

STATE OF MARYLAND

Department of Health and Mental Hygiene

# BOARD OF PHARMACY



## FISCAL YEAR 2013 ANNUAL REPORT

July 1, 2012

through

June 30, 2013

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 2013 BOARD 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*

**Vacant**

*Acute Care Hospital Representative*

**David Jones**

*Long Term Representative*

**Lenna Israbian-Jamgochian**

*Chain Drug Store Representative*

**Richard W. Matens**

*Consumer Representative*

**Zeno St. Cyr, II**

*Consumer Representative*

**Jermaine Smith**

*Chain Drug Store Representative*

## **BOARD COUNSEL**

**Linda Bethman, AAG**

**Brett Felter, Staff Attorney**

## FY 2013 BOARD STAFF

### EXECUTIVE 410-764-4794

|  |  |
|--|--|
| <b>LaVerne Naesea</b> , Executive Director<br><b>Stephen J. Holmes</b> , Executive Assistant | Board Operations, Board Members<br>and Board Minutes |
|--|--|

### ADMINISTRATION 410-764-5929

|  |   |
|--|---|
| <b>Patricia Gaither</b> , Administration & Public Support Manager<br><b>Janet Seeds</b> , Public Information Officer<br><b>Anasha Page</b> , APS Assistant<br><b>Rhonda Goodman</b> , Secretary/Receptionist | Fiscal, Budget, Procurement,<br>Travel, Personnel and Public<br>Information |
|--|---|

### LEGISLATION AND REGULATIONS 410-764-4794

|   |  |
|---|--|
| <b>Anna Jeffers</b> , Legislation and Regulations Manager | Legislation and Regulations and<br>Pharmacy Practice Committee |
|---|--|

### COMPLIANCE 410-764-5988

|  |  |
|--|--|
| <b>YuZon Wu</b> , Pharmacist Compliance Officer<br><b>Emory Lin</b> , Pharmacist Inspector<br><b>Vacant</b> , Pharmacist Inspector<br><b>Nancy Richard</b> , Lead Inspector<br><b>Janelle McKnight</b> , Inspector<br><b>Shanelle Young</b> , Inspector<br><b>Kerri Weigley</b> , Inspector<br><b>Vanessa Gray</b> , Compliance Investigator<br><b>Steven Kreindler</b> , Compliance Coordinator<br><b>Courtney Johnson</b> , Compliance Secretary | Complaints, Pharmacy Practice,<br>Disciplinary, Inspections,<br>Investigations and Pharmacists<br>Rehabilitation |
|--|--|

### LICENSING 410-764-4756

|  |   |
|--|---|
| <b>Latoya Waddell</b> , Licensing Manager<br><b>Doris James</b> , Licensing Specialist<br><b>Keisha Wise</b> , Licensing Specialist<br><b>Tiffany Duncan</b> , Licensing Specialist<br><b>Janelle Jamerson</b> , Licensing Secretary | Licensing, Permits, and<br>Registration, Reciprocity, and<br>Scores |
|--|---|

### MANAGEMENT INFORMATION SERVICES 410-764-4685

|  |  |
|--|--|
| <b>John Johnson</b> , MIS Manager<br><b>Michelle Hsu</b> , Database Officer<br><b>John Bozek</b> , Computer Specialist | Computer, Database and Website<br>and On-line Renewals |
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## **REMARKS FROM THE BOARD PRESIDENT**

Lenna Israbian-Jamgochian, RPh, Pharm.D



I am now in my seventh year on Maryland Board of Pharmacy and excited to serve as the new President. I am pleased to highlight some the exciting activity at the State level impacting the profession of pharmacy and the patients we serve. While much work remains on the implementation side, we took many important steps this past year to advance our mission - *“To protect Maryland consumers and to promote quality healthcare in the field of pharmacy through licensing pharmacists and registering pharmacy technicians, issuing permits to pharmacies and distributors, setting pharmacy practice standards and through developing and enforcing regulations and legislation, resolving complaints, and educating the public.”*

The Maryland State Legislature voted this year to expand pharmacists’ authority to vaccinate patients. This legislation allows pharmacists to administer vaccinations with a prescription to patients at least 11 years old. Adult vaccines may be administered through a protocol. The Board of Pharmacy is working closely with our colleagues in the Department of Health and Mental Hygiene on the regulations for such protocols to help meet the growing health care needs of our residents.

Another law was enacted requiring any sterile compounding facility to hold a sterile compounding permit issued by the Maryland Board of Pharmacy before that sterile compounding facility may provide sterile compounded products to Maryland residents. The initiative will help prevent distribution of a contaminated injectable drug. The Board of Pharmacy is now working on regulations expected to apply to all permit holders engaging in sterile compounding, whether they are a pharmacy or not.

The Board of Pharmacy also updated its disciplinary sanctions, monetary penalties, and civil fines. The new sanctioning guidelines include: (1) a range of sanctions for each type of violation for pharmacy permit holders, pharmacists, pharmacy technicians, and wholesale distributors; and (2) a list of mitigating and aggravating circumstances that may be used to decide if a sanction falls within or outside the established range of sanctions. The sanctioning guidelines will be used by the Board to assure consistent decisions when sanctioning pharmacy permit holders, pharmacists, pharmacy technicians, and wholesale distributors in formal and informal proceedings.

A new regulation was also enacted for pharmaceutical services to residents in assisted living programs and group homes. The purpose of this action was to reflect the current practice of pharmacy in assisted living programs and group homes, some of which were previously included in the same chapter as long term care facilities. There are different levels of care and regulations required there to be two separate chapters.

Finally, the current regulation for automated systems was revised to include: (1) exclusions for supply towers; (2) verification of a pharmacy technician selection of medications by a pharmacist; (3) return of unused medications; (4) the inclusion of group model health maintenance organizations; and (5) clarification that decentralized and remote automated medication systems are designed for the distribution of medications.

## MESSAGE FROM THE EXECUTIVE DIRECTOR

LaVerne Naesea



This Annual Report is prepared to provide an overview of the Maryland Board of Pharmacy's (the Board) operations between July 1, 2012 and June 30, 2013. The Board continued to strengthen protection for Maryland pharmacy patients in FY 2013. The theme throughout this report vacillates between challenge and optimism.

With the Management Information Services (MIS) Unit having been absent a manager since June 2012, new Manager, John Johnson was a welcomed addition to the MIS Unit beginning in the second quarter. The MIS team was made complete following the permanent recruitment of a Network Specialist. The two additional staff members enabled the Board to tackle tough

technical issues related to the recently installed MIS system. Their combined knowledge working along with the unit's Database Specialist proved to be just the fix needed to resolve system glitches and stabilize functions. Among other achievements made by the MIS team were revisions to the Board's disaster recovery plan (including negotiating enhanced contract features with the remote site host); and development of plans and contract specifications for a major scanning project to electronically store or archive over 30 years of pharmacy board records.

The Board also recruited a new pharmacy technician Inspector at the end of the fiscal year; filling a vacancy created in the Compliance Unit in October 2012. For close to eight-months, the unit operated without one of its four technician inspectors. Almost immediately after the position was filled, the unit's half-time pharmacist Inspector Supervisor resigned during the fourth quarter. Unit Manager, YuZon Wu, was required to perform supplementary fieldwork while complaint investigations and monitoring of licensees under Board orders were on-going back at the Board's office. The number of FY 2013 cases investigated and requiring formal actions more than doubled over the past five years because of new Board mandates and responsibilities. Despite workload challenges, Manager YuZon Wu persevered and managed to work with the Disciplinary Committee in revising inspections forms, securing training for all unit staff on USP Sterile Compounding and site monitoring, and inspecting all wholesale distributors in the State prior to their renewal.

Several transitional changes during FY 2013 also confronted the Licensing Unit. The passage of new mandates in the previous legislative session, as well as the installation of the new MIS system required the unit to revise most of its business rules, while also being required to process an increased number of new applicants for licensure. One of several new statutes passed during the 2012 legislative session required non-resident pharmacies to employ a Maryland licensed pharmacist in order to obtain a Maryland pharmacy permit. Other new mandates created the need to revise new applications for pharmacists, pharmacy technicians, and establishments during the last quarter. The Board was fortunate to have recruited Latoya Waddell as the unit's new Licensing Manager. Manager Waddell instituted numerous initiatives to address the many new assignments. Top on her agenda during FY 2013 was to successfully cross-train the unit's four Licensing staff to assure that the expanded number of new and renewal applications were manageable.

