STATE OF MARYLAND

BOARD OF PHARMACY

FISCAL YEAR 2012

ANNUAL REPORT

July 1, 2011

through

June 30, 2012

Vision:

To set a standard for pharmaceutical service 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 standards for the practice of pharmacy through regulations and legislation; receiving and resolving complaints and educating consumers.

FY 2012 BOARD OF COMMISSIONERS

President
Michael Souranis
Independent Representative

Secretary
Rodney Taylor
At Large Representative

Treasurer
Lynette Bradley-Baker
At Large Representative

David Chason
Acute Care Hospital Representative

Harry Finke, Jr.
Independent Representative

Mitra Gavgani
Home Infusion / Home Care Representative

Stephanie Hammond
Acute Care Hospital Representative

Mayer Handelman
Long Term Representative

Lenna Israbian-Jamgochian
Chain Drug Store 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

FY 2012 BOARD STAFF	
EXECUTIVE **410-764-4794**	
LaVerne Naesea, Executive Director **Stephen J. Holmes**, Executive Assistant	Board Operations, Board Members and Board Minutes
ADMINISTRATION **410-764-5929**	
Patricia Gaither, Administration & Public Support Manager **Janet Seeds,** Public Information Officer **Anasha Page,** APS Assistant **Rhonda Goodman,** Secretary/Receptionist	Fiscal, Budget, Procurement, Travel, Personnel and Public Information
LEGISLATION AND REGULATIONS **410-764-4794**	
Anna Jeffers, Legislation and Regulations Manager **Stephen J. Holmes**, Executive Assistant	Legislation and Regulations and Pharmacy Practice Committee
COMPLIANCE **10-764-5988**	
YuZon Wu, Pharmacist Compliance Officer **Emory Lin,** Pharmacist Inspector **Cheryl Johnson,** Pharmacist Inspector **Nancy Richard,** Lead Inspector **Jeannelle McKnight,** Inspector **Shanelle Young,** Inspector **Yin Chan,** Inspector **Vanessa Gray,** Compliance Investigator **Steven Kreindler,** Compliance Coordinator **Courtney Jackson**, Compliance Secretary	Complaints, Pharmacy Practice, Disciplinary, Inspections, Investigations and Pharmacists Rehabilitation
LICENSING **410-764-4756**	
Demetrius Daniels, Licensing Manager **Doris James,** Licensing Specialist **Keisha Wise,** Licensing Specialist **Latoya Waddell,** Licensing Specialist **Tiffany Duncan,** Licensing Secretary	Licensing, Permits, and Registration, Reciprocity, and Scores
MANAGEMENT INFORMATION SERVICES **410-764-4685**	
Vacant, MIS Manager **Michelle Hsu**, Database Officer	Computer, Database and Website and On-line Renewals

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REMARKS FROM THE BOARD PRESIDENT

Michael Souranis

On behalf of the Maryland Board of Pharmacy (Board), I am privileged and pleased to present the Fiscal Year (FY) 2012 Annual Report unequivocally as evidence that the Board has grown stronger, more committed, and is providing greater protection for Maryland's pharmacy patients.

Fiscal Year 2012 was a year of transition for the Board of Pharmacy as it worked diligently, tirelessly, and successfully to meet its mission of protecting Maryland patients and promoting quality healthcare in the field of pharmacy. The Board experienced a few challenges related to technology, personnel vacancies, support of legislation; and in responding to practice violations of which many are discussed in this report. Nevertheless, it achieved several accomplishments that fulfilled legislative mandates and Board identified goals. For example, four pieces of major legislation were successfully supported by the Board in FY 2012, including: *Jurisdiction Over Nonresident Pharmacies; Wholesale Distributor Permits, Application Requirements; Health Care Practitioners – Personally Preparing and Dispensing Prescription Drugs and Devices;* and its *Sunset Extension and Revisions* law. The Board also revised or amended six sets of regulations related to *Inpatient Institutional Pharmacies, Opening and Closing of Pharmacies, Continuing Education for Pharmacists, Services for Patients in Comprehensive Care, Delivery of Prescriptions, Administration of Vaccinations*, and *Pharmacy Infusion Services as Alternate Site Care Environments*. Each of these initiatives addressed issues that impacted the quality of care and services provided to Maryland's pharmacy patients.

The impact that the Board has had on safe dispensing in Maryland is most evidenced by the outcome of the Board's Sunset Evaluation, conducted during FY 2012. A Sunset Evaluation is a periodic legislative review performed by the Maryland Department of Legislative Services (DLS) every ten years for each of the state health occupation boards and commissions. The Evaluation helps determine whether a board should be re-authorized to regulate the health occupation professionals and industries under its purview. The Evaluation is also conducted to help identify changes required to address health care trends for the regulated health care disciplines. The Board of Pharmacy's 2001 Sunset Evaluation supported related sunset legislation passed in 2002. The 2002 legislation required the Board to respond to certain recommendations through 2012. The 2012 DLS report concluded that the Board had successfully implemented a "significant" number of the recommendations made by the DLS in its 2001 sunset evaluation and found the Board to be on the right track in its operations and in the manner it had addressed issues over the previous ten years.

The FY 2012 Evaluation noted that "the board has done an excellent job at keeping pace with changes impacting the practice of pharmacy." In addition, it described the "significant" statutory regulatory and procedural changes that impacted the board operations and pharmacy practice, including: promulgation of patient safety regulations (2002); establishment of the Drug Therapy Management Program (2002); administration of vaccines by pharmacists (2004); establishing a prescription drug repository program (2006); registration of pharmacy technicians (2006); Board monitoring of impaired pharmacists under disciplinary orders (2007); enhanced regulation of wholesale distributors (2007); Board assumption of pharmacy inspections annually (2008) and wholesale distributor inspections biennially (2008); and the establishment of the Prescription Drug Repository Program (2011).

The Board's success over the past ten years is partially attributable to the hard work and commitment of Board and staff members, but also to pharmacy practitioners who worked with the Board on task forces and work groups to support legislation. The greatest reason for the Board's success has been because the majority of entities regulated by the Board have consistently met and exceeded standards set to protect Maryland's pharmacy patients.

As I enter the last year of my second four-year term on the Board begins, I can attest to the strong patient advocacy by Board members and staff. I have witnessed the resolve of my Board colleagues persevering to address difficult problems that threatened the patient protection safety net established in 1902. 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.

The Board exhibited national leadership in FY 2012 through its efforts to better regulate non-resident pharmacies, effectuate safe dispensing standards for non-pharmacists, strengthen wholesale distributor rules while making them less onerous; and resolve long standing assisted living and long term care issues.

In closing, special recognition must be given to the Secretary of the Department of Health and Mental Hygiene, Dr. Joshua Moses Sharfstein; 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. The Maryland Board of Pharmacy, working with its staff members, the Department of Health and Mental Hygiene, and representatives of the bodies it regulates, invested significant time and energy again in FY 2012 to plan, refine, upgrade and implement initiatives and operations. This FY 2012 report reflects those efforts and accomplishments, and I am confident that the Board will continue its strong legacy long after my tenure ends.

MESSAGE FROM THE EXECUTIVE DIRECTOR

La Verne Naesea

I am again honored and pleased to present the Annual Report summarizing activities in which the Maryland Board of Pharmacy engaged for the period July 1, 2011 through June 30, 2012. An Acute Care Hospital representative was appointed to the Board during FY 2012. Also, the two four-year terms of the Chain and Long Term Care representatives ended in April of this fiscal year although their replacements have yet to be appointed.

