); and developing strategies to ensure that existing programs continued with limited interruptions and adequate support (i.e., Drug Therapy Management, Registration of Technicians, Wholesale Distributions, Prescription Repository, Pharmacists Administration of Vaccines).

Goals pursued in FY 2011 and that will continue to be pursued during FY 2012 include: fully implementing the new SQL-based Management Information System (MIS); streamlining all of the Board's licensing processes, improving coordination and processes between the Board of Pharmacy and other state units and entities (e.g., other Health Occupation Boards, PEAC, and Division of Drug Control); and strengthening the Board and staff members' capacities through training and revisions to standard operational procedures. Continued support from legislators, Department representatives, licensees and the public is necessary to assure the Board's success in meeting these goals.

June 31, 2011 ended another very active, challenging, but productive chapter in the Board's hundred and nine (109) year history. The commitment of Board and staff members in preparing legislation and regulations for complicated new program areas; managing budgets, procuring contracts and equipment and arranging appointments and interviews for new staff; processing a two-fold increase in licensing applications; taking on annual and biennial inspections and increased complaint investigations; writing programs and preparing legacy information for the new data base system; responding to increasingly high volumes of phone calls and requests for public information; and attending and staffing meeting, after meeting, after meeting.... has been no less than awesome!! I must acknowledge and thank each Board and staff member for performing with little protest and much enthusiasm!!

In closing, the Board also thanks those who continue on this *patient safety* journey and welcomes aboard all new supporters. As the Maryland Board of Pharmacy continues to enhance its infrastructure in FY 2012, the ride into the real "age of technology" promises to be much smoother!

## ADMINISTRATION AND PUBLIC SUPPORT UNIT REPORT

### **OVERVIEW**

The Administration and Public Support Unit (APS) consisting of four professional staff persons, a Manager, a Public Information Officer, an Assistant to the Manager and a Secretary/Receptionist is responsible for managing four key administrative functions at the Board, which include: fiscal, personnel, procurement, and public information and educational activities. APS also makes recommendations regarding the Board's annual budget and audit functions. 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 of the Department of Health and Mental Hygiene, the Governor's office and subsequently by the State Legislature. Funding for new program areas, personnel and procurement are routinely included in the Board's budget request. Based on the budget request the Board is allocated a certain amount of monies for expenditures. The Board's budget allocation for fiscal year 2011 was \$2,539,794. In July 2011 the Board submitted a Request for Budget Deficit to increase the allocation by \$366,500 to purchase and install an integrated, automated database system since the previous database contract was terminated due to numerous cost and time overruns. In April 2011 the budget allocation for fiscal year 2011 was amended to 2,906,294 to include the \$366,500.

Board fiscal functions include collection of fees from licensees and permit holders and revenue and budget reconciliation activities. Other fiscal functions include the processing of contractual agreements, procurement of equipment and supplies, payment of invoices and travel requests, expense reports and vehicle mileage reports and inventorying and archiving documents for the Board. Fiscal activities also include reviewing proposed legislations and preparing fiscal notes.

Additionally the APS unit plans all personnel and educational activities for Board employees including: communicating personnel policies, preparing personnel documents, retaining confidential personnel records, processing personnel timesheets and staff training development.

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.

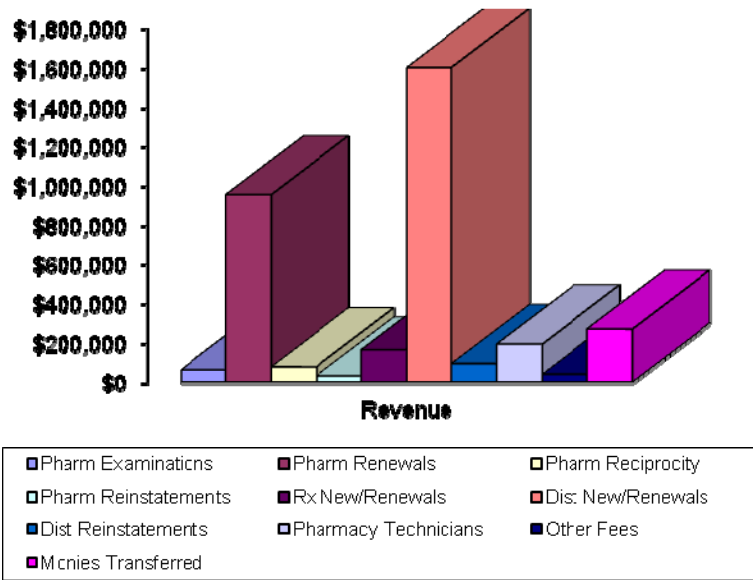
### **FISCAL**

#### Revenue

Total revenue collections for fiscal year 2011 were \$3,210,246. However \$267,687 of the revenue collections were transferred out of the Board's revenue for BRFA (BRFA is The Budget Reconciliation and Financing Act implemented to balance the budget and to make significant progress in resolving the structural budget gap). Therefore, the total revenue collections credited to the Board of Pharmacy for FY 11 were \$2,942,559. The revenue collected reflects the changes in the renewal periods for pharmacy and distributor establishments from every year to biennial alternate years. The Board collected fees for distributor establishments in fiscal year 2011. In fiscal year 2012 the Board will collect fees for pharmacy establishments.