The Legislative Regulations section of this report describes the many mandates and regulations that affected Board operations in FY 2013. Unit Manager, Anna Jeffers worked tirelessly with Board committees, legislators, other Board regulators, stakeholders, and consumers to address trends and societal changes that threatened the safety of the prescription drug chain, from manufacturing to being dispensed to patients. The Legislation and Regulations Unit reviewed over two hundred bills during FY 2013. Thirteen (13) bills were enacted that had significant impact on Board operations, including bills related to sterile compounding, wholesale distribution, and non-resident pharmacies and pharmacists.

Under the strong leadership of Manager Patricia Gaither, the Administration and Public Support Unit (APS), served as the engine and the glue that provided the infrastructure to support the aforementioned units in meeting Board goals in FY 2013. In addition to recruiting all contractual and permanent staff, this four-person unit assured that staff payroll and Board member per diems were tracked; personnel was trained; travel was arranged; and staff evaluations were completed. The APS Unit requisitioned and ensured maintenance of all computers; equipment and supplies; prepared and procured all contracts for services and systems; planned and manned all continuing education events and Board exhibitions; responded to all public information requests; processed all mail and fees received at the Board; and facilitated the development and issuance of all Board publications.

The effort put forth by the Board's five organizational managers in FY 2013 not only helped the Board overcome many very difficult challenges, it also earned the management team a *Team Award for Excellence* from the Department of Health and Mental Hygiene.

Board and staff members were also a strong team, committed to protecting Maryland consumers and promoting quality health care in the field of pharmacy. The following pages provide statistical information as well as other details about the Board's successes and challenges during a very active FY 2013. The challenges experienced in implementing significantly more complicated mandates in FY 2013 led to the creation of new ways to address issues and respond to customers. The Board of Pharmacy will apply the lessons learned in 2013 as it enters 2014 with greater optimism for improved and enhanced operations.

## **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: 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 based on an annual budget request that must be approved by the Secretary of the Department of Health and Mental Hygiene (DHMH), the Governor's office, and subsequently by the State Legislature. Funding to support new program areas, personnel, purchases and/or 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 FY 2013 was \$2,834,668. Board fiscal functions include collection of fees and revenue and budget reconciliation activities.

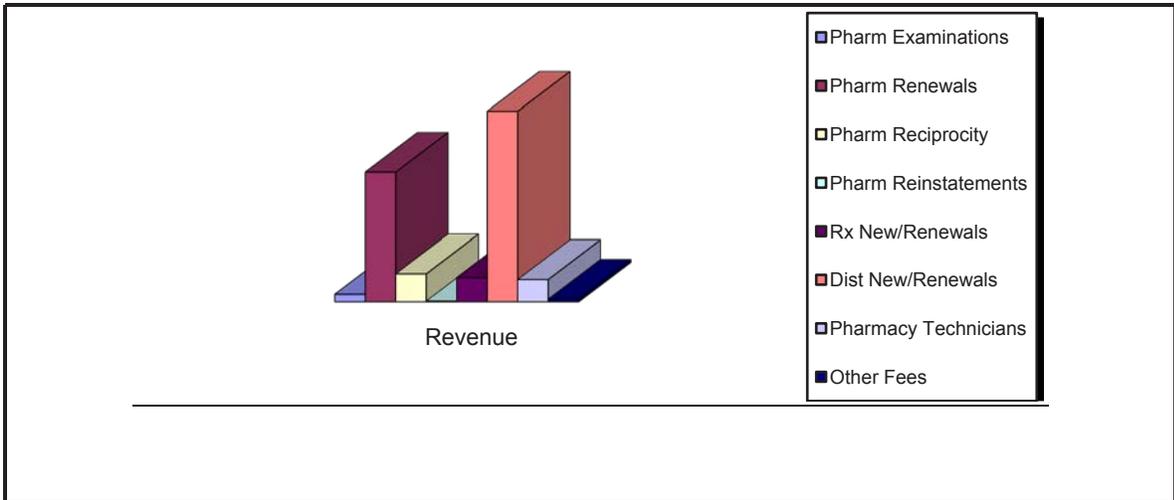
Other fiscal functions include the processing of contractual agreements, procurement of equipment and supplies, payment of invoices and travel requests, expense reports and vehicle mileage reports and inventorying and archiving documents for the Board. Fiscal activities also include reviewing proposed legislation and preparing fiscal notes. Additionally, the APS unit plans all personnel and training 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 pharmacy community.

### **Board Revenue**

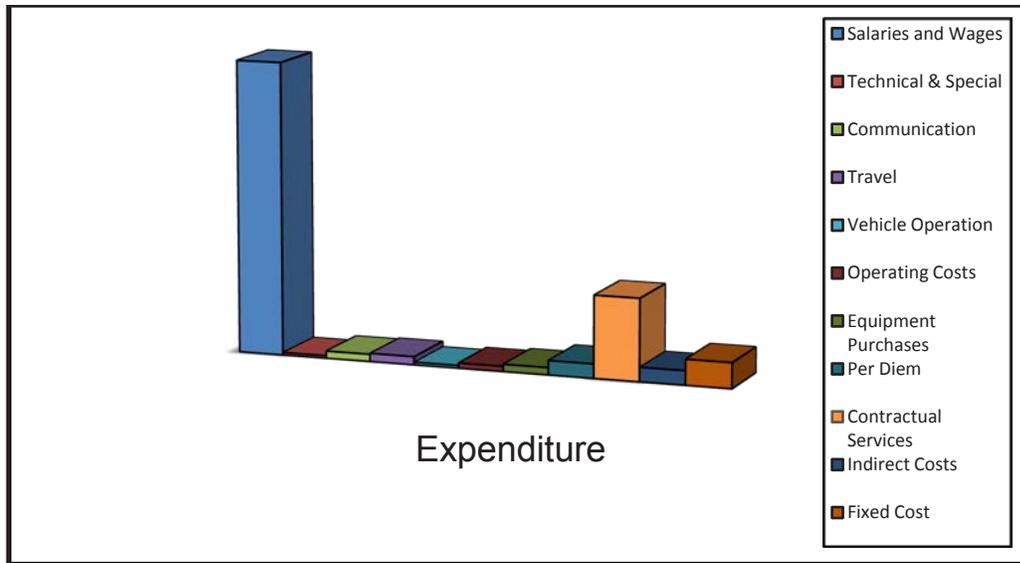
The total revenue collected for FY 2013 was \$3,713,014. The revenue in the chart below reflects changes in the renewal periods for pharmacy and distributor establishments during the previous legislative session. Respective establishment fees will be collected biennially in future years. Additionally, in FY 2013, the Board moved the respective establishment renewal periods from December 2012 to May 2013. The Board collected two years of fees for distributor establishments in May 2013. The Board will collect fees for pharmacy establishment renewal in May 2014. The increase in reciprocity applications was due to the new regulations requiring a Maryland-licensed pharmacist to be on staff at non-resident pharmacies licensed in Maryland.

### **Expenditures**

Board expenditures for FY 2013 were \$2,700,654; reflecting a less than 1% increase in expenditures over the previous year. The Board's budget allocation for FY 2013 was \$2,834,668. An increase in expenditures for salary and contractual agreements was due to hiring an interim contractual manager and temporary staff. Other increases were due to new equipment purchases required to support the new database.



| FY 2013 Revenue Detail   |                  |
|--|------------------|
| Pharmacists Examination  | 68,850           |
| Pharmacist Renewals  | 1,187,442        |
| Pharmacists Reciprocity  | 256,120          |
| Pharmacists Reinstatements   | 6,600            |
| Pharmacy New/Renewals/Reinstatements                                       | 221,300          |
| Distributor New/Renewals/Reinstatements                                    | 1,744,050        |
| Pharmacy Technicians   | 203,996          |
| Other Fees   | 24,656           |
| <b>TOTAL REVENUE COLLECTIONS CREDITED TO THE BOARD OF PHARMACY FY 2013</b> | <b>3,713,014</b> |



| FY2013 Expenditure Detail   |                  |
|-----------------------------|------------------|
| Salaries and Wages          | 1,710,529        |
| Technical & Special Service | 14,429           |
| Communication               | 42,459           |
| Travel                      | 48,060           |
| Vehicle Operation           | 15,517           |
| Operating Costs             | 30,201           |
| Equipment Purchases         | 42,631           |
| Per Diem                    | 84 060           |
| Contractual Services        | 478,006          |
| Indirect Costs              | 84,531           |
| Fixed Costs                 | 150,231          |
| <b>TOTAL EXPENDITURE</b>    | <b>2,700,654</b> |

## **Personnel**

In FY 2013 the Board was granted another permanent position. The Board now has 24 permanent (PIN) positions, of which 22 were filled with permanent staff during most of the year. In addition to filling the new PIN position, the Board filled the vacancy for MIS Manager. The Board also promoted a Licensing Specialist to Licensing Manager and reclassified the Licensing Secretary to Licensing Specialist. A temporary employee (TE) was hired to fill the Licensing Secretary position until a permanent secretary is hired. Two Board inspectors resigned in FY 2013. However, one position was filled in late FY 2013 and the other position is expected to be filled in early FY 2014. A contractual Help Desk position was also on staff during the year.

