

STATE OF MARYLAND

Department of Health and Mental Hygiene

# BOARD OF PHARMACY



## FISCAL YEAR 2016 ANNUAL REPORT

July 1, 2015

through

June 30, 2016

Vision:

*Setting 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 2016 BOARD COMMISSIONERS

President

**Mitra Gavgani**

*Home Infusion Representative*

Secretary

**David Jones**

*Long Term Care Representative*

Treasurer

**Jermaine Smith**

*Chain Drug Store Representative*

**Daniel Ashby**

*Acute Care Hospital Representative*

**Efstratios (Steve) Bouyoukas**

*Chain Drug Store Representative*

**Zeno St. Cyr, II**

*Consumer Representative*

**Roderick Peters**

*Independent Pharmacist Representative*

**Trinita Robinson**

*Consumer Representative*

**Chairmaine Rochester**

*At-Large Representative*

**Sajal Roy**

*Acute Care Hospital Representative*

**Ellen H. Yankellow**

*At Large Representative*

**Bruce Zagnit**

*Independent Pharmacist Representative*

## BOARD COUNSEL

**Linda Bethman, AAG**

**Brett Felter, Staff Attorney**

**Fiscal Year (FY) 2016 BOARD STAFF 410-764-4755**

<b>EXECUTIVE</b>	
<b>Deena Speights-Napata</b> , Executive Director <b>John Johnson</b> , MIS Manager <b>Anasha Page</b> , Management Associate <b>Janet Seeds</b> , Public Information Officer <b>YuZon Wu</b> , Compliance Officer <b>Vacant</b> , Legislation and Regulations Manager	Board Operations, Board Members and Board Minutes
<b>OPERATIONS</b>	
<b>Latoya Waddell</b> , Operations Manager <b>Rhonda Goodman</b> , Operations Assistant <b>Lawrence Tate</b> , Operations Secretary	Fiscal, Budget, Procurement, Travel, Personnel and Public Information
<b>DATA INTEGRITY</b>	
<b>Doris James</b> , Data Integrity Supervisor <b>Achia Brockington</b> , Data Integrity Specialist <b>Kimberley Goodman</b> , Data Integrity Specialist <b>Daisha Lyell</b> , Data Integrity Specialist	Scans all documents into licensee files.
<b>COMPLIANCE</b>	
<b>Jason Clements</b> , Laboratory Scientist Surveyor <b>Vanessa Gray</b> , Compliance Investigator <b>Sandra Kracke</b> , Compliance Investigator <b>Heather McLaughlin</b> , Compliance Coordinator <b>Shiela West</b> , Compliance Investigator	Complaints, Pharmacy Practice, Disciplinary, Investigations and Pharmacists Rehabilitation
<b>INSPECTION</b>	
<b>Amanda Barefield</b> , Pharmacy Inspector <b>Cheryl Johnson</b> , Pharmacist Inspector <b>Emory Lin</b> , Pharmacist Inspector <b>Nancy Richard</b> , Lead Inspector <b>Kerri Weigley</b> , Pharmacy Inspector <b>Shanelle Young</b> , Pharmacy Inspector	Inspections, Pharmacy Practice
<b>LICENSING</b>	
<b>Patricia Brown</b> , Licensing Specialist <b>Courtney Jackson</b> , Licensing Specialist <b>Janey Partin</b> , Licensing Specialist <b>Keisha Wise</b> , Licensing Specialist	Licensing, Permits, and Registration, Reciprocity, and Scores
<b>MANAGEMENT INFORMATION SERVICES</b>	
<b>John Bozek</b> , Computer Specialist <b>Jacqueline Green</b> , Database Specialist, Customer Service Supervisor	Computer, Database and Website and On-line Renewals
<b>CUSTOMER SERVICE</b>	
<b>Leroy Jackson</b> , Customer Service Specialist	Answering Calls and Emails