The Board remains fiscally strong, thanks to the Administration and Public Support (APS) Unit's management of the Board's FY 2012 appropriation. Legislative involvement during FY 2012 was lively, in light of the Board's continuing concerns related to safety for patients that receive medications from dispensing prescribers. Board concerns led to successful legislation requiring dispensing prescriber sites to be inspected at least twice every five years. Despite this success, the Board will continue to pursue the same safety net for patients that receive prescriptions from dispensing prescribers as that which is in place for Maryland's pharmacy patients.

Under new leadership, the Licensing Unit focused on implementing new procedures for processing pharmacy technician applications. New quality assurance measures were instituted to address customer service complaints about data entry errors. Pharmacist and pharmacy technician applications were also revised to clarify instructions and assure that the formats were more user-friendly. Also under new leadership, the Compliance Unit began refining and making its processes more uniform for performing inspections and investigating complaints. All Compliance Unit inspection staff also engaged in sterile compounding training during FY 2012.

Phase I implementation of the Board's new SQL-based database system was delayed due to the untimely vacancy created by the former MIS manager's leaving the Board. The Board contracted an interim project manager in the third quarter that supported the continuation of the project which is slated to "go-live" in the first quarter of FY 2013. In addition to allowing on-line renewals and certain other interactive services with most types of licensees (EGov), it will retain all licenses, registrations and permits records in a primary system (MLO); enable the entry of disciplinary information directly into MLO records; allow the remote transfer of establishment inspection reports (Compliance); and require fee payments, and fines to be associated with issued licenses, registrations and permits.

Operations at the Board were challenged during most of FY 2012 as Board personnel were required to respond to and prepared for transitioning to the Board's new database system. The system promises to streamline efficiency and information capabilities while providing greater access and convenience to licensees and consumers. However, all Board personnel were required to convert data, define business rules, respond to numerous questionnaires, and test several components of the system throughout the year, which affected their routine activities. Additionally, preliminary training on the new system also began in FY 2012.

FY 2013 is projected to again create challenges to Board operations, related to preparing licensees and staff on usage of the many new database system's applications. Unit managers have been working with their respective staffs to reduce some of the strain through various planned training activities. Operational initiatives planned in FY 2013 include: training all Board personnel on use of the new system (including

receiving instruction on entering data, preparing statistical reports, and meeting new security requirements); cross-training of licensing staff to allow any application type to be processed by all members of the unit; supplementary training on sterile compounding and other specialty pharmacy practices for Compliance Unit staff; refining community outreach methods by the APS Unit, while Unit members also learn new business rules for processing fees and fines received through the new system; training for MIS staff on the new system programming, configuration and report preparation; and preparation by the Legislative/Regulations Unit of several reports in relation to the Sunset Legislation and other required Annual Reports on recent legislative initiatives.

This Fiscal Year was no less eventful than previous years. The Maryland Board of Pharmacy exhibited vigilant regulatory oversight and tracking of trends and issues that could affect Maryland's pharmacy patients. The Board's resolve to protect patients, irrespective of from where prescriptions were dispensed, remained strong – though not completely met. Also, as with any organization, operational trials faced by Board presented a few set-backs. Nonetheless, plans are in place to continue moving forward and, overall, the Maryland Board of Pharmacy's efforts during FY 2012 have positively impacted the health and well-being of all of Maryland's pharmacy patients!

ADMINISTRATION AND PUBLIC SUPPORT UNIT REPORT

Overview

The Administration and Public Support Unit (APS) consists of four professional staff persons, a Manager, a Public Information Officer, an Assistant to the Manager and a Secretary/Receptionist. The Unit 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 licenses, 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 to support new program areas, personnel, purchases and/or purchases contract procurements 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 2012 was $2,630,396.

Board fiscal functions include collection of fees 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 legislation 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 training development.

The Public Information activities conducted through the APS Unit include the provision of information and education about the Board to the public and pharmacist community.

Board Revenue

The total revenue collected for fiscal year 2012 was $2,748,020 of which $237,888 was transferred to State general funds through the Budget Reconciliation and Financing Act (BRFA), legislation implemented to balance the State budget. Thus, the total revenue credited to the Board of Pharmacy in FY 12 was $2,510,140. The revenue in the below chart reflects changes in the renewal periods for pharmacy and distributor establishments during the previously legislative session. Specifically, the Board collected two years' of fees for pharmacy establishments in fiscal year 2012. In fiscal year 2013 the Board will collect two years' of fees for distributor establishments. The respective establishment fees will be collected biennially in future years

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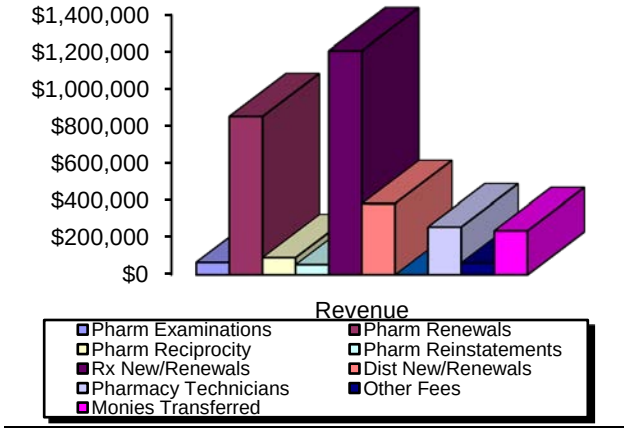
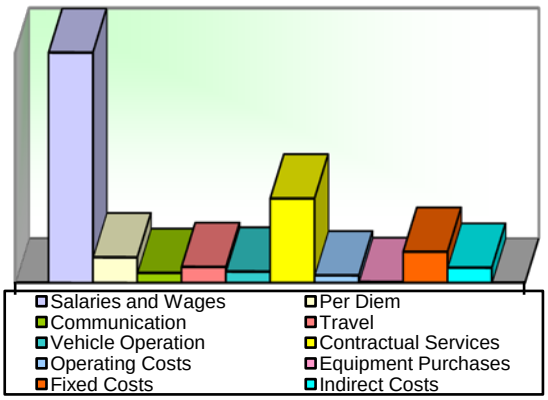


FY 2012 Revenue Detail

Total Collections FY 2012	2,748,020
Pharmacists Examination	67,508
Pharmacist Renewals	853,940
Pharmacists Reciprocity	93,535
Pharmacists Reinstatements	55,483
Pharmacy New/Renewals/Reinstatements	1,207,844
Distributor New/Renewals/Reinstatements	383,800
Pharmacy Technicians	258,118
Other Fees	65,680
Monies Transferred out of Revenue for BRFA	(237,888))
TOTAL REVENUE COLLECTIONS CREDITED TO THE BOARD OF PHARMACY FY 2012	$2,510,132

Expenditures

Board expenditures for FY 2012 were 2,418,330; reflecting a 4.5% decrease in expenditure activity from the previous year. Projected expenditures were not met because the MIS Manager position became vacant during FY 2012 and database contracting activity and equipment purchases was significantly reduced. Other activities were delayed or postponed, pending the recruitment of another MIS Manager. The third quarter of FY 12 the Board hired a Database Consultant to manage the database Project until a permanent replacement was hired.