## **Procurement**

The new database project was initiated in October 2012. However, the Board continues to experience challenges with the new database project. The contractual Project Manager was replaced by a permanent MIS manager to continue with implementation of Phase II of the new database system. The Board continued its long-standing Pharmacist Rehabilitation Services contract with the Pharmacists' Education & Advocacy Council (PEAC) of Maryland to support impaired practitioners under Board orders and practitioners who voluntarily (and anonymously) entered into treatment. In FY2013, the Board also continued its contracts with Maryland State Archives to provide web hosting and web statistics and with the National Association of Boards of Pharmacy (NABP) to perform inspections of out of state pharmacy establishments. The Board's newsletter and annual report printing is now done by Maryland Correctional Enterprises (MCE). The Board has contracted with the Maryland Pharmacy Laws book printer, Lexis Nexis, to provide an eBook version of the Maryland Pharmacy Laws. The Maryland Pharmacy Laws is now available in both print and eBook format.

## **Public Information**

Public Information staff in 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 56 PIA requests responded to in FY 2013. The staff in the unit is assigned to assure that information released does not violate state and federal confidentiality rules.

The unit assists year-round recruitment and coordinates training for volunteer pharmacists. Gathering articles for the Board's quarterly newsletter; compiling and consolidating unit reports for the Board's Annual Reports; and developing/updating 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.

Two other important public information responsibilities in the APS Unit include monitoring and coordinating responses to pharmacy-related news media and planning. Unit personnel staff the Emergency Preparedness Task Force and the Public Relations Committee, as well as coordinate Board training and public relations 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 2013 Summary of Public Relations Activities**

Exhibit at the Maryland ASCP Mid-Atlantic Conference, Ellicott City, MD, August 2012

Baby Boomer Expo, Timonium Fair Grounds, MD, October 2012

Baltimore Flower Mart, Mt. Vernon Place, Baltimore City, May 2013

Maryland Pharmacists Association (MPhA) Annual Convention, Ocean City, MD, June 2013

## **FY 2013 Summary of Pharmacist Training & Education**

Board of Pharmacy Annual Continuing Education Breakfast, Radisson Cross Keys, Baltimore, MD, October 2012

## **FY 2013 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.

## **Staff Training**

During FY 2013, the Board Staff participated in various trainings. Various Unit staff participated in DHMH Training courses such as Management (PEP) Training, Risk Management, Share Point, Google and "Thinking Inside the Box", Emergency Preparedness and Response Training. In-house training included Systems Automation database training and new Xerox Copier Training. Specialized Training included SQL and Crystal Reports Training for MIS staff, USP 797 and NCIT Training for Compliance Unit staff, NABP Training for Licensing staff, and Citizen Advocacy Center training for the APS staff. The Executive and Legislative Units and Board Members participated in out of state trainings such as NABP and Federation of Association of Regulatory Boards (FARB) Conferences.

## **Out of State Travel**

NABP Annual Conference, St. Louis, MO - Two Board Members and One Staff Member

NABP District I & II Conference, Skytop, PA - Two Board Members and One Staff Member

FARB Attorney Certification Conference, Atlantic Beach, FL - Assistant Attorney General

### **Next Year At a Glance**

The Board anticipates an increase in expenditures to complete Phase II of the Database project and to implement the new Sterile Compounding statutory mandate. Completion of the new MIS system is expected to begin in FY 2014. Additionally, the Board will hire a scanning contractor to assist in documents management. Along with the scanning contractor, the Board will hire temporary emergency employees to prepare licensing and compliance documents for database entry and archiving. The Sterile Compounding mandate entails establishing a new licensure category and monitoring licensees. It will require the Board to recruit four new employees. The Board expects recruitment to begin during the last quarter of FY2014. The unit will continue training, educational, and emergency preparedness activities to heighten visibility of patient safety efforts throughout the state.

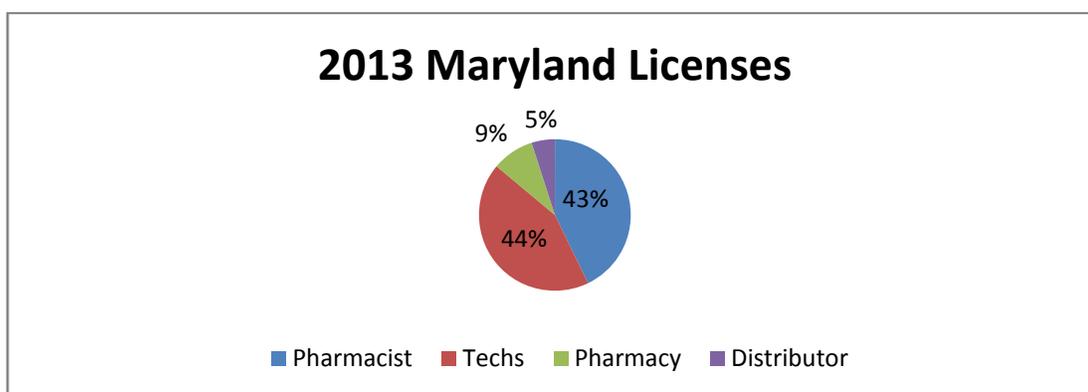
## LICENSING UNIT

### Overview

The Licensing Unit is responsible for all activities related to the evaluation of candidates for Maryland licensure and the processing of related licenses, registrations, and permits to pharmacists, pharmacy technicians, pharmacy owners, and pharmaceutical distributors that meet Maryland standards for practice. The unit also evaluates applications for administering Influenza, Herpes Zoster, and Pneumococcal Pneumonia vaccines. The Licensing Unit consists of five professional licensing staff persons: a Manager, three (3) Licensing Specialists, and a Secretary.

### Licensing Processing Statistics

Despite initially slow progress in reducing the length of time required to process licenses new initiatives were taken to balance the set back. One important initiative involved cross-training all Licensing Unit staff members to process and enter data for any application type. The Licensing Unit processed a total of 22,725 licensees and certificates during FY 2013.



Nearly ten thousand pharmacists (9,795) were included in the number of licensees, reflecting an increase of 1,038 from the previous fiscal year. The growth is attributable to: non-resident pharmacies preparing to meet the new requirement of employing at least one Maryland licensed pharmacist; and two new Board approved schools of pharmacy, Notre Dame University and University of Maryland Eastern Shore, graduating their first classes in May 2013.

Maryland licensed pharmacies also experience an increase of 122, bringing the total to 1941 by the end of FY 2013. This increase resulted partially from Durable Medical Devices pharmacies seeking licensure following changes in federal law. Licensed Wholesale distributors increased in FY 2013 by 169 bringing the total number of distributors to 1089 by end of FY13. The number of registered pharmacy technicians 9,900 decreased slightly in FY 2012 which may have been related to the new MIS database system being able to filter out duplicate records for pharmacy students whose statuses had changed from pharmacy technicians following graduation and becoming licensed pharmacists. The new database system now prevents system errors that previously reflected individuals holding pharmacist licenses and technician registrations concurrently.

## Next Year at a Glance

The Licensing Unit is looking forward to another busy year in FY 2014. It plans to continue to support unit staff members that specialize in processing one of the four key license types and to begin issuing permits to the new category of Sterile Compounds. 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. Additional training on use of the Board new database system, including functions to be installed with the implementation of Phase II of the MIS project, is also anticipated. Phase II entails the receipt of new applications on-line in addition to the renewal applications. Staff will continue participation in cross-training to process 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 staff members are absent. All vacancies were filled at the end of FY 2013 and the Unit Manager is working on initiatives to encourage staff retention.