### FY 2011 Revenue Detail

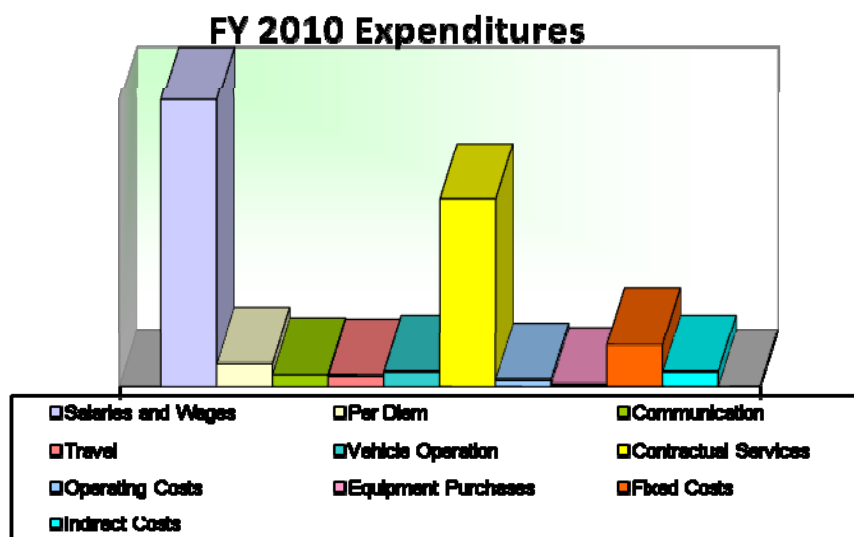
<b>Revenue Carryover from Fiscal Year 10</b>	<b>1,071,433</b>
<b>Total Collections FY 2011</b>	<b>3,210,246</b>
Pharmacist Examination	61,670
Pharmacist Renewals	952,523
Pharmacists Reciprocity	76,610
Pharmacist Reinstatements	30,456
Pharmacy New/Renewals	163,200
Distributor New/Renewals	1,601,260
Distributor Reinstatements	93,000
Pharmacy Technicians	191,832
Other Fees	39,695
Monies Transferred out of Revenue for BRFA	(267,687)
<b>TOTAL REVENUE COLLECTIONS CREDITED TO THE BOARD OF PHARMACY FY 2011</b>	<b>\$2,942,559</b>



### Expenditures

Board expenditures for FY 2011 were 2,522,902. This is an 18% increase in expenditure activity from the previous year. The increase was due to the services provided for the database contract and the purchase of two new hybrid vehicles.

FY 2011 Expenditure Detail	
Salaries and Wages	1,440,811
Per Diem	77,670
Communication	41,244
Travel	36,401
Vehicle Operation	50,520
Contractual Services	650,930
Operating Costs	22,529
Equipment Purchases	6,620
Fixed Costs	145,960
Indirect Costs	50,217
<b>TOTAL EXPENDITURES</b>	<b>2,522,902</b>



## 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 2011. Due to resignations and staff transfers the Board experienced six (6) vacancies in FY 2011. These positions are expected to be filled early FY 2012.

## PROCUREMENT

In November 2010 the Board contracted Systems Automation/Gantech to efficiently complete the Board's data base project. This project is expected to be up and running early Fiscal Year 2013. 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. In fiscal year 2011 the Board also continued its contracts with Maryland State Archives to provide service web hosting

and web statistics, The League for the printing of the Board's newsletter and National Association of Boards of Pharmacy (NABP) to perform the inspections of out of state pharmacy establishments.

#### PUBLIC INFORMATION AND EDUCATION

The Public Information Officer (PIO) 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 PIO functions. 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 PIO coordinates responses to all requests made to the Board under the Public Information Act (PIA). The PIA allows certain Board information to be released regarding licensees and Board activities. There were 49 PIA requests responded to in FY11. The PIO is responsible for ensuring that information released does not violate state and federal confidentiality rules.

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

#### FY 2011 Summary of Training/Education Opportunities

- October 2010 – Pharmacist Continuing Education Brunch, Baltimore, MD

#### FY 2011 Summary of Public Relations Activities

- May 2011 – Flower Mart Exhibit in partnership with the Maryland Pharmacy Coalition, the University of Maryland School of Pharmacy, the Notre Dame University School of Pharmacy, and the University of Maryland Eastern Shore School of Pharmacy
- June 2011 – Maryland Pharmacist Association (MPhA) Exhibit, Ocean City, MD

#### FY 2011 Summary of Emergency Preparedness Activities

- Participated monthly on the State RSS Committee.
- Was an active agency in the State's CDC annual review.
- Worked in coordination with DHMH and other State agencies in writing the State's RSS Emergency Plan including pharmacists as active participants in protecting the citizens of Maryland during emergency situations.

### NEXT YEAR AT A GLANCE

The Board projects a decrease in revenue for FY 2012 based on anticipated pharmacy renewal fees expected to be collected in FY 12. The fees will be collected from pharmacy renewals are less than those collected from wholesale distributor renewals.

Board expenditures are anticipated to increase due acquisition and installation of the new Database System. Full implementation of the new system is expected in FY 2013. The Board will continue training, educational and emergency preparedness activities. To help maintain a focus on quality and efficiency, the Unit will also coordinate a Board and Staff retreat in FY 2012. The Board expects to heighten visibility on pharmaceutical related patient safety throughout the state via its public information and education program and emergency preparedness activities.

## LICENSING UNIT

### *Overview*

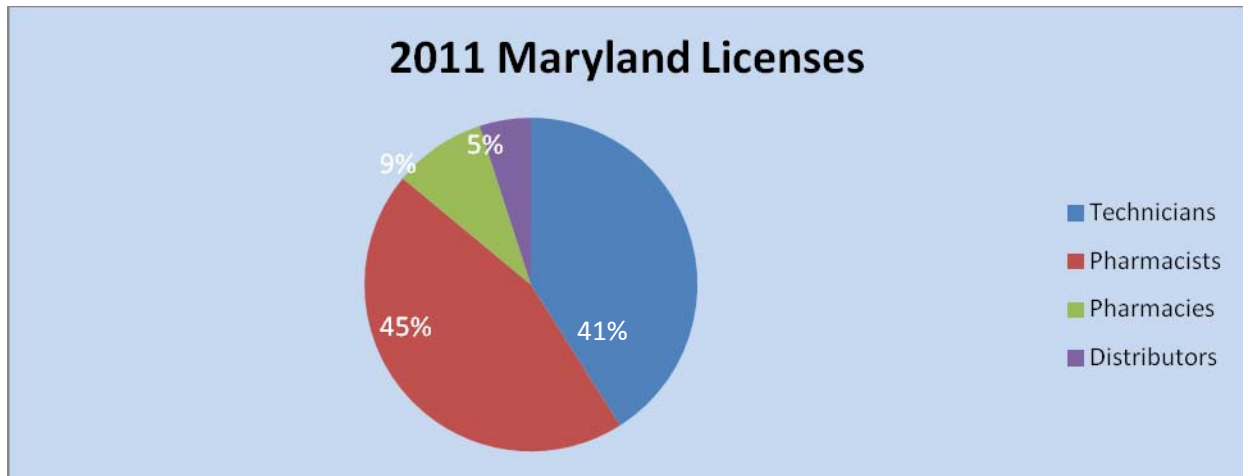
The Licensing Unit is responsible for all activities related to the issuance of new and renewed licenses, permits and registrations to qualified pharmacists, pharmacy technicians, pharmacy owners and pharmaceutical distributors that operate or practice in Maryland. The Unit also processes applications for the Prescription Drug Repository Program as well as for qualified pharmacists to administer Influenza, Herpes Zoster, and Pneumococcal Pneumonia Vaccinations. The Licensing Unit consists of five professional licensing staff persons: a Manager, three (3) Licensing Specialists and a Secretary.