FY 2012 Expenditure Detail

Salaries and Wages	1,548,009
Per Diem	110,345
Communication	42,399
Travel	68,341
Vehicle Operation	48,216
Contractual Services	366,912
Operating Costs	31,689
Equipment Purchases	2,734
Fixed Costs	134,501
Indirect Costs	65,184
TOTAL EXPENDITURES	$2,418,330

Personnel

The Board had 23 permanent (PIN) positions during FY 2012 of which 22 were filled with permanent staff during most of the year. The one vacancy was a managerial position, MIS Manager. The Board hired a Database Consultant late FY 12 while waiting for the MIS Manager's position to be filled and vacancies are expected to be filled early FY 2013. A contractual Help Desk position was also on staff during the year.

Procurement

Due to the vacancy in the MIS Manager's position the Board experienced delays is the implementation of the new database project. It had been projected to be up and running during the first month of FY 2013. The Board contracted with a Project Manager lead the implementation of the new database system. The Board continued 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 2012 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 the National Association of Boards of Pharmacy (NABP) to perform inspections of out of state pharmacy establishments.

Public Information and Education

Public Information staff in the unit performs 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 functions assigned to this staff. These informational tools are produced and disseminated to ensure that practitioners and consumers are informed of changes in legal requirements, board procedures and recommended safety measures.

The Unit 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 84 PIA requests responded to in FY12. The staff in the Unit is assigned to assure that information released does not violate state and federal confidentiality rules.

Two other important public information responsibilities in the APS Unit include monitoring and coordinating responses to pharmacy-related news media and planning. Unit personnel are assigned to staff the Emergency Preparedness and Public Relations Committees, as well as coordinate Board training and public relation events around the state. 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 2012 Summary of Training & Education

- October 2011– Pharmacist Continuing Education Breakfast, Baltimore, MD

FY 2012 Summary of Public Relations Activities

- May 2012 – 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 2012 – Maryland Pharmacist Association (MPhA) Exhibit, Ocean City, MD

FY 2012 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 anticipates an increase in revenue for FY 2013 based on distributor renewal fees expected to be collected in FY 13 and FY 2014. The fees collected from wholesale distributor renewals are greater than those collected from pharmacy renewals.

Projected Board expenditures will increase as a result of initiatives related to completing Phase I and initiating Phase II of the Board's Database System. Completion of the new system's implementation is expected in FY 2014. The Board will continue training, educational and emergency preparedness activities to heighten visibility of patient safety efforts throughout the state, the 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 and from pharmacists to who wish 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

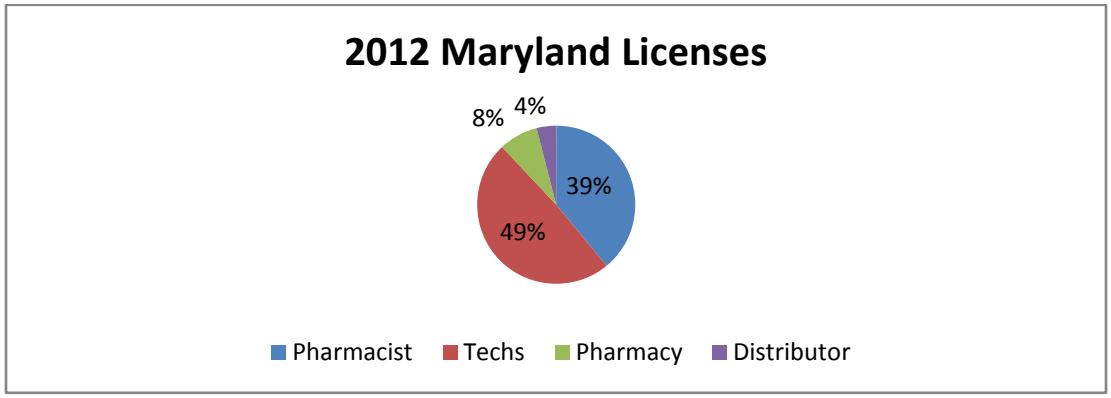
The new Unit Manager, who had been recruited during the last quarter of 2011, faced several new initiatives and issues that required addressing in FY 2012. As a result of Sunset Review legislation proposed during the FY 2012 session (see *Board Chairman Remarks*), renewal dates for pharmacies and wholesale distributors were changed from the end of December to the end of May. This change extended wholesale distributor and pharmacy permits to May 31, 2013 and May 31, 2014 (respectively) and will continue biennially renewal thereafter. Another bill passed during the January 2012 session that may have impacted the Licensing Unit's workload requires non-resident pharmacies to employ at least one Maryland licensed pharmacist, effective October 2012. The new requirement's effective date is in FY 2013 may have been related to the slight increase in the number of Board-licensed pharmacists. Also, in the Spring of FY 2012 (April) the Criminal Justice Information System (CJIS) stopped receiving CJIS or FBI ink fingerprint cards, transitioning to an electronic, digitally captured process. The Licensing Unit was required to revise its Pharmacy Technician and Wholesale Distributor processes to reflect the new process.

Another set of developments that impacted the Licensing Unit in FY 2012 involved wholesale distributors. There was a significant spike in the number of wholesale distributors (113) who had either not applied or were pending approval until after the Board began recognizing several new entities that could inspect and accreditation non-resident wholesale distributors (the Accreditation Committee for Health Care (ACHC), Community Health Care Accreditation Program (CHAP), and Joint Commission). Additionally, statutory amendments in FY 2012 allowed manufacturers of prescription devices that distribute their own products into Maryland to comply only with federal requirements. The new amendments also removed the requirement of a physical inspection of a wholesale distributor if it does not hold product (virtual manufacturers). These Board decisions were determined to have significantly contributed to an increased workload in the Licensing Unit during 2012.

Other challenges experienced by Licensing Unit staff during the year involved responding to the Board's 10 year Sunset Review process while engaging in Phase I implementation of the MIS Database project. The new MIS system retains records, which allows payments of fees and fines to be associated with issued licenses, registrations and permits. It also allows licensees to change certain information on line such as their changes of address. The MIS project entailed transferring all licensing data into a new database, up-grading the on-line renewal system to allow Pharmacy Technicians, Pharmacies and Distributors to renew on-line, in addition to Pharmacists who have traditionally renewed on-line, and revising all unit business rules for application processing and on-line renewals.

Statistics

The Licensing Unit processed applications and other required documents for a total of 22,486 licensees during FY 2012. Nearly nine thousand pharmacists (8,757) were included in the number of licensees, reflecting an increase of 62 from the previous fiscal year. The growth may be partially attributable to non-resident pharmacies preparing to meet the new requirement of employing at least one Maryland licensed pharmacist. Pharmacies licensed in Maryland also experience an increase by 58, bringing the total to 1819 permit holders in FY 2012. Wholesale distributors licensed at the end of the year increased from 759 to 920. Also as expected, the number of registered pharmacy technicians increased the greatest from 8,052 to 10,990 in FY 2012 -- an increase of 2,938. The major increase in technician registrations may not level off for several more years, as members of this group continue to meet eligibility requirements under the four year old statute. The chart below provides the percentage of each type of license category in Maryland.