Finally, the Unit has set a goal to reduce the time for processing all categories of applications Unit by developing procedures to refine processing methods and eliminate time lost during peak application periods.

## New Developments

The new Licensing Unit Manager, appointed during the last quarter of 2012, faced several challenging initiatives and issues in FY 2013. As a result of Sunset Review legislation proposed during the FY 2012 session, renewal dates for pharmacies and wholesale distributors changed from **December 31 to May 31**. (See Md. Code Ann., Health Occ. § 12-407.) Also beginning in FY2013, wholesale distributor personnel were statutorily required to submit criminal background check reports from the states where the facilities were located. Other legislation that became effective October 1, 2012 required non-resident pharmacies to have at least one Maryland licensed pharmacist in its employ. The new requirement contributed to an increase in the number of Board-licensed pharmacists during FY 2013. Also, in the Spring of FY 2013 (May), two new pharmacy schools, Notre Dame University of Maryland and University of Maryland Eastern Shore both graduated their first class of pharmacy students, many of whom applied to become Maryland licensed pharmacists.

Other non-routine activities in which the Licensing Unit staff engaged included responding to the Board's ten-year Sunset Review, concurrent with testing and learning the new MIS SQL database system. 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. The system associates fees and fines payments to issued licenses, registrations, and permits. The new database system also allows licensees to directly change certain information, such as their addresses. After initial implementation during the beginning of the second quarter of 2013, several of the system's functions required adjustments and reconfiguration, which significantly slowed processing and printing of licenses. Staff members were required to manually review and process licenses. In lieu of their actual licenses, letters also had to be sent to all applicants for use in verifying their licensure statuses. Licenses were eventually printed and mailed, which created double work for the unit's staff.

## PHARMACY COMPLIANCE UNIT

The Compliance Unit protects the public health of Maryland's citizens by ensuring compliance with state laws and regulations governing the practice of pharmacy. Unit staff consists of a Pharmacy Compliance Manager, 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; and
- Inspect pharmacies and wholesale distributors.

The unit experienced several personnel concerns and computer software issues that affected certain operations, as detailed below. Specifically, the Board lost one full time inspector in September 2012, an inspector was out on maternity leave for 2 months, another inspector was out on medical leave for a month, and a part-time pharmacist inspector left in April 2013. For the first three or four months of FY 2012, the inspectors spent much of their time assisting with and training for the new computer software the Board was planning to implement. Despite these setbacks, the unit was able to conduct annual inspections, wholesale distributor inspections, attend additional training on Sterile Compounding, and support the Board in developing more uniform complaint reviews.

An Inspection Form Review Subcommittee was formed in November 2012 to review and update all current inspection forms and develop new forms for Durable Medical Equipment (DME) opening inspections and waiver sterile compounding inspections. This Subcommittee continues to meet at present time.

### 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.dhmf.maryland.gov/pharmacy](http://www.dhmf.maryland.gov/pharmacy) and may submit the completed form via fax, mail, email, or in person. All information related to each complaint is investigated and the results are presented to the Board's Disciplinary Committee for review and recommended follow-up action by Compliance Unit staff or the full Board. If an issue is outside the Board's scope or jurisdiction, the complaint is referred to the appropriate authority.

Figure 1, below, provides the number of new complaints received in the past six fiscal years. The highest number of new complaints was processed in FY2012, at 358.. The number of new complaints processed in Fiscal Year 2013 was 314. Complaints received by the Board may include, but are not limited to, actual complaints made by individuals, referrals from other state of federal agencies, or deficiencies found during inspections.

Figure 1 Complaints Processed July 1, 2012 - June 30, 2013

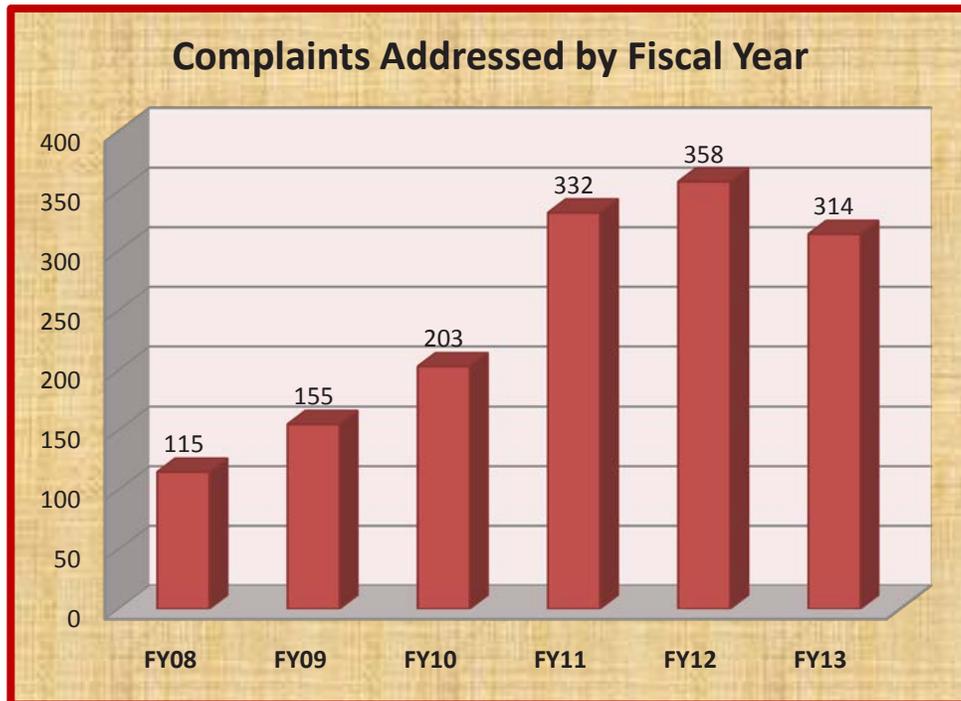
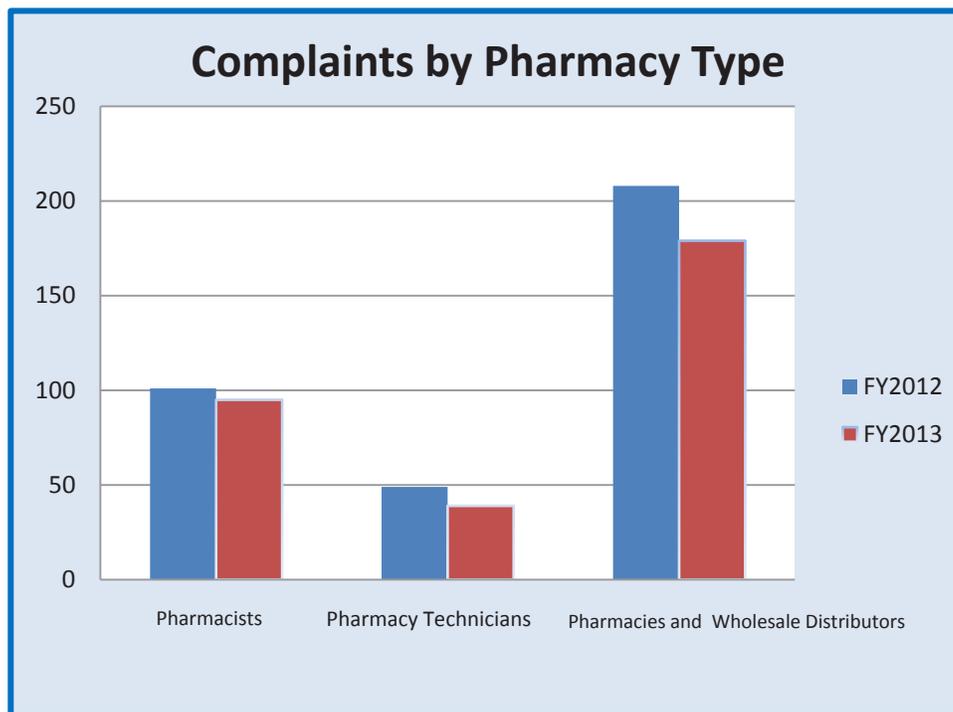
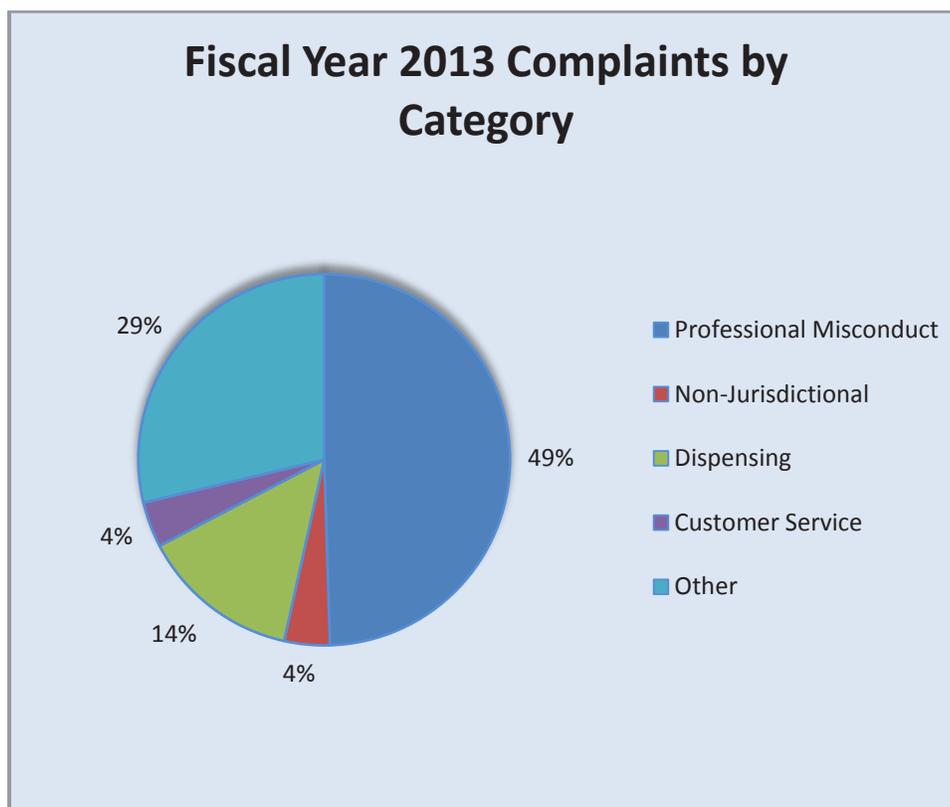