### *New Developments*

FY 2011 was also the first year that registered technicians were required to renew. This has increased the workload for Licensing Unit staff members who are required to process a significant number of first-time applicants. Amendments to the Distribution Permitting and Prescription Drug Integrity Act, proposed and approved by the FY2010 Maryland legislature, required out-of-state distributors to be accredited by a board-approved accreditation organization if they did not qualify for reciprocity in Maryland. This cost saving measure was necessitated in order for the Board not to be required to fund staff or contractors to perform inspections of out of state distributors.

### *Statistics*

The Licensing Unit processed applications and other required documents that served a total of 19,494 licensees. This number included 8,815 pharmacists; which reflects an increase of 203 since the end of FY 2010. When the two newest schools of pharmacy, Notre Dame University School of Pharmacy and the University of Maryland Eastern Shore School of Pharmacy, begin graduating pharmacy students in 2013 along with graduates of the long-standing University of Maryland School of Pharmacy, the Board anticipates an even greater increase in the number of pharmacists applying to practice in Maryland. Pharmacies licensed in Maryland grew by 86 to a total of 1,766 at the end of the fiscal year, while the number of wholesale distributors licensed at the end of the year decreased slightly from 872 to 861. The decrease may have been attributable to time lags experienced by a few renewing permit holders in acquiring VAWD accreditation following the change in the statute. As expected, the number of registered pharmacy technicians increased the greatest from 7,188 to 8,052 in FY 2011; an increase of 864. These significant increases in technician registrations are not expected to level off for several more years, as members of this group continue to meet eligibility requirements under the three year old statute. The chart below provides a breakdown of the percentage of each group licensed in Maryland.



### *Accomplishments*

Following challenges presented in FY 2010 related to staffing vacancies and the need for enhanced procedures for processing criminal background reports and evaluating technician training programs, the Unit was able to secure permanent staff for most of FY 2011. The unit was further challenged because the Board's new SQL-based database system was not completed in FY 2011 and Licensing Unit staff continues to employ many manual functions to process licensing applications. Despite all of these challenges, all categories of applications were revised in FY 2011 to capture essential information using a uniform template. The Licensing Unit has also continued to successfully update all of its licensure procedures to complement the new business rules anticipated when the new automated database project is completed.

### *Next Year At A Glance*

New processes are being established to expedite dissemination of information to the public through a new SharePoint web access portal anticipated to be installed by the Department of Health and Mental Hygiene for all units and agencies under its umbrella. The Board of Pharmacy anticipates its web site to also convert to the SharePoint software in FY 2012. It will allow more rapid access to licensee information including:

- On-line licensure for renewing pharmacists;
- Downloadable applications and forms;
- Downloadable PDF documents of all Public Board actions;
- Lists of programs and localities for the Board approved Pharmacy Technician Training and Prescription Drug Repository programs;
- Verification information for all licensees; and
- Blank Inspection Reports for Establishments.

As had been projected in last year's Annual Report, all new formatting has been completed so it can be migrated from the Unit's current multitude of independent databases to the Board of Pharmacy's new SQL-based system. Unit staff received some training during FY 2011 in preparation for use of the new system and will receive additional training during FY 2012. This will be required because, in addition to the required new business rules, new standard operating procedures (SOPs) will also need to be employed by Licensing staff to



assure a smooth transition to and successful use of the SQL-based system. The Licensing staff projects greater efficiency and speed in processing submitted data. In addition, there should be considerably fewer errors resulting from the new system as it will support a single point for new data entry and eliminate the need for duplicate entry of data as is currently experienced. The Licensing Unit will continue its commitment in FY 2012 to providing efficient, quality services to new and renewing Board of Pharmacy licensees, permit holders, registrants and other applicants requiring support from the Board.

## 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, pharmacist inspector supervisor, compliance coordinator, compliance investigator, four (4) compliance inspectors, and a unit secretary. 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

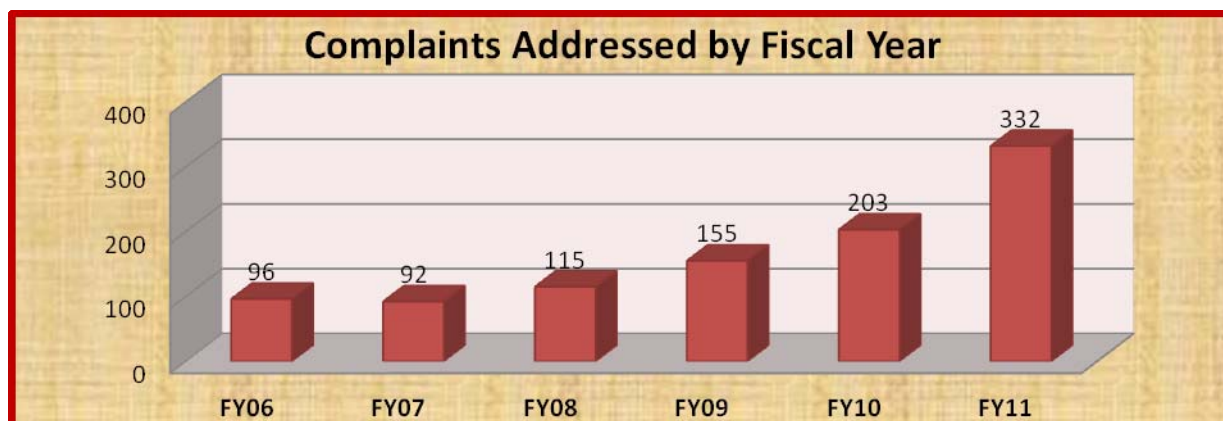
The Unit experienced several personnel concerns that affected certain operations. Specifically, the Board Compliance Manager and one of the inspector positions were vacant throughout the first half of the fiscal year. Despite these setbacks, the Unit was able to provide additional training to staff members, implement a post-inspection evaluation process to assure efficient inspections, and support the Board in developing more uniform complaint reviews.