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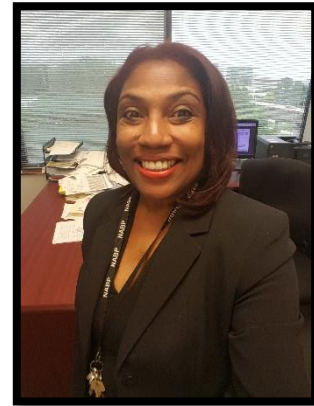
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## **MESSAGE FROM THE EXECUTIVE DIRECTOR**

*Deena Speights-Napata*

### **The Maryland Board of Pharmacy—Looking Back at 2016**

The Maryland Board of Pharmacy has devoted a significant amount of time and energy this year to systems improvement and personnel training and productivity. In order to fulfill our mission to serve the public we realized the importance of also improving services to our stakeholder community, so that they would be empowered to better serve the citizens of Maryland. To this end, I'd like to highlight some of the Board of Pharmacy's significant achievements in 2016. These achievements have resulted in improved response times, a better informed stakeholder population, improved relationships with stakeholders, and more effective customer service.



#### **Systems Improvements**

**New computer software system for phone calls, emails, and faxes** that records every incoming query and response. This new system has helped us to improve our response time and create a permanent record that can be used to verify queries and update responses

**Additional phone lines** have been added to our call center to respond to calls more quickly during peak license renewal periods

**Call Center and Data Entry staff have been cross-trained** creating a more knowledgeable staff to be able to respond to the areas needing increased resources

A contract was established with a national vendor to process license renewals **using a lock box system**. The use of the system has significantly reduced the number of processing errors and has improved our rate of speed in creating and mailing licenses

**Weekly staff customer service trainings** using a nationally recognized on line library of training modules has produces a well trained staff focused on providing quality customer service. Call center in person and phone surveys administered to callers have indicated customer satisfaction rates with Board of Pharmacy customer service at excellent or good levels 99% of the time.

Procurement of **software engineering services that will create a hand held data entry tool** that will create an environment for the real time entry of inspection data directly into the boards licensing database by board inspectors. This will improve the board's ability to share data with the national pharmacy board as well as other state boards; and it will improve follow up to pharmacies requiring technical support

**Additional staff hired to improve services:** 1 laboratory scientist to conduct sterile compounding inspections and follow up technical assistance; 2 additional pharmacists on our compliance team (one already hired, one currently in interview process); 1 new social media specialist; 1 new call center lead employee to train and assign tasks; 2 new licensing staff to process applications and 1 new licensing manager(interviews in process)

**Addition of board lobby information kiosk and two renewal kiosks**, allowing technician renewals.

**Development of distributor renewals on line** to be available for use in March of 2017

**Restored exchange of information with the National Boards of Pharmacy (NABP)** resulting in improved speed in processing reciprocity and license verification requests

#### **Public Relations/Communications**

**Improved quarterly newsletter** that includes NABP articles, new Frequently Asked Questions column, and increased pharmacy articles of interest

**New Facebook and Twitter Access**

**First Continuing Education event offered in person and by web access**

**Increased use of surveys**

**Increased involvement in pharmacy conferences and events**

#### **Licensing and Compliance**

**Increased training** in inspection and investigation techniques

**Staff certification** in sterile compounding

Inspection staff now verifying licensing data at inspections and sharing with data entry staff to ensure the accuracy of licensee data

None of these achievements would have been possible without the hard work and dedication of a staff of professionals that work hard for the Board of Pharmacy every day, and a smart and dedicated group of Board Commissioners that provide guidance and support.

I am confident that 2017 will be yet another year of landmark improvements as the board focuses on reestablishing internships with pharmacy school students, partnering with stakeholders on legislative initiatives, growing our pharmacy community by enabling them to practice innovative programs that have been successful in other states, increasing our ability to monitor prescription drug repository programs, and implement an expanded rehabilitation committee across the entire state of Maryland.