Next Year at a Glance

The Licensing Unit is looking forward to another busy year in FY 2013. It plans to continue to support unit staff members that specialize in processing one of the four key license types. However, to refine processes and eliminate time lost during peak application periods, staff absenteeism or vacancies, all staff will participate cross-training for processing all application types. This will assure that all but the most complicated applications can be processed -- when the Unit is overloaded during a peak application period or a staff member is absent for an extended period. The Licensing Unit staff also plans to work with the Licensing Committee in updating all Unit applications to reflect new and projected changes to Board statutes and regulations. Additionally all staff will be trained on the new MIS system and business methods for processing applications -- including processes for entering data and preparing statistical reports as well as meeting new security requirements. The Unit also anticipates additional training as the Board prepares for implementing Phase II of the MIS project that will involve the receipt new applications on-line in addition to the renewal applications.

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, two (2) half-time pharmacist inspector supervisors, four (4) compliance inspectors, a compliance coordinator, a compliance investigator, 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 was fully staffed with the addition of a half-time pharmacist inspector supervisor in early 2012. Working with the Board's Disciplinary Committee, the Unit was able to provide additional training to staff members, develop and 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. Individuals may obtain a complaint form by mail or from the Board of Pharmacy website at www.dhmh.maryland.gov/pharmacy and submit the completed form via fax, mail, email, or in person. All information related to each complaint is investigated and the results presented to the Board's Disciplinary Committee for review and recommended action for follow-up by Compliance Unit staff or to the full Board. If an issue is outside the Board's scope or jurisdiction, the complaint will be referred to the appropriate authority.

Figure 1, below, provides the number of complaints received in the past six fiscal years. Compared to previous years, the highest number of complaints was processed in FY2012 with 358 complaints. Complaints received by the Board may include, but is not limited to, an actual complaint made by the public, referrals from other state or federal agencies, or deficiencies found during inspections.

Figure 1 **Complaints Processed July 1, 2011-June 30, 2012**

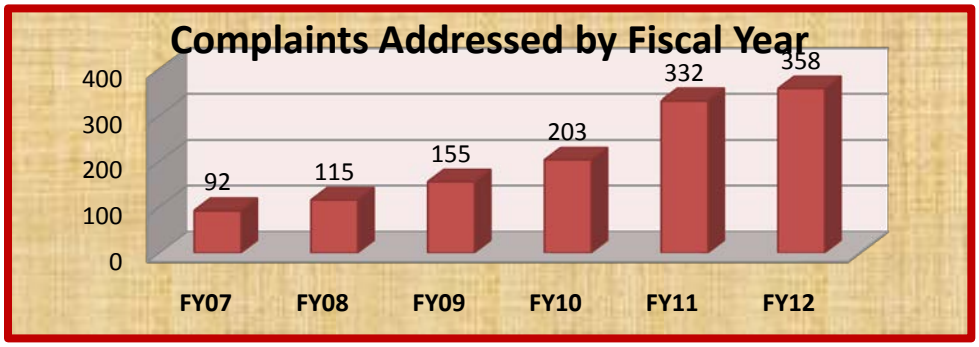
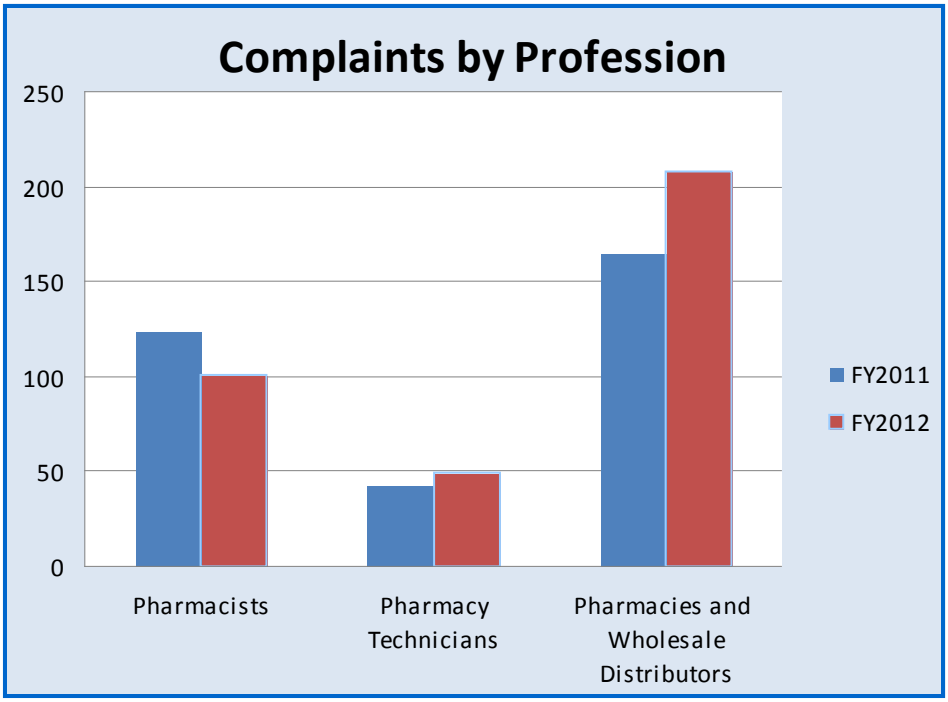
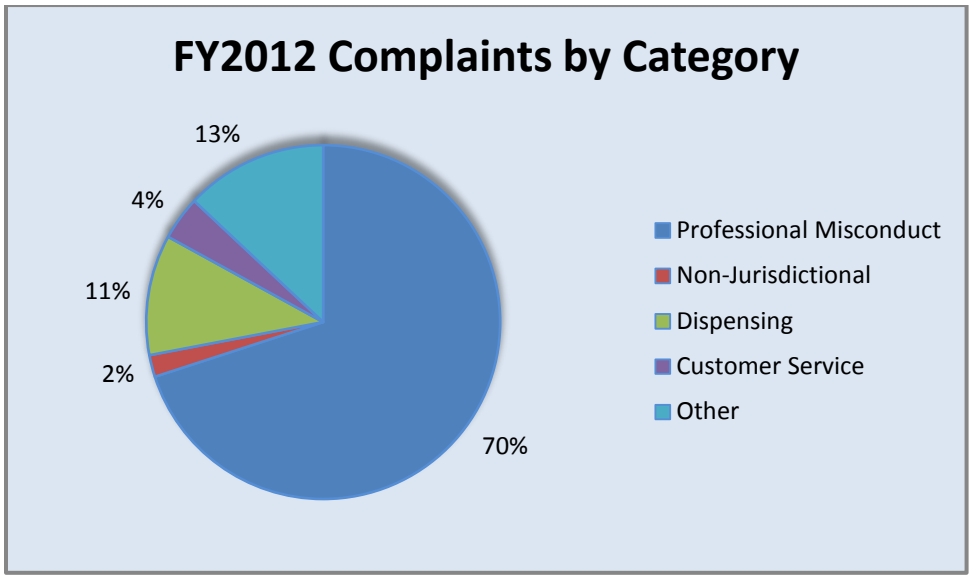


Figure 2 **Complaints against Licensees, Registrants, and Permit Holders**



This is the 4rd year that the Maryland Board of Pharmacy has registered pharmacy technicians. As a result, technician compliance monitoring is also part of the Board's purview. Figure 2 above reveals 14% of the complaints filed in this fiscal year were against pharmacy technicians. This is three times higher compared to fiscal year 2009, during the early implementation of pharmacy technician registration, but comparable to fiscal year 2011.