### Complaints

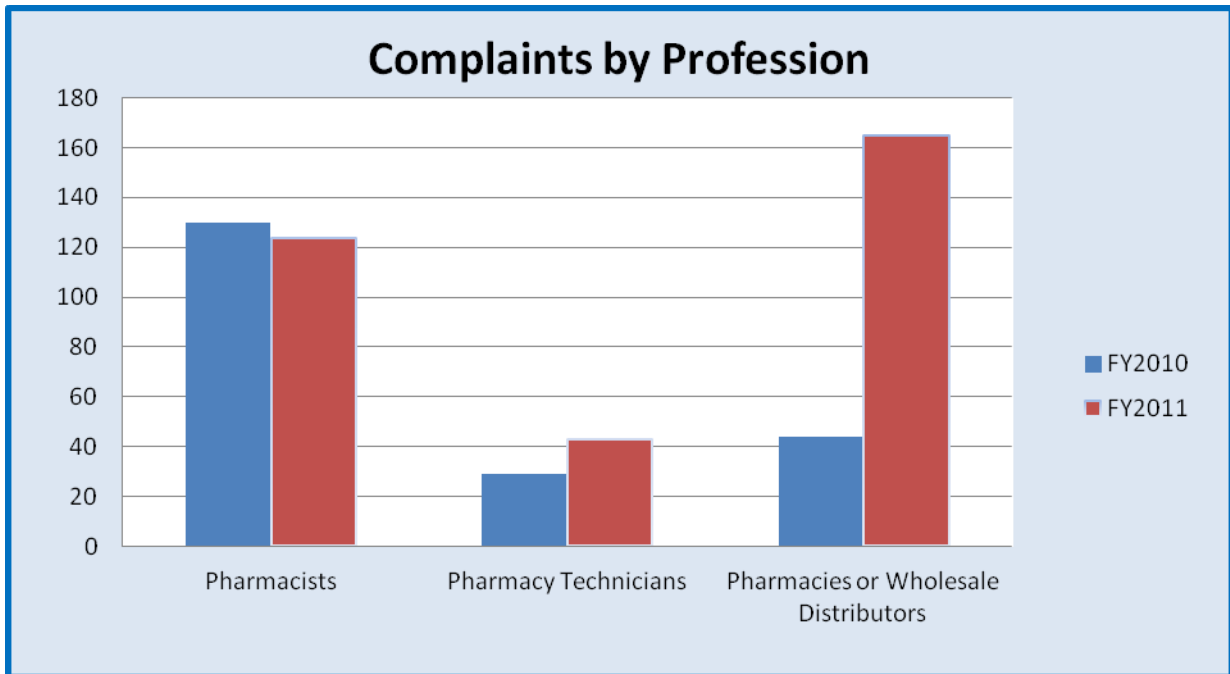
The compliance Unit receives complaints from a variety of sources and is charged with addressing each complaint. An individual may obtain a complaint form from the Board of Pharmacy website at [www.dhmh.maryland.gov/pharmacy](http://www.dhmh.maryland.gov/pharmacy) and may file a completed complaint form via fax, mail, email, or in person. 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 the Board's scope or jurisdiction, the complaint will be referred to the appropriate authority.

Figure 1, below, shows the number of complaints processed in each of the last six fiscal years. Compared to previous years, the highest number of complaints was processed in FY 2011, representing a 165% increase over the previous year's processed complaints and an almost 350% increase since FY06.