Figure 2 Complaints against Licensees, Registrants, and Permit Holders



This is the 5th 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 12% (37) of the complaints filed in this FY were against pharmacy technicians. This is three times higher compared to FY2009, during the early implementation of pharmacy technician registration, but comparable to FY2012.

**Figure 3**      **Types of Complaints July 1, 2012 - June 30, 2013**



The types of complaints received are broadly categorized (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 examples of professional misconduct.

### Disciplinary Cases

All complaints are investigated by Board staff. For the current fiscal year, the Board has taken formal or informal actions on 324 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 orders 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 29% (91) of the complaints remained open, pending more investigation because of the back log from the previous fiscal year.

Figure 4 shows the number of formal and informal actions taken for FY 2013, compared to the previous 5 years.

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

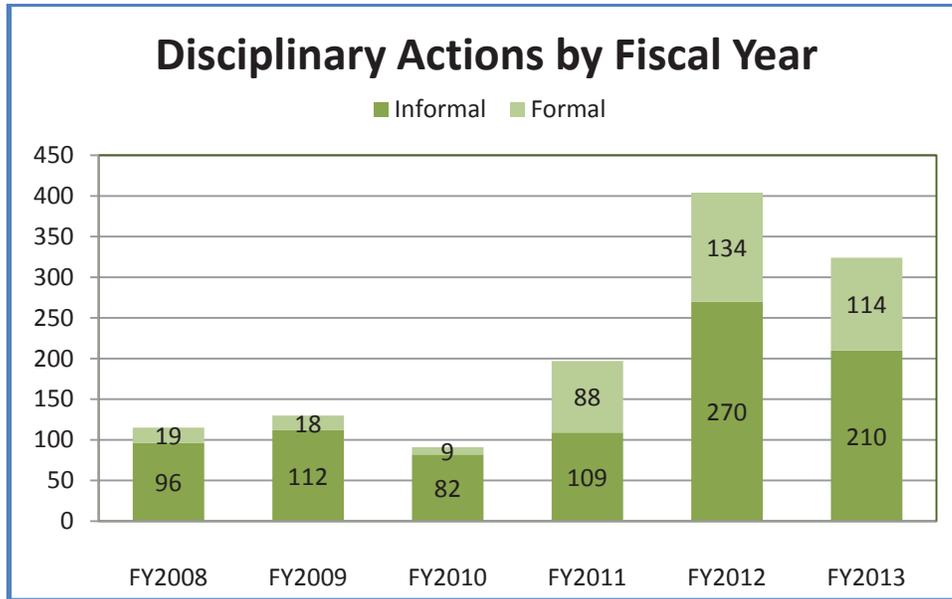
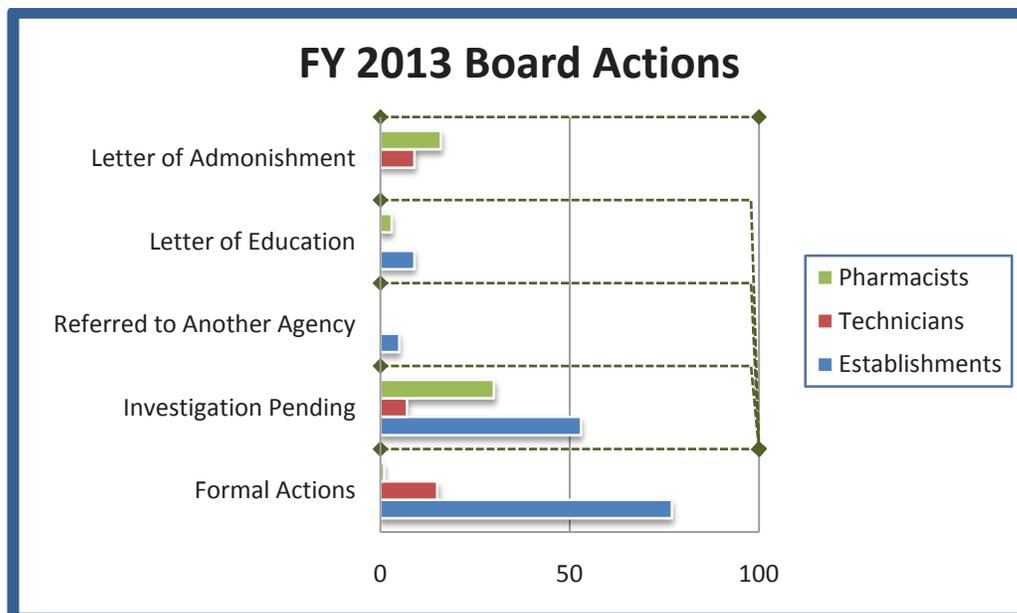