Figure 3 **Types of Complaints July 1, 2011-June 30, 2012**



The types of complaints received are broadly categorized (see Figure 3). The majority relates to professional misconduct. Violations from annual inspections, unlicensed personnel engaged in the practice of pharmacy,

unauthorized dispensing, theft or loss of drugs, employee pilferage, and sexual harassment are among a few examples of professional misconduct. This fiscal year, there is a significant increase in professional misconduct as compared to previous years that relates mostly to establishments resulting from deficiencies found during annual inspections.

Disciplinary Cases

All complaints are investigated by Board staff members. For the current fiscal year, the Board has taken formal or informal actions on 404 complaint cases including the opened complaints that were carried over from the previous fiscal year. Examples of informal actions include letters of education, letters of admonishment, and letters of agreement, deficiency letters, and consent order issued to certain technicians to submit to a criminal background check upon their first renewal. Examples of formal actions include a license or permit being placed on probation, suspension, revocation, as well as fines issued. Approximately 65% of the complaints remained open, pending more investigation. This is due to the back log from the previous fiscal year where the compliance unit was without a Compliance Officer, compliance investigator, as well as vacancies in the inspector positions for approximately 7 or 10 months. Figure 4 shows the number of formal and informal actions taken for Fiscal Year 2012, compared to the previous 5 years.

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

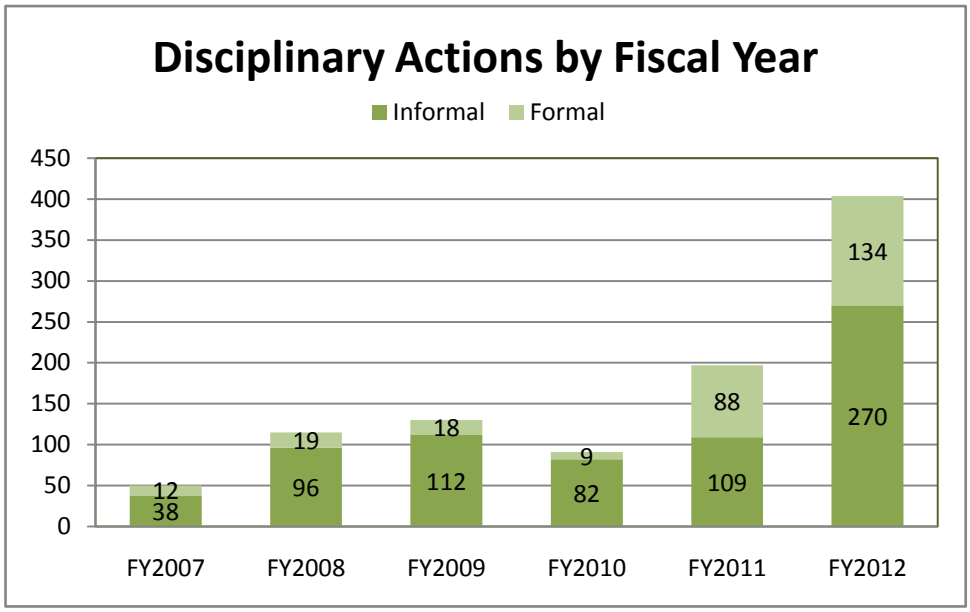
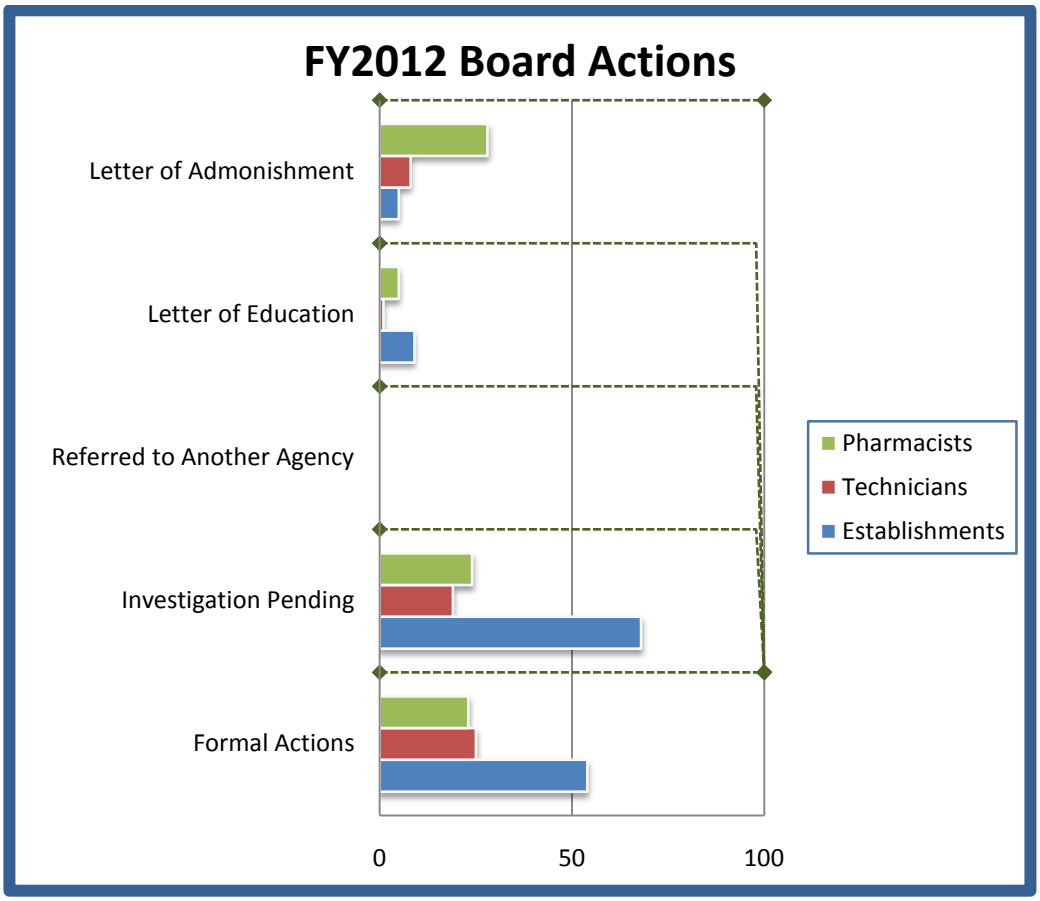