**Figure 1**      **Complaints Processed July 1, 2010-June 30, 2011**

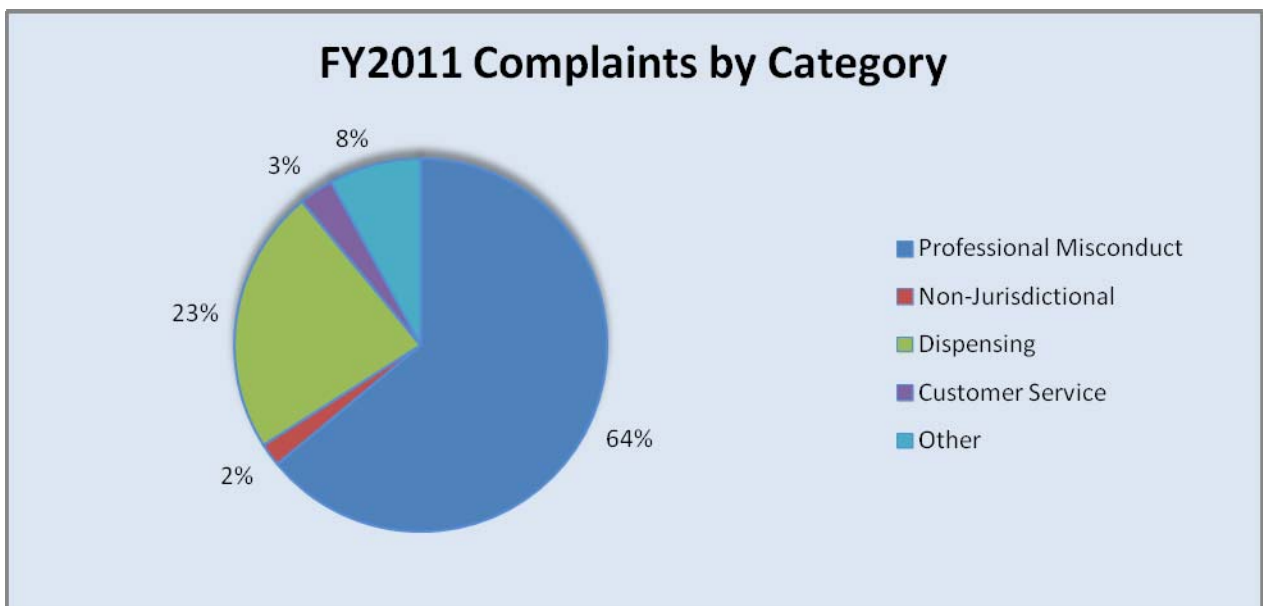


**Figure 2**      **Complaints against Licensees, Registrants, and Permit Holders**



This is the 3<sup>rd</sup> year that the Maryland Board of Pharmacy has registered technicians. As a result, technician compliance monitoring is also under the Board’s purview. Figure 2, above, reveals that 13% of the complaints filed in this fiscal year were against pharmacy technicians. This is three times higher than in fiscal year 2009, but comparable to fiscal year 2010.

**Figure 3** Types of Complaints July 1, 2010-June 30, 2011



The types of complaints received are broadly categorized (see Figure 3). The majority relates to professional misconduct, followed by dispensing errors. There was a significant increase in professional misconduct

compared to previous years that related mostly to establishments for FY2011. Violations from annual inspections, employing unlicensed personnel, and unauthorized dispensing are a few examples of professional misconduct complaints related to establishments.

### Disciplinary Cases

All complaints are investigated by Board staff members. Approximately 60% 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 letters 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 40% of complaints remained open, pending more investigations at the close of FY 2011. One reason for this was that the compliance unit was without a Compliance Officer for the first 7 months of the fiscal year. Also the Supervising Pharmacist Inspector became a half time employee. This Pharmacist Supervising Inspector, who usually performed investigations in addition to inspections, had to allocate more time doing inspections due to an inspector vacancy and investigator vacancy for the first 7 months and 10 months respectively of this fiscal year. Figure 4 shows the number of formal and informal actions taken for Fiscal Year 2011, compared to the previous 5 years.

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

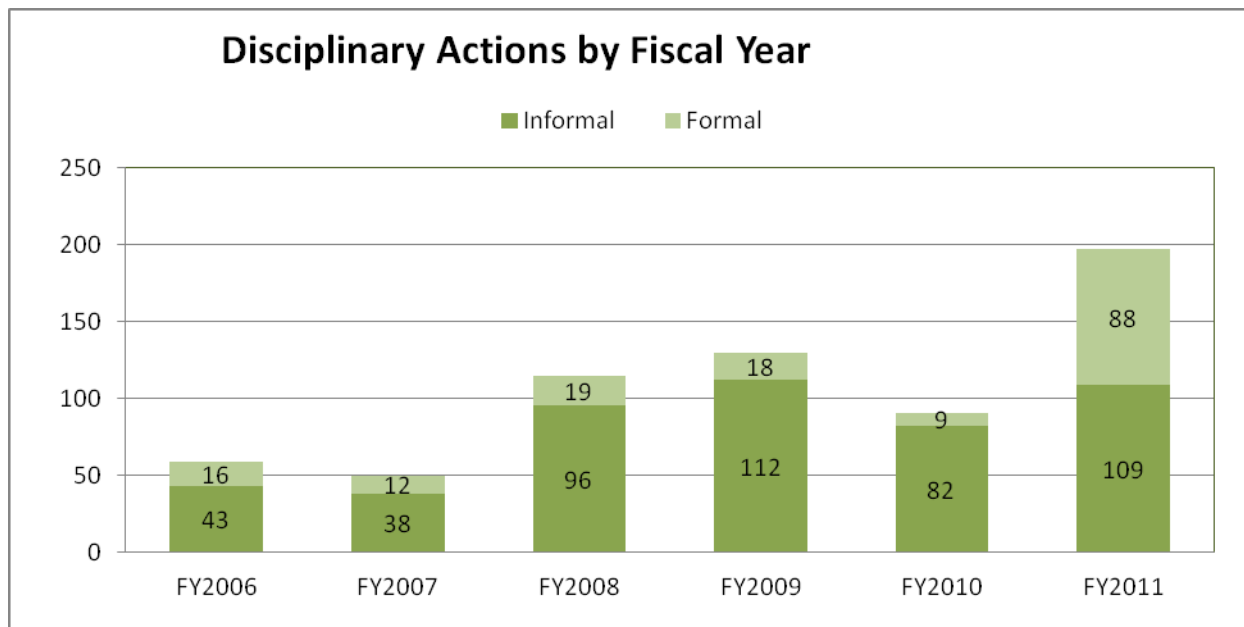
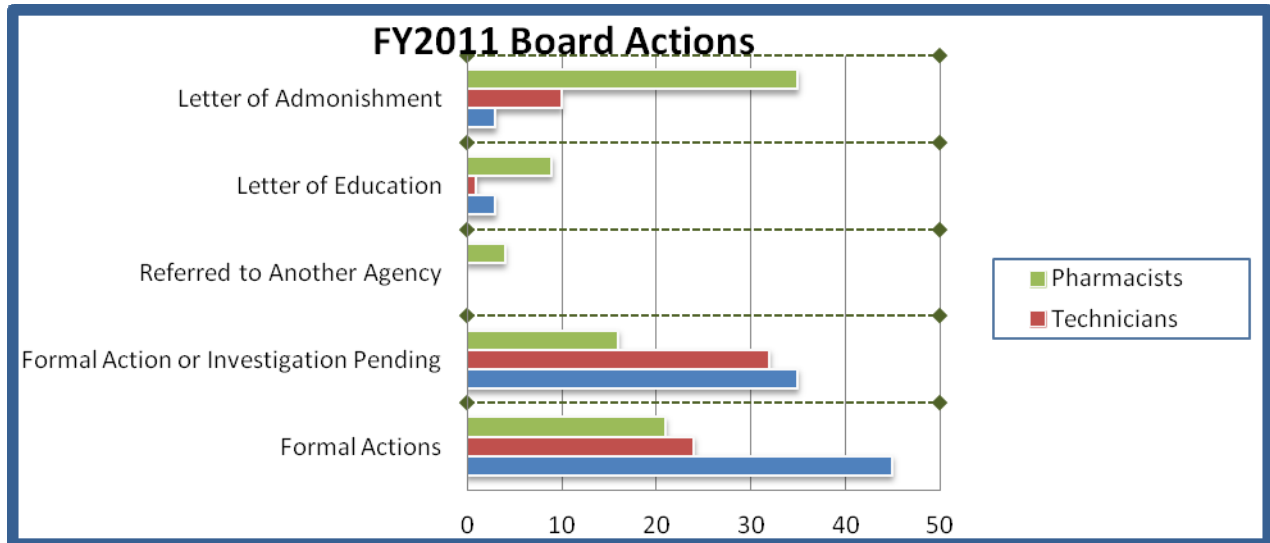