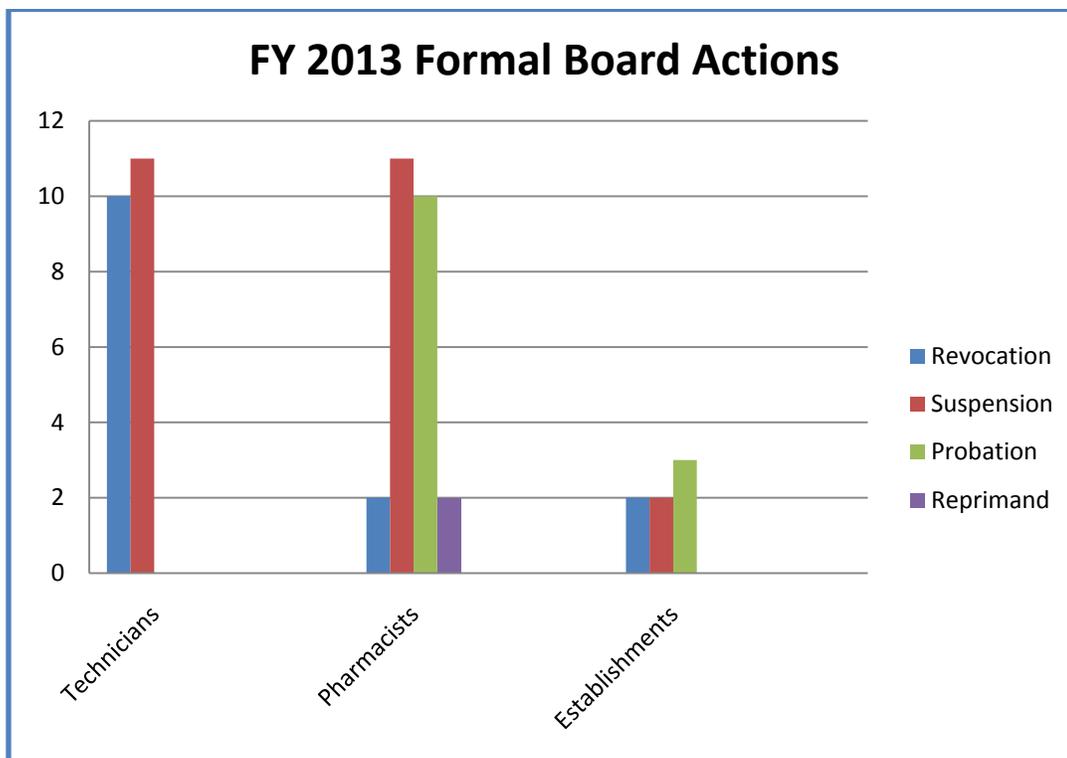
Figure 5 represents a categorical description of the various types of formal and informal actions taken against pharmacists, pharmacy technicians, and establishments in FY 2013.

**Figure 5** Board Action July 1, 2012 - June 30, 2013



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 FY2013. 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, 2012 - June 30, 2013



### Inspections

The Compliance Unit continues to work closely with the Division of Drug Control (DDC) in performing inspections. The Board of Pharmacy conducts opening inspections, some closing inspections, relocation inspections, change of ownership inspections, and annual inspections of instate pharmacies. The 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 inspections, opening inspections, miscellaneous inspections (relocation, change of ownership, investigative inspections), and distributor inspections performed in FY 2013. Despite limitations due to vacancies and inspectors having to spend most of their time at the office during the beginning of the fiscal year to work with the new computer system, the Board completed approximately 79% (1026) annual inspections of the 1298 facilities permitted in Maryland.

**Figure 7**

|                          |      |
|--------------------------|------|
| Annual Inspections       | 1026 |
| Opening Inspection       | 96   |
| Miscellaneous Inspection | 58   |
| Distributors             | 121  |
| Total Inspections        | 1301 |

The Board was also required to inspect all new and renewing wholesale distributors under the Wholesale Distribution Permit and Prescription Drug Integrity Act. During FY 2013, the Board of Pharmacy completed 100% of its wholesale distributor facilities inspections located in Maryland.

This is the first year where the Board licensed DME facilities and there were ten opening inspections performed in June 2013. These are included in Figure 7, under Opening Inspections.

All Board of Pharmacy inspectors received refresher training in Sterile Compounding provided by the United States Pharmacopeia (USP) in February 2013.

### **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 incidence of dependency 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;
- Continuing education (CE) requirements; and/or
- 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 FY 2013, the Board monitored ten pharmacists and one 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. One public order related to substance abuse was issued to a registered pharmacy technician during FY2013.

The Maryland Board also contracts with the Pharmacist Education and Advocacy Council (PEAC) of Maryland, 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 contract are violated.

In FY 2013, PEAC monitored a combined total of 22 clients: 20 pharmacists and 2 pharmacy technicians.

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

For FY 2014, the Compliance Unit plans to:

- Provide additional training to staff in sterile compounding and other specialty pharmacy practices, as well as in enhanced investigation techniques;
- Reduce the number of open investigation cases carried over to the next fiscal year;
- Have more uniform review and better defined categories for the different types of complaints;
- Recruit and retain a full cadre of compliance staff including pharmacy inspectors and investigators; 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 Board operations and help accomplish its mandate to protect pharmacy patients and assure quality pharmacy health care in the State of Maryland. The unit is comprised of 3 full-time staff members, including a Supervisor/Manager, Computer Network Specialist and Database Specialist.

### New Developments

The Board contracted a project manager in FY 2012 to facilitate the database implementation project that had been halted because of key MIS staff vacancies and issues experienced by the contractor. During the second quarter in FY 2013 the Board partially implemented its new SQL-based automation system. Problems related to updates and configuration contributed to pharmacists and pharmacy technicians initially experiencing problems renewing online. Configuration to allow the pharmacy and wholesale distributors to renew on-line also had not been completed. The project manager resigned shortly prior to the recruitment of permanent staff during the second quarter of FY 2013.

A permanent Unit Manager/Supervisor and a permanent Computer Network Specialist were recruited in the third quarter. Working with the vendor the MIS team adjusted the system to accommodate on-line renewal by most pharmacists and pharmacy technicians. However, the new system could not accommodate all of the business rules required for field inspection processes. At the end of FY 2013, the MIS staff and the vendor continued to be engaged in configuring the system to support inspections and also to allow pharmacy and wholesale distributor permit holders to renew on-line.

### Accomplishments

All Board staff received training in FY 2013 to learn about unique features of the new system and how to gain the greatest benefit from the new data collection processes. MIS Unit Staff supported the development of new business rules, preparation of written operating procedures and provided training and technical support for the new system users. MIS staff also received training for preparing *Crystal* reports in FY 2013. Reports can now be generated by the Board. The new MIS system includes an online verification site where citizens and interested parties can do searches to verify the validity of licenses. Future updates and configuration of this site will allow the public to download search results into a document.

The MIS Unit also secured a remote disaster-recovery site at Maryland State Archives that houses the Board's network licensing servers. Additionally, mobile hotspots were secured so the Board's field inspectors could access the Board's network licensing data remotely. Also during FY 2013, the MIS Unit took steps to secure the Board's IT infrastructure, negotiated to acquire a remote disaster-recovery site at Maryland State Archives and requisitioned and configured new equipment (scanners, laptops, etc.) to better automate and support new business rules resulting from implementation of the new system. Moreover, MIS staff secured mobile hotspots for the Board's field inspectors to allow them to access

Other accomplishments for the 2013 fiscal year included evaluation and replacement of older computer equipment at the board, and updating desktop software/hardware to meet DHMH policy standards.

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

Through the bidding process the board will secure a vendor to scan and archive approximately 2 million paper documents. This will prevent the Board from having to move the older files when it relocates to new offices (planned later in FY 2014). The electronic document management system, in which scanned documents will be uploaded, will enable staff users to digitally retrieve older documents rather than sift through thousands of paper files. This will also reserve space at the Board of Pharmacy offices because the scanned documents will be stored offsite by MD State Archives.

The MIS Unit plans to work with the Board's software vendor to enhance the new online system. This second phase of the MIS project is planned to begin in FY 2014. Enhancements will enable pharmacies and wholesale distributors to renew permits online. New applications for some license types are also planned to be accepted on-line through system enhancements next year. The MIS Unit staff will explore the availability of compatible mobile inspection applications to integrate into the current IT environment since inspection requirements have not been met by the recently implemented system.

## LEGISLATION/REGULATIONS UNIT

### Legislation/Regulations Unit Overview

The Legislation and Regulations 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 routinely staffed by the unit in FY 2013 included Pharmacy Practice and Legislative. During FY 2013, the unit also staffed the Drug Therapy Management and Sterile Compounding Subcommittees and the Durable Medical Equipment Provider Task Force.

The Board routinely revises regulations as laws and the practice of pharmacy change. Identified problems and new trends in patient care also influence the Board's decision to propose changes to regulations. The unit worked on a number of revisions to various chapters within the Board of Pharmacy Regulations that had not completed the promulgation process by the end of FY 2013. Revisions to regulations for **Sterile Pharmaceutical Compounding** were begun in order to accommodate HB 986. HB 986 established a new license type for sterile compounding and a waiver for distributors of sterile drug products who do not qualify for oversight under the Food and Drug Administration (FDA). Several other sets of regulations worked on by the unit to accommodate statutes enacted during the 2013 session included regulations to accommodate: **SB 595/HB 591 State Board of Pharmacy – Wholesale Distribution – Pharmacies, 2013; and HB 179 Pharmacist Administration of Vaccinations.** The bills related to these regulations are discussed below.