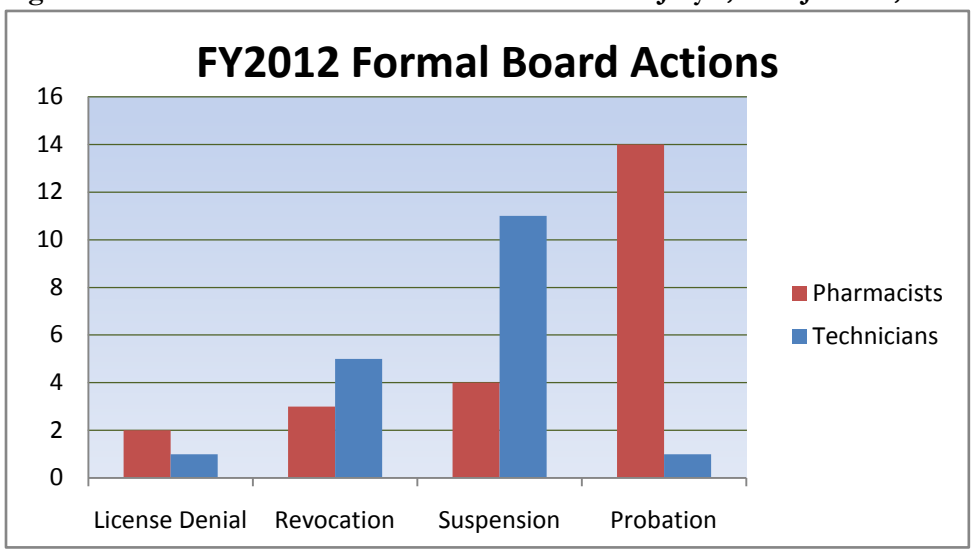
Figure 5 represents a categorical description of the various types of formal and informal actions taken against pharmacists, pharmacy technicians, and establishments in the most recent fiscal year

Figure 5 **Board Action July 1, 2011-June 30, 2012**



If 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 2012. Some formal actions against licensees or permit holders included fines which are excluded from figure 6. All formal actions, including some of the fines issued are published in the Board of Pharmacy newsletter along with name of the licensee, permit holder, or applicant.

Figure 6 **Formal Board Actions Taken July 1, 2011-June 30, 2012**



Inspections

The compliance unit continues to work closely with the Division of Drug control (DDC) in performing inspections. The Board of Pharmacy conducts opening, some closing, relocation, change of ownership, and annual inspections of instate pharmacies, while DDC performs most closing inspections on behalf of the Board and the Department. The Board has a goal of inspecting all in-state pharmacies annually. The chart in Figure 7 reflects the total number of annual, opening inspections, miscellaneous inspections (relocation, change of ownership, investigative inspections), and distributor inspections performed in Fiscal Year 2012. As result of being fully staffed during much of this fiscal year, the Board completed approximately 97.6% of annual inspections for all the facilities permitted in Maryland.

Figure 7

Annual Inspections	1209
Opening Inspection	80
Miscellaneous Inspection	69
Distributors	22
Total Inspections	1380

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 2012, the Board of Pharmacy inspected 22 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 10 facilities on the Board's behalf and submit records and paperwork for the Board's review.

Practitioner, Substance Abuse and Compliance Monitoring

Chemical dependence among health care professionals has been observed over the years to be at least as prevalent as with the plague in society. In addressing disciplinary actions, the Maryland Board of Pharmacy may opt to mandate substance abuse treatment. If treatment is so ordered, Compliance Unit staff is assigned to monitor the mandated licensees to ensure compliance with the terms of their orders. Public Orders may require routine reports to be submitted from the various programs that provide services to the monitored licensee. Services directly monitored may include, but are not limited to, referrals for:

- 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's information is reported to the National Practitioner Data Bank and/or the Healthcare Integrity and Protection Data Bank. In Fiscal Year 2012, the Board monitored 11 pharmacists and 1 pharmacy technician 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 2012.

The Maryland Board also contracts with the Pharmacist Education and Advocacy Counsel (PEAC), a pharmacist 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 submitted 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 the terms of their contracts are violated.

In Fiscal Year 2012, PEAC monitored a combined total of 27 clients: 25 pharmacists and 2 pharmacy technicians.

Next Year at a Glance

For Fiscal Year 2013, the Compliance Unit plans to:

- provide additional training to staff in sterile compounding and other specialty pharmacy practices;
- reduce number of investigation cases carried over into the next fiscal year;
- have more uniform review and better defined categories for the different types of complaints;
- continue to have a full cadre of compliance staff and pharmacy inspectors; and
- update/review inspection forms.

MANAGEMENT AND INFORMATION SYSTEMS UNIT

Unit Overview

The MIS Unit is responsible for implementing and maintaining automated systems that enhance the operations 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 2 permanent staff members; they are the Information Technology (IT) Supervisor/Manager, and Database Specialist.

New Developments

The Unit's former MIS Manager resigned from the Board at the end of FY 2011, which resulted in the need for the Board to delay completion of Phase I implementation of its new Data base MIS system. A Project Manager was recruited in the FY 2012 second quarter, to carry out related tasks and supervise Unit staff until a permanent Manager was hired. The Board also continued to contract with Computer Network Specialist (CNS) personnel throughout FY 2012. The Board was successful in securing a new contract vendor to implement an off-the-shelf SQL-based MIS data system. The vendor, Systems Automation, was selected by the Department as a preferred provider. The Board was strongly encouraged to use the vendor's off-the – shelf product despite its preference to use vendor that could develop a customized system product. The MIS Unit made many improvements to the Board's IT infrastructure during FY 2012 including securing and offsite disaster-recovery location through a contract with MD State Archives. The Board's network servers were also moved to that location because the Board's office location had experience several power outages in the past. The Unit also secured mobile hotspots for the Board's Compliance field Inspectors. The hotspots will allow access to the new MIS system.

Accomplishments

Throughout the year the MIS Unit supported implementation of the new database and participated in preparing staff to use the system throughout FY 2012. The system will eventually allow all licensees to renew on-line, and allow online verifications by the public to learn about the statuses of licensees. The Board also redesigned its web pages during FY 2012 to accommodate the Department-wide transition to a new SharePoint portal for e-mail and web-services. MIS staff was also trained during FY 2012 to use Crystal reporting with the new MIS database system.

Next Year at a Glance

The Board anticipates recruiting a permanent MIS Unit Manager during the first or second quarter of FY 2013. Also, a permanent Computer Network Specialist was approved in the Board's budget and will also be recruited in FY 2013. Additional training will be provided to all staff of the unit in reporting, network configuration and SharePoint. Working with the contracted vendor, the MIS Unit intends to complete implementation and begin testing the SQL-based system in FY 2013. Unit staff will also support the contracted vendor in training Board staff in use of the new system. Finally, to the Unit will begin to develop specifications for a Phase II of the project that will include enabling new applicants to apply on-line.

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 review, some recommended responses are brought to the Board at its Public meetings for approval. During Fiscal Year 2012 the Unit responded to 1,442 phone calls and provided written responses to 536 e-mail and letter inquiries.

The Unit also anticipates another busy legislative session as the Board continues to strength 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.

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 39 bills (of approximately 2,580 bills) to present to the Board of Pharmacy's Legislative Committee for consideration during FY 2012. The Unit tracked, drafted position papers and/or letters to legislative committees for 21 of the 39 bills. Below is provided a chart of the 21 bills (companion bills are counted as one bill) and the results.