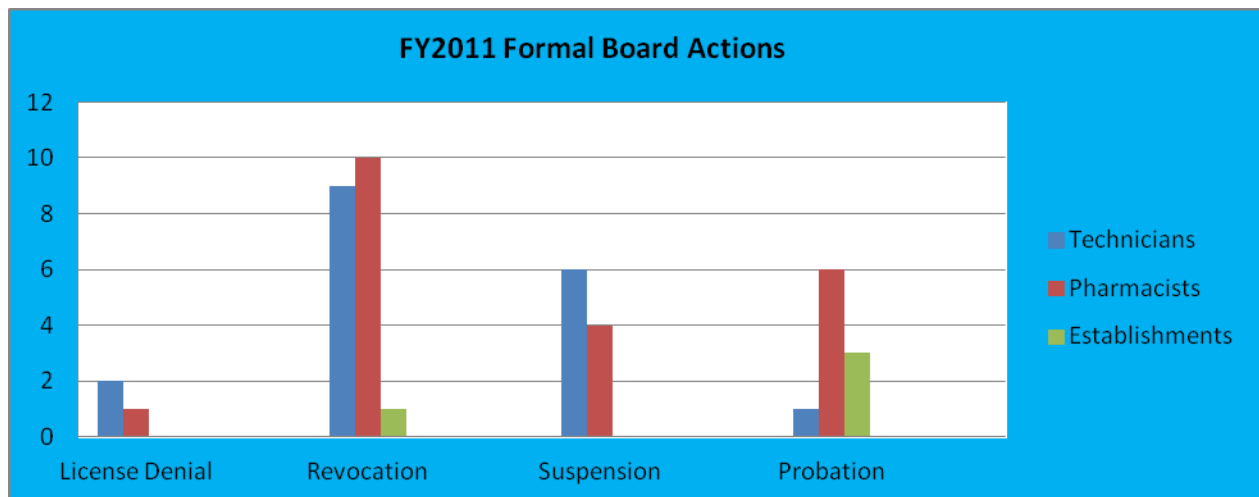
Figure 5 represents a categorical description of the various types of formal and informal actions taken against pharmacists, pharmacy technicians, and establishments in the most recent fiscal year.

**Figure 5 Board Action July 1, 2010-June 30, 2011**



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 2011. (Formal actions against licensees or permit holders that were exclusively fines are excluded from Figure 6.) All 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, 2010-June 30, 2011**



## 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 2011.

**Figure 7**

Annual Inspections	1073
Opening Inspections	76
Total Inspections	1149

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 2011, the Board of Pharmacy inspected 139 wholesale distributor facilities located in Maryland. 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.

## Practitioners, Substance Abuse and Compliance Monitoring

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/registrants which include but are not limited to:

- random drug testing
- substance abuse treatment or psychotherapy
- participation in local NA/AA programs
- psychiatric evaluations
- employer reports
- continued education (CE) requirements
- any exams or courses as deemed necessary by the Board

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 2011, the Board monitored 10 pharmacists and 1 pharmacy technician who were under Board Orders that involved substance abuse. The Board will also monitor registered pharmacy technicians who are issued public orders for actions involving substance abuse. There was 1 public order related to substance abuse issued to the registered pharmacy technician during Fiscal Year 2011.

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 anonymously and voluntarily request substance abuse assistance. Individual assistance provided by PEAC is confidential, with monthly aggregate reports provided to the Board. Each client served by PEAC is required to sign a contract indicating that he or she understands that the Board of Pharmacy will be notified if they violate the terms of their contracts.

In Fiscal Year 2011, PEAC monitored a combined total of 25 clients: 23 pharmacists and 2 pharmacy technicians.

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

For Fiscal Year 2012, the Compliance Unit plans to:

- provide additional training to staff;
- implement feedback from establishments regarding their inspection experience;
- reduce the 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 of excessive delays, cost overruns and staffing issues that resulted in the vendor's contract being terminated.

### **Accomplishments**

The MIS Unit diligently worked 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 new licenses of pharmacists 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 submissions 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. Their computers connect with the Board's network database.

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**

### **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, which consists of a Manager and Administrative Assistant, 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, Drug Therapy Management and Legislative.

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 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 2011 the Unit responded to 1,934 phone calls and provided written responses to 648 e-mail inquiries.

### **Legislative Initiatives**

During the interim period before the Maryland Legislative Session begins, the Unit assists the Board as it determines whether 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 (EHE) Committee’s Chairman and the House Health and Government Operations (HGO) Committee’s 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 30 bills (of approximately 2,350 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 16 of the 30 bills. Below is provided a chart of the 16 bills (companion bills are counted as one bill) and the results.