Other regulatory revisions initiated by the Board and prepared by the unit during FY 2013 included:

- **COMAR 10.34.03 Inpatient Institutional Pharmacy;** regulations were revised to address the numerous decentralized pharmacies that operate under a single hospital pharmacy permit. Changes proposed will allow better monitoring of the activities at each of the decentralized pharmacies that operate under a hospital umbrella. (published in the Maryland Register for comment at the end of FY 2013);
- **COMAR 10.34.14 Opening and Closing of Pharmacies,** revised to clarify permit holder notification requirements and the roles of the Board and designated agents in conducting closing inspections (Notice of Final Action was published at the end of FY 2013, with an effective date in early FY 2014);
- **COMAR10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors** revised to address legislation passed during the 2012 and 2013 Legislative Sessions;
- **COMAR 10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities,** revised to strengthen long term care patient protections by requiring a pharmacist to perform final checks on the prescription drugs placed in interim boxes located at comprehensive care facilities (published in the Maryland Register at the end of FY 2013);

- **COMAR 10.34.30 Change to Permit – Pharmacy or Wholesale Distributor Permit Holder**, revised to require permit holders to notify the Board when it changes days and/or hours of operation to assist Board inspectors in scheduling inspections of pharmacies and wholesale distributors (Notice of Final Action was published at the end of FY 2013, with an effective date in early FY 2014); and

- **COMAR 10.34.37 Pharmacy Permit Holder – Wholesale Distribution**, revised to comply with SB 595/HB 591 State Board of Pharmacy – Wholesale Distribution – Pharmacies, no longer allowing wholesale distribution by a pharmacy with a waiver permit to a wholesale distributor. Waiver pharmacies will be required to keep proper records of wholesale distribution. Full service pharmacies may distribute to a wholesale distributor with proper record keeping and by submission to the Board of a “Reporting Form” within a week of the wholesale distribution.

During FY 2013 the unit responded to 1,556 phone calls and provided written responses to 452 e-mail and letter inquiries from the public, applicants, licensees, permit holders, Maryland agencies, pharmaceutical companies, legislators, lobbyists, prescribers, other state boards, attorneys, and students from around the country. The unit responded in detail to all the issues presented, in the order in which they were received. Questions posed to the unit that required Board interpretation or involved controversial issues were presented at the monthly Practice Committee meeting. Depending on the Practice Committee's review, some recommended responses were brought to the Board for consideration during a Public meeting.

### **Legislative Initiatives**

During the interim period before the Maryland Legislative Session begins, the unit assists the Board in determining whether changes to the Maryland Pharmacy Practice Act may be appropriate. The unit prepares Legislative Proposals for submission to and review by the DHMH Office of Governmental Affairs. Additionally, the unit arranges for meetings in Annapolis to apprise the Chairs (or “Chairmen”) of the Senate Committee on Education, Health, and Environmental Affairs (EHE) and the House Committee on Health and Government Operations (HGO) 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 Board 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 53 bills (of approximately 2,610 bills) to present to the Board of Pharmacy's Legislative Committee for consideration during FY 2013. The unit tracked, drafted position papers and/or letters to legislative committees for 15 of the 53 bills. Provided below is a chart of the 15 bills (companion bills are counted as one bill) and the results.

| <b>Bill #</b> | <b>Bill Name</b>   | <b>Result</b> |
|---------------|--|---------------|
| HB 148        | State Government – Refund of Fees - Policy   | Failed        |
| SB 109        | Criminal Law – Controlled Dangerous Substances – Research – Synthetic Cannabinoids   | <b>PASSED</b> |
| HB 267        | Criminal Law – Controlled Dangerous Substances – Research – Synthetic Cannabinoids   | Failed        |
| SB 139        | Health Care Practitioners - Prescription Drug or Device Dispensing - Medical Facilities or Clinics That Specialize in Treatment Reimbursable Through Workers' Compensation Insurance | <b>PASSED</b> |
| HB 1237       | Health Care Practitioners - Prescription Drug or Device Dispensing - Medical Facilities or Clinics That Specialize in Treatment Reimbursable Through Workers' Compensation Insurance | <b>PASSED</b> |
| SB 166        | Dentists, Physicians, and Podiatrists - Dispensing Prescription Drugs - Inspection by Division of Drug Control   | Not voted     |
| HB 1032       | Dentists, Physicians, and Podiatrists - Dispensing Prescription Drugs - Inspection by Division of Drug Control   | Withdrawn     |
| SB 273        | Veterans Full Employment Act of 2013   | <b>PASSED</b> |
| HB 225        | Veterans Full Employment Act of 2013   | <b>PASSED</b> |
| SB 401        | Pharmacists - Administration of Vaccinations - Expanded Authority and Reporting Requirements   | <b>PASSED</b> |
| HB 179        | Pharmacists - Administration of Vaccinations - Expanded Authority and Reporting Requirements   | <b>PASSED</b> |
| SB 595        | State Board of Pharmacy – Wholesale Distribution – Pharmacies  | <b>PASSED</b> |
| HB 591        | State Board of Pharmacy – Wholesale Distribution – Pharmacies  | <b>PASSED</b> |
| SB 515        | State Board of Pharmacy – Jurisdiction over Dentists Who Prepare and Dispense Dental Products and Antibiotics  | Failed        |
| HB 783        | State Board of Pharmacy – Jurisdiction over Dentists Who Prepare and Dispense Dental Products and Antibiotics  | Failed        |
| SB 781        | Pharmacists – Biosimilar Biological Products   | Failed        |
| SB 617        | Drug Therapy Management - Physician-Pharmacist Agreements  | <b>PASSED</b> |

|         |  |               |
|---------|--|---------------|
| HB 716  | Drug Therapy Management - Physician-Pharmacist Agreements                                      | <b>PASSED</b> |
| SB 761  | Health Occupations - State Board of Pharmacy - Waivers - Pharmacies That Only Dispense Devices | <b>PASSED</b> |
| HB 868  | Health Occupations - State Board of Pharmacy - Waivers - Pharmacies That Only Dispense Devices | <b>PASSED</b> |
| HB 736  | Health Insurance – Pharmacy Benefits Managers – Specialty Drugs                                | Failed        |
| SB 928  | Health Insurance – Pharmacy Benefits Managers – Specialty Drugs                                | Failed        |
| SB 783  | State Board of Physicians – Naturopathic Doctors   | Withdrawn     |
| HB 1029 | State Board of Physicians – Naturopathic Doctors   | Withdrawn     |
| SB 896  | State Board of Pharmacy - Sterile Compounding – Permits  | Not voted     |
| HB 986  | State Board of Pharmacy - Sterile Compounding – Permits  | <b>PASSED</b> |
| HB 1323 | State Government – State Boards and Commissions – Minority Party Representation                | Failed        |

- Summaries of major bills from the 2013 Legislative Session are provided below: HB 179 Administration of Vaccination – Expanded Authority and Reporting Requirements -HB 179** will allow Maryland pharmacists, with a prescription, to administer a vaccination listed in the Centers for Disease Control and Prevention’s (CDC) Recommended Immunization Schedule to an individual who is at least 11 years old, but under the age of 18 years old. Pharmacists will also be allowed to administer vaccinations to an adult that is listed in the CDC’s Recommended Immunization Schedule or recommended in the CDC’s Health Information for International Travel. The adult vaccines must be administered under a written protocol that is vaccine specific and meets criteria established by DHMH in regulations. Additionally, all vaccinations administered by a pharmacist are required to be reported to the ImmuNet Program. The pharmacist is also required to document at least one effort to notify the authorized prescriber of the administration of the vaccine. If the authorized prescriber is not the individual’s primary care provider, or if the vaccination has not been administered in accordance with a prescription, then the pharmacist shall document at least one effort to notify the individual’s primary care provider of the administration of the vaccine.

- **HB 225 Veterans Full Employment Act of 2013** - HB 225 Veterans Full Employment Act of 2013, will require all Health Occupation Boards to expedite the licensing process for veterans, military spouses, or active duty service members in the armed forces, reserves, or the National Guard. Veterans may apply for the expedited process within one year after discharge from active duty under circumstances other than dishonorable. Military spouses may apply through the expedited process if a surviving spouse of a veteran or a service member died within 1 year before the date on which the application for a license or registration is submitted. Members of an armed force deployed outside of the U.S. or its territories will be allowed to renew their licenses or registrations after the expiration of the renewal period without payment of a penalty or reinstatement fee if the late renewal is a direct result of the deployment. Under HB 225, the Board may allow a licensee or registrant to complete any continuing education or criminal history records check required for renewal within a reasonable time after renewing the license or registration if they have been deployed outside of the U.S. or its territories. Eligible applicants will be assigned an advisor from the Board's licensing unit to assist with the application process and expedite the issuance of a license or registration. If necessary, the advisor will assist the applicant in identifying education, training, or experience requirements for licensure or registration. Licenses or registrations will be issued within 15 days of receipt of a completed application. The Board's process for veterans, military spouses, or active duty service members in the armed forces, reserves, or the National Guard will be posted on the Board's website in the near future.