Chart 1 – FY 2012 BILL TRACKED by the BOARD OF PHARMACY

Bill #	Bill Name	Result
HB 15	Maryland Medical Marijuana Act	Failed
HB 23	Dedicated State Funds Protection Act	Failed
HB 63	Child Abuse and Neglect - Failure to Provide Notice or Report - Civil Liability and Criminal Penalty	Failed
HB 66	Public Health - Glucose Testing – Permit	Failed
HB 76	Criminal Law - Controlled Dangerous Substances - Research - Synthetic Cannabinoids	Failed
SB 132	Health Occupations - State Board of Pharmacy - Jurisdiction Over Nonresident Pharmacies	**PASSED**
HB 334	Health Occupations - State Board of Pharmacy - Jurisdiction Over Nonresident Pharmacies	**PASSED**
SB 133	State Board of Pharmacy - Wholesale Distributor Permits - Application Requirements	**PASSED**
HB 316	State Board of Pharmacy - Wholesale Distributor Permits - Application Requirements	**PASSED**
SB 140	Crimes - Child Abuse and Neglect - Failure to Report	Failed
SB 274	State Board of Pharmacy - Sunset Extension and Revisions	**PASSED**
HB 283	State Board of Pharmacy - Sunset Extension and Revisions	**PASSED**
SB 408	Pharmacists - Administration of Vaccinations - Expanded Authority	Failed
HB 561	Pharmacists - Administration of Vaccinations - Expanded Authority	Failed
HB 531	State Government - Commemorative Days - Prescription Drug Take Back Day	Failed
HB 589	Criminal Law - Controlled Dangerous Substances – Mephedrone	**PASSED**
SB 603	Health Care Practitioners - Licensed Dentists, Physicians, and Podiatrists - Personally Preparing and Dispensing Prescription Drugs and Devices	**PASSED**
HB 689	Health Insurance - Pharmacy Benefits Managers - Specialty Drugs	Failed
SB 782	Health Insurance - Pharmacy Benefits Managers - Specialty Drugs	Failed
SB 833	Regulations - Fees and Fines - Legislative Approval Required	Failed
HB 758	Health Occupations Boards - Regulations - Scope of Practice Advisory Committees	Failed

SB 866	Health Occupations Boards - Regulations - Scope of Practice Advisory Committees	Failed
HB 838	Health Insurance - Pharmacy Benefits Managers - Audits and Reimbursement of Pharmacies or Pharmacists	Failed
SB 903	Health Insurance - Pharmacy Benefits Managers - Audits and Reimbursement of Pharmacies or Pharmacists	Failed
SB 916	Criminal Law – Robbery and Burglary – Pharmacies	Failed
HB 1066	Criminal Law – Robbery and Burglary – Pharmacies	Failed
HB 909	Crimes - Synthetic Cannabinoid - Schedule I – Penalties	Failed
HB 1024	Medical Marijuana Commission	Failed
HB 1234	Regulations Affecting Small Businesses - Extensions for Compliance	Failed

Summaries of major bills from the 2012 Legislative Session are provided below.

SB132/ HB334 Health Occupations - State Board of Pharmacy - Jurisdiction Over Nonresident Pharmacies

This legislation required nonresident pharmacies to comply with specific pharmacy laws of Maryland when dispensing prescription drugs or prescription devices to Maryland citizens and otherwise engaging in the practice of pharmacy in Maryland. If there is a conflict between Maryland law and the laws of the state in which the non-resident is located, the non-resident pharmacy will follow the laws of the state in which it is located. This bill assures that a pharmacist licensed in Maryland dispenses prescription medications and provides other pharmaceutical services to consumers/patients in Maryland. It requires a pharmacist answering a nonresident pharmacy's toll-free telephone service to refer patients in Maryland to the responsible Maryland pharmacist, as appropriate. This legislation clarifies the inspection requirements applicable to a nonresident pharmacy, requiring a nonresident pharmacy to submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the nonresident pharmacy is located. A nonresident pharmacy that violates the specific pharmacy requirements listed in the bill would be subject to the same disciplinary actions as a Maryland pharmacy. This legislation passed.

SB133/HB316 State Board of Pharmacy - Wholesale Distributor Permits - Application Requirements

This legislation proposed three amendments to the Wholesale Distribution Permitting and Prescription Drug Integrity Act (the "Act"). The first amendment removes the requirements for a physical inspection of a wholesale distributor location that does not hold product. The second amendment substitutes requiring a state criminal background check from Maryland for the designated representative or the supervising designated representative, with requiring a criminal background check of these individuals from the state

where the wholesale distributor is located. The third amendment allows Maryland applicants to submit their fingerprints and fees for a criminal background check directly to the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services. After introduction of this bill a fourth amendment was added that allows a manufacturer of prescription devices that distributes its own product into Maryland to comply only with federal requirements. This is consistent with current requirements for a manufacturer of prescription drugs that distributes its own product into Maryland and would remove unnecessary burdens on eligible distributor applicants. This legislation passed.

SB274/HB283 State Board of Pharmacy - Sunset Extension and Revisions

This legislation continued the Board of Pharmacy in accordance with the provisions of the Maryland Program Evaluation Act (sunset law) by extending the statutory and regulatory authority of the Board to July 1, 2022. It changed the renewal dates for pharmacy and wholesale distributor permit holders from December 31st to May 31st and also alters the dates when the Board is required to send renewal information to permit holders. This legislation makes substantive revisions to the Subtitle 6A. Therapy Management Contracts, by repealing the requirement that physician-pharmacist agreements, protocols, and therapy management contracts be approved by both the Board of Physicians and the Board of Pharmacy. Under this legislation, each applicant will submit their application materials to their respective licensing board for approval. A therapy management contract shall now apply only to conditions for which protocols have been agreed to by a licensed physician and a licensed pharmacist in accordance with the regulations to be adopted. Drug Therapy Management fees have also been stricken. The legislation includes uncodified sections that require reports on the Drug Therapy Management Program; reducing the length of time to process pharmacy technician applications; the status of Pharmacists Education and Advisory Contracts (PEAC); the implementation of the Board's IT system; and the Board's five year financial outlook. This legislation passed.

SB 603 Health Care Practitioners - Licensed Dentists, Physicians, and Podiatrists - Personally Preparing and Dispensing Prescription Drugs and Devices

This legislation required dentists, physicians, and podiatrists to comply with dispensing, labeling, inspection, packaging, recall procedure, record keeping, purchase, verification, reporting and continuing education requirements as a condition of being allowed to safely personally prepare and dispense prescription drugs or devices to patients in Maryland with the same safety standards as pharmacies. It does not restrict prescribers from administering drugs in their offices, dispensing starter doses, or dispensing samples. The Board of Pharmacy, Board of Dental Examiners, Board of Podiatric Medical Examiners and the Maryland Board of Physicians are required to report those persons holding a dispensing permit to the Division of Drug Control (DDC) so that DDC may perform inspections twice within 5 years. Additionally, DDC is required to report the results of inspections of prescribing dispensers to their respective boards. It also provides for a phase-in of continuing education requirements for prescribing dispensers so that they are aware of the safe dispensing practices. 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.

CHART 2: FY 2012 BOARD OF PHARMACY REGULATORY, REVISIONS (COMAR 10.34.01 - .35)

COMAR Citation	Title	Effective Date
10.34.03	Inpatient Institutional Pharmacy	October 1, 2011
10.34.14	Opening and Closing of Pharmacies	June 1, 2012
10.34.18	Continuing Education for Pharmacists	April 30, 2012
10.34.23	Pharmaceutical Services to Patients in Comprehensive Care Facilities	April 2, 2012
10.34.25	Delivery of Prescriptions	March 1, 2012
10.34.32	Pharmacist Administration of Vaccinations	Emergency Effective Date October 1, 2011. Final Effective Date: January 23, 2012
10.34.35	Infusion Pharmacy Services in an Alternate Site Care Environment	March 1, 2012

Maryland Board of Pharmacy Regulations, COMAR 10.34.01 - .36 in the revision or promulgation process during FY 2012:

COMAR Citation	Title	Proposal Status
10.34.03	Institutional Pharmacy	Practice Subcommittee met in May and June 2012 to consider revisions regarding decentralized pharmacies located at hospitals
10.34.11	Disciplinary Sanctions, Monetary penalties, and Civil Fines	Disciplinary Subcommittee continued to meet to consider revisions to implement SB 291/HB 114 Health Occupations Boards – Revisions, 2010. Board approved proposal at June 20, 2012 Board Meeting and the Unit submitted the proposal for publication.
10.34.22	Licensing of Wholesale Prescription Drug or Device Distributors	Drafting began to implement SB 133/HB 316 State Board of Pharmacy – Wholesale Distributor Permits – Application Requirements, 2012. Reinstatement and Closing Regulations included.
10.34.28	Automated Medication Systems	Board approved proposal at the August 17, 2011 Board Meeting and the Unit submitted the proposal for publication. Published December 2, 2011. Notice of Final Action published April 6, 2012 with a delayed effective date for October 1, 2012.