<b>Bill #</b>	<b>Bill Name</b>	<b>Result</b>
HB 3	Pharmacies – Taking Back and Disposing of Unused Drugs	Failed
SB 570	Pharmacies – Taking Back and Disposing of Unused Drugs	Withdrawn
HB 82	Health Care Decisions Act – “Medical Orders for Life-Sustaining Treatment” Form	<b>PASSED</b>
SB 203	Health Care Decisions Act – “Medical Orders for Life-Sustaining Treatment” Form	<b>PASSED</b>
SB 237	Criminal Law – Selling a Controlled Dangerous Substance to a Minor – Causing Death	Failed
HB 359	Criminal Law – Selling a Controlled Dangerous Substance to a Minor – Causing Death	Failed
HB 291	Public Health – Maryland Medical Marijuana Model Program Work Group	<b>PASSED</b>
SB 308	Public Health – Affirmative Defenses – Maryland Medical Marijuana Model Program Work Group	<b>PASSED</b>
SB 560	Health Occupations – State Board of Naturopathic Medicine	Failed
HB 1100	Health Occupations – State Board of Naturopathic Medicine	Failed
HB 460	Prescription Drug Repository Program – Disposal of Prescription Drugs and Medical Supplies	<b>PASSED</b>
SB 770	Prescription Drug Repository Program – Disposal of Prescription Drugs and Medical Supplies	<b>PASSED</b>
SB 698	Pharmacy Benefits Managers – Specialty Drugs	Failed
HB 1144	Pharmacy Benefits Managers – Specialty Drugs	Failed
SB 700	Pharmacies – Delivery of Controlled Dangerous Substances	Failed
HB 1149	Pharmacies – Delivery of Controlled Dangerous Substances	Withdrawn
SB 701	Health Insurance – Prescription Eye Drops – Refills	<b>PASSED</b>
HB 888	Health Insurance – Prescription Eye Drops – Refills	<b>PASSED</b>
SB 713	Pharmacists – Administration of Vaccines – Regulations	Failed
SB 769	State Board of Pharmacy – Pharmacists – Practice of Pharmacy and Licensure	Withdrawn
HB 549	State Board of Pharmacy – Pharmacists – Practice of Pharmacy and Licensure	Withdrawn
HB 986	Pharmacists – Administration of Vaccines – Children	<b>PASSED</b>
HB 1051	Freestanding Pain Management Clinics – Regulation	Failed
SB 845	Pharmacists – Administration of Vaccines – Children	<b>PASSED</b>

SB 884	Prescription Drugs – Dispensing Permits	Withdrawn
HB 1268	Prescription Drugs – Dispensing Permits	Withdrawn
HB 1338	Health Insurance – Pharmacy Benefits Managers – Contracts, Disclosures, and Audits	<b>PASSED</b>
SB 974	Health Insurance – Pharmacy Benefits Managers – Contracts, Disclosures, and Audits	<b>PASSED</b>

**Summaries of major bills from the 2011 Legislative Session are provided below.**

**HB460/SB770 Prescription Drug Repository Program – Disposal of Prescription Drugs and Medical Supplies** This legislation expanded the purpose of the Prescription Drug Repository Program to include the return of prescription drugs and medical supplies to a pharmacy for the purpose of proper disposal in addition to the current Board intent that they be returned for the sole purpose of dispensing to indigent patients. Any pharmacy that volunteers to be a disposing pharmacy would be required to apply to the Prescription Drug Repository Program. The prescription drugs and medical supplies will be disposed of in accordance with State and federal law. The Board asked that this legislation be introduced and it passed.

**HB888/SB701 Health Insurance – Prescription Eye Drops – Refills** This legislation required that health insurers and health maintenance organizations provide coverage for refills of prescription eye drops when the refill is requested by a patient less than 30 days after the later of the date the original prescription was dispensed to the patient or the date the last refill of the prescription was dispensed to the patient. It required that health insurers and health maintenance organizations provide coverage for refills of eye drops when the prescribing health care practitioner indicates on the original prescription that additional quantities of the prescription eye drops are needed. Additionally, HB 888 required that health insurers and health maintenance organizations provide coverage when the refill requested by the patient does not exceed the number of additional quantities indicated on the original prescription by the prescribing health care practitioner. Finally it required coverage when the prescription eye drops prescribed are a covered benefit under the policy or contract of the patient. The Board supported this legislation because pharmacists see firsthand the need of patients, especially elderly patients, for additional eye drops before the schedule time to refill their prescriptions. This legislation passed.

**HB986 Pharmacists – Administration of Vaccines – Children** This legislation lowered the age in which a pharmacist may administer a vaccine, from an individual who is an adult, to an individual who is at least 9 years old. Regulations are to be promulgated in consultation with the Department of Health and Mental Hygiene. A pharmacist will also be required to report to the Maryland Immunization Registry an influenza vaccination administered by the pharmacist to individuals who are from 9 to 18 years of age. This legislation passed.

**HB1149/SB700 Pharmacies – Delivery of Controlled Dangerous Substances** This legislation required pharmacies that dispense and deliver Schedule II controlled dangerous substance prescriptions to patients to require an adult to sign for the controlled dangerous substance when delivered to a residence. This legislation would prevent the theft of Schedule II controlled dangerous substances from mailboxes or interception by minors living in the home. This legislation failed.

**HB1229/SB883 Prescription Drug Monitoring Program** This legislation established the Prescription Drug Monitoring Program in the Department of Health and Mental Hygiene. It required the Program to carry out its mission by monitoring the prescribing and dispensing of specified substances by specified prescribers and dispensers. It also established the Advisory Board on Prescription Drug Monitoring to assist in the design, implementation, and evaluation of the Program. This legislation passed.