- **HB 986 State Board of Pharmacy – Sterile Compounding – Permits**—HB 986 requires all sterile compounded drugs dispensed or distributed into or out of Maryland to be prepared in compliance with COMAR 10.34.19 Sterile Pharmaceutical Compounding and USP 797 Standards. The Board will regulate sterile compounding in Maryland in three ways.

- First, sterile compounding facilities, whether in or outside of Maryland, that compound pursuant to a patient specific prescription will now be required to obtain a separate Sterile Compounding Permit from the Board. Sterile compounding facilities are defined as a pharmacy, a health care practitioner's office, or any other setting in which sterile compounding is performed pursuant to a patient specific prescription. Information concerning how to apply for a Sterile Compounding Permit will be forthcoming.

- Second, an entity that prepares and distributes sterile drug products into Maryland is not required to hold a Sterile Compounding Permit if it holds 1) a manufacturer's permit or other permit designated by the FDA to ensure the safety of sterile drug products; and 2) a wholesale distributor's permit issued by the Board. Sterile drug products are defined as a drug product that must be prepared using aseptic techniques and is not required to be prepared in response to a patient specific prescription.

- Third, since some entities do not fit under the first two licensing schemes, yet provide much needed medications to Maryland, an entity may apply to the Board for a “waiver” of the above requirements. This is a stop-gap measure until the FDA is able to license and inspect these types of entities under a new FDA permit. A waiver may be issued only for specified sterile compounded preparations or sterile drug products for which there is a clinical need, as determined by the Board, with input from licensed health care providers in Maryland. Exigent circumstances must also exist that, as determined by the Board, which would otherwise prevent health care professionals from obtaining, in the size and strength needed, the specified sterile compounded preparations or sterile drug products. Finally, if an entity is a sterile compounding facility, or both a wholesale distributor and an FDA manufacturer, it must provide at the time of application to the Board for the waiver 1) reports of inspections conducted by a designee of the Board or the FDA; 2) a statement of compliance with USP 797 Standards; 3) a review of adverse regulatory action; and 4) any other requirements as determined by the Board.

- **SB 595/HB 591 State Board of Pharmacy – Wholesale Distribution – Pharmacies** – HB 591 limits the authority of a pharmacy permit holder to distribute prescription drugs and prescription devices to only another pharmacy permit holder unless certain criteria exist. Waiver pharmacies may conduct wholesale distribution only with another pharmacy permit holder. Full service pharmacies may conduct wholesale distribution with another pharmacy permit holder so long as it maintains records of wholesale distribution separately from its other records; and makes those records available for inspection by the Board. If a full service pharmacy distributes to a wholesale distributor, the full service pharmacy is required to do three things:

- The pharmacy must report to the Board that it is conducting wholesale distribution with a wholesale distributor. The pharmacy must maintain records of wholesale distribution with wholesale distributors separately from its records of wholesale distribution with pharmacy permit holders. The pharmacy must make the records of wholesale distribution available for inspection by the Board.

Finally, the bill clarifies that all pharmacies are considered wholesale distributors if the wholesale distribution business accounts for more than 5% of the pharmacy’s annual sales.

- **SB 761/ HB 868 Health Occupations – State Board of Pharmacy – Waivers – Pharmacies That Only Dispense Devices** - SB 761/HB 868 waives the requirement to employ a pharmacist for entities that dispense prescription devices/DME in Maryland. Entities that dispense prescription devices/DME to patients in Maryland have always been required to be licensed in Maryland as a pharmacy, or non-resident pharmacy if applicable. This bill waives only the pharmacist requirement if the device/DME does not contain a prescription drug. The FDA determines whether a device/DME is "prescription."

### **Regulatory Initiatives**

The unit assists in revising the Board’s regulations as needed. See chart of the regulatory revisions and accomplishments.

**Maryland Board of Pharmacy Regulations, COMAR 10.34.01 - .36, revisions effective during FY 2013**

| <b>COMAR Citation</b> | <b>Title</b>  | <b>Effective Date</b> |
|-----------------------|---|-----------------------|
| 10.34.06              | Reporting Pharmacist's and Pharmacy Technician's Mailing Address and Location of Employment | March 18, 2013        |
| 10.34.11              | Disciplinary Sanctions, Monetary Penalties, and Civil Fines                                 | December 24, 2012     |
| 10.34.28              | Automated Medication Systems  | October 1, 2012       |
| 10.34.29              | Drug Therapy Management   | April 15, 2013        |
| 10.34.36              | Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes            | June 15, 2013         |

**Summaries of regulatory changes that became effective in FY 2013 are provided below:**

**10.34.06 Reporting Pharmacist's and Pharmacy Technicians Mailing Address and Location of Employment**

This proposal revised current regulations to require that pharmacy technicians report their current mailing address on their renewal form. More important, pharmacy technicians will also now be required to notify the Board in writing within 30 days of the date when pharmacy technicians change their mailing address. This will assist the Board in communicating with pharmacy technicians for renewal purposes and service of process in disciplinary proceedings.

**10.34.11 Disciplinary Sanctions, Monetary Penalties, and Civil Fines**

This proposal revised current regulations to include new Board of Pharmacy sanctioning guidelines, including: (1) a range of sanctions for each type of violation for pharmacy permit holders, pharmacists, pharmacy technicians, and wholesale distributors; and (2) a list of mitigating and aggravating circumstances that may be used to decide if a sanction falls within or outside the established range of sanctions. The sanctioning guidelines may be used as a guide for sanctioning pharmacy permit holders, pharmacists, pharmacy technicians, and wholesale distributors in formal and informal proceedings.

### **10.34.28 Automated Medication Systems**

This proposal revised current regulations to include: (1) Exclusions for supply towers; (2) Verification of a pharmacy technician selection of medications by a pharmacist; (3) Return of unused medications; (4) The inclusion of group model health maintenance organizations; and (5) Clarification that decentralized and remote automated medication systems are designed for the distribution of medications.

### **10.34.29 Drug Therapy Management**

This proposal revised current regulations to include repealing Regulations .05, .06, .09, and .10 and amending other regulations throughout the chapter by removing references to the Joint Committee and approval by the Board of Pharmacy and the Board of Physicians of any physician-pharmacist agreement or protocol specified in a physician-pharmacist agreement. The Board will continue to approve the qualifications of pharmacists participating in this program. Other revisions include updating the names of national organizations and adding language requiring certain documents be sent to both Boards. The fees were decreased to reflect elimination of the Joint Committee and elimination of approval by either Board of physician-pharmacist agreements or protocols specified in physician-pharmacist agreements.

### **10.34.36 Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes**

This proposal promulgated a new chapter to reflect the current practice of pharmacy in assisted living programs and group homes, excluding pharmacies providing only emergency services for assisted living programs or group homes. Previously, Assisted Living Programs and Group Homes were included in the same chapter as Long Term Care Facilities. However, the different levels of care and regulations required two separate chapters.

### **Legislative Reports**

The unit also drafted annual legislative reports including:

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

## Next Year at a Glance

The Legislation/Regulations Unit anticipates another busy legislative session in FY 2014 as the Board continues to strengthen protections 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 pharmacy in Maryland.

The unit will be busy in the beginning of FY 2014, preparing three legislative reports due January 1, 2014. 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
- Report pursuant to SB 896 State Board of Pharmacy – Sterile Compounding – Permits, Section 3, Chapter 397, 2013, on the implementation of Title 12, Subtitle 4A of the Health Occupations Article.

Additionally, the unit will support preparation of the Report mandated by HB 283 State Board of Pharmacy – Sunset Extension and Revisions, Section 4, Chapter 658, 2012 on the implementation of non-statutory recommendations contained in the October 2011 Sunset Evaluation Report. This report, prepared by all five units of the Board, is due the second quarter of FY 2014 (October 2013).

# Notes



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