10.34.29	Drug Therapy Management	Drafting began to implement SB 274/HB 283 State Board of Pharmacy – Sunset Extension and Revisions, 2012.
10.34.36	Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes	Practice Subcommittee began meeting September 26, 2011 to consider a new chapter. Proposed revisions were released for informal comment January 18, 2012 – February 17, 2012. Board approved proposal at the March 21, 2012 Board Meeting and the Unit submitted the proposal for publication.

Summaries of regulatory changes that became effective in FY 2012 are provided below.

COMAR 10.34.03 Inpatient Institutional Pharmacy

The purpose of this action was to update and revise COMAR 10.34.03 Inpatient Institutional Pharmacy pursuant to the Regulatory Review and Evaluation Act, State Government Article, §§10-130—10-139, Annotated Code of Maryland. The revisions included:
1) Adding new definitions and deleting obsolete definitions;
2) Adding more details to Regulation .04 Policies and Procedures, along with grouping all the policies and procedures in one regulation;
3) Clarifying Regulation .05 Personnel, to include pharmacy technicians and provide for the delegation of responsibility for the operations of the pharmacy when the director of pharmacy is not available;
4) Revising Regulation .07 Physical Requirements and Equipment, to require compliance with COMAR 10.34.19, COMAR 10.34.28 and State and federal laws regarding disposal of hazardous materials;
5) Updating Regulation .08 Responsibilities of Director of Pharmacy, for clarification purposes and adding a section concerning administration of medications in an institution and self-administration of drugs not on the institutions formulary;
7) Revising Regulation .09 Medication Packaging – Record Keeping, to accommodate packaging from an original manufacturer's container, appropriate expiration dates, and labeling; and
8) Revisions overall to reflect the current practice of pharmacy, and for clarification and grammatical purposes.

COMAR 10.34.14 Opening and Closing of Pharmacies

The purpose of this action was to add a regulation setting forth the requirements for opening a pharmacy. The regulation also adds a section rescinding a pharmacy permit if the pharmacy is not an operational pharmacy within 60 days of issuance of the permit by the Board. Additional stylistic and regulatory reference corrections were made.

COMAR 10.34.18 Continuing Education for Pharmacists

The purpose of this action was to provide a definition for "Live Instruction". The number of continuing education credits required for renewal has not changed, but the definition should make it easier for pharmacists to determine which courses satisfy the requirement for "Live Instruction."

COMAR 10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities

The purpose of this action was to correct Regulation .07 Medication Packaging, to comply with the definition of "Packaging" so that a pharmacy technician's name, who packaged medication, is included on packaging logs maintained by the comprehensive care pharmacy. The revisions also add "name of the patient" under Regulation .08 Labeling of Patient Medications, when medication is labeled in a single container, slot, blister package, any other method of delivering an entire single dosing unit, or as part of a multi-dose dispensing package.

COMAR 10.34.25 Delivery of Prescriptions

The purpose of this action was to revise this chapter to ensure the delivery of prescriptions by the United States Postal Service, common carrier, or delivery system to an address within Maryland in a timely and safe manner so as not to interrupt continuity of therapy. The revisions included:
1) Redefining "patient" to include companion animals;
2) Reorganizing the packaging requirements where prescription medications must be:
(a) Enclosed in a container that reveals to the patient any tampering of the container that occurred during delivery or storage;
(b) Packaged in a shipping container in a manner that does not indicate that the contents are medications;
(c) Packaged in a manner that indicates:
(i) The name and address of the patient or authorized agent; and
(ii) Any special storage conditions or requirements.
The medications must be packaged to:
(1) Contain written information regarding the prescription drug or device which is considered significant in the professional judgment of the pharmacist;
(2) Contain a local or toll free telephone number for the pharmacy; and
(3) Notification to the patient if the appearance of the patient's medication has changed from the patient's last refill
The pharmacy permit holder shall inform the patient if the patient's prescription is a temperature sensitive medication that is at risk for damage due to extreme hot or cold temperatures or moisture during shipment; or after delivery to the patient's mailbox or other designated location. Finally, the pharmacy permit holder shall inform the patient within 24 hours of being notified of the delay if the scheduled delivery of the patient's prescription will be interrupted or late.

COMAR 10.34.32 Pharmacist Administration of Vaccinations

The purpose of this action was to implement SB 845 Pharmacists – Administration of Vaccinations – Children, by revising the regulations to allow pharmacists to administer influenza vaccinations to children age 9 years old and above. For all other vaccinations, the pharmacist may not administer vaccinations to any individual younger than 18 years old. The regulations also have been revised to include the requirement that a pharmacist report to the Maryland Immunization Registry an influenza vaccination administered by the pharmacist to individuals who are from 9 to 18 years of age. As part of the required training program for registration to administer vaccinations in Maryland, pharmacists are trained to observe patients for 15 minutes.

COMAR 10.34.35 Infusion Pharmacy Services in an Alternate Site Care Environment

The purpose of this action was to establish regulatory requirements to set uniform standards for pharmacies that provide infusion therapy to patients in alternate site care environments in Maryland. The regulations set forth responsibilities for the permit holder, supervising pharmacist, pharmacist, and support personnel. It requires policies and procedures that address personnel, security, standards of patient care, infection control, initial and ongoing home safety assessments, patient education, patient care operations, delivery arrangements, patient confidentiality, and pharmacist availability after hours. Training requirements for all staff is required to addresses patient care, universal precautions, warehouse and equipment orientation, waste management, hazardous substances, customer service, patient confidentiality, policies and procedures, and other activities. Specific training requirements are broken down by pharmacist, pharmacy technician and unlicensed personnel. A performance improvement program is also required to address medication errors, adverse drug reactions and equipment malfunctions. The regulations address discontinuation of infusion therapy and end of therapy orders. Finally, the regulations require specific reference materials beyond what is required in COMAR 10.34.07.03, such as Material Safety Data Sheets, IV compatibility references, stability and extended stability references, websites and electronic references, and other appropriate clinical references for the population served.

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.

Next Year at a Glance

The Unit will be busy in the beginning of Fiscal Year 2013, preparing two legislative reports due January 1, 2013. 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; and

The Unit will also begin preparing a report to the Senate Education, Health and Environmental Affairs Committee and the House Health and Government Operations Committee in accordance with the Board's Sunset Legislation - SB274/HB283 State Board of Pharmacy - Sunset Extension and Revisions due October 1, 2013.

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