**Regulatory Initiatives**

The Unit assists in revising the Board’s regulations as needed. 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 2011:

<b>COMAR Citation</b>	<b>Title</b>	<b>Effective Date</b>
10.34.05	Pharmacy Security	July 1, 2010
10.34.07	Pharmacy Equipment	July 1, 2010
10.34.12	Removal of Expired Medications	July 1, 2010
10.34.13	Reinstatement of Expired License for Pharmacists	July 1, 2010
10.34.15	Licensure by Reciprocity	July 1, 2010
10.34.18	Continuing Education for Pharmacists	July 1, 2010
10.34.20	Format of Prescription Transmission	October 4, 2010
10.34.23	Pharmaceutical Services to Patients in Comprehensive Care Facilities	June 1, 2011

Pursuant to the **Regulatory Review and Evaluation Act**, throughout Fiscal Year 2011, Board subcommittees continued to revise COMAR 10.34.03 Inpatient Institutional Pharmacy 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. Numerous meetings between the Board of Pharmacy and the Boards of Dental Examiners, Podiatric Medical Examiners, Physicians, and the Division of Drug Control. HB 1228/SB 884 introduced in the 2011 Legislative Session. The EHE Committee requested that the issue be worked out during the interim.

10.34.01	Disciplinary Proceedings	Ongoing Board Subcommittee meeting to determine Sanction guidelines pursuant to HB 114 Health Occupations Boards – Revisions, 2010, Chapter 534.
10.34.03	Inpatient Institutional Pharmacy	Released for informal comment in June 2009. Proposal published June 3, 2011.
10.34.25	Delivery of Prescriptions	Proposal submitted to the Department for sign-off June 21, 2010. Meeting with Secretary Sharfstein May 17, 2011. Proposal resubmitted to department for sign-off on July 28, 2011 and anticipated to be published October 21, 2011.
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.  Published January 14, 2011. Comment received and the Board recommended withdrawing proposals and submitting anew. Revisions released informally June 21, 2011.
10.34.35	Infusion Pharmacy Services in an Alternate Site Care Environment	Task Force meeting regularly to draft regulations. Proposed regulations submitted to the Department on April 26, 2011. Anticipated to be published August 12, 2011.

**Summaries of regulatory changes that became effective in FY 2011 are provided below.**

**10.34.05 Pharmacy Security; 10.34.07 Pharmacy Equipment; 10.34.12 Removal of Expired Medications; 10.34.13 Reinstatement of Expired License for Pharmacists; 10.34.15 Licensure by Reciprocity; 10.34.18 Continuing Education for Pharmacists**

These COMAR chapters were revised pursuant to the Regulatory Review and Evaluation Act. COMAR 10.34.05 Pharmacy Security revisions included increased requirements for pharmacy security and adding to whom one should report when drugs or devices are stolen. COMAR 10.34.07 Pharmacy Equipment revisions included defining material safety data sheets and adding, where applicable a) freezers; b) material safety data sheets; and c) utilization of websites as supplemental reference materials. COMAR 10.34.12 Removal of Expired Prescription Drugs revisions included reflecting that the Board no longer regulates manufacturers or the act of manufacturing, yet regulates manufacturers if they distribute prescription drugs or devices into Maryland. COMAR 10.34.13 Reinstatement of Expired Licenses for Pharmacists revisions included amending the name of the licensing exam to refer to the Multistate Pharmacy Jurisprudence Examination (MPJE).

COMAR 10.34.13 Reinstatement of Expired Licenses for Pharmacists revisions included:

- deleting the definition of “Practice of Pharmacy Reinstatement Examination” since it is obsolete;
- amending reinstatement requirements so that it is clear what is expected for pharmacists applying for reinstatement after 2 years and before 5 years, between 5 and 10 years, and for 10 years or more after license expiration;
  - adding that in addition to the general requirements for reinstatement for between 2 and 5 years, the licensee has to pass the MPJE;
  - adding that in addition to the general requirements for between 5 and 10 years, the licensee has to pass the MPJE, and submit evidence satisfactory to the Board of having performed 1,000 hours of service in a pharmacy with a valid pharmacy permit under the supervision of a licensed pharmacist; and
  - adding that in addition to the general requirements for 10 years or more, the licensee has to pass the Multistate Pharmacy Jurisprudence Examination (MPJE), submit evidence satisfactory to the Board of having performed 1,000 hours of service in a pharmacy with a valid pharmacy permit under the supervision of a licensed pharmacist, and pass NAPLEX examination.

COMAR 10.34.15 Licensure by Reciprocity revisions include correcting Regulation .01A(4) to reflect the current practice of taking the MPJE.

**COMAR 10.34.20 Format of Prescription Transmission**

This chapter was revised to reflect verification of electronic prescriptions through an electronic intermediary certified by the Maryland Health Care Commission. The revisions included clarification of the manner in which prescriptions may be transmitted and a rewording of record-keeping requirements.

**COMAR 10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities** This chapter was revised to reflect the current practice of pharmacy in a comprehensive care facility and to revise outdated terminology and regulatory references. The revisions deleted the broader definition of “long term care facility” and added the definition of “comprehensive care facility”, which narrows the focus of these regulations to facilities that admit patients suffering from disease, disabilities, or advanced age, requiring medical service and nursing service rendered by or under the supervision of a registered nurse. The policies and procedures of the permit holder must now include access to a pharmacy, provisions for safe and efficient dispensing and delivery, and appropriate labeling and storage. Requirements were added for packaging medications received from another pharmacy. The regulation that covers drug control and accountability now sets forth requirements for (1) returns and discontinued medications; and (2) the content of prescriptions, chart orders, and verbal orders; and (3) the manner in which prescriptions, chart orders, and verbal orders are received by the pharmacy.

### **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; and
- Other legislative reports as required.

### **Year at a Glance (Projections for FY 2012)**

The Unit will be busy in the beginning of Fiscal Year 2012, preparing two legislative reports due January 1, 2013. Those reports are:

- 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 also anticipates a busy legislative session as the Board continues to strengthen protection for Maryland citizens who are dispensed prescription medications from a variety of entities including, in-state and out-of-state pharmacists and pharmacies, physicians, dentists, podiatrist, and nurses. The Board will also continue to review laws and regulations that govern the settings and practices of the professions it regulates during FY 2012.**



## NOTES

## NOTES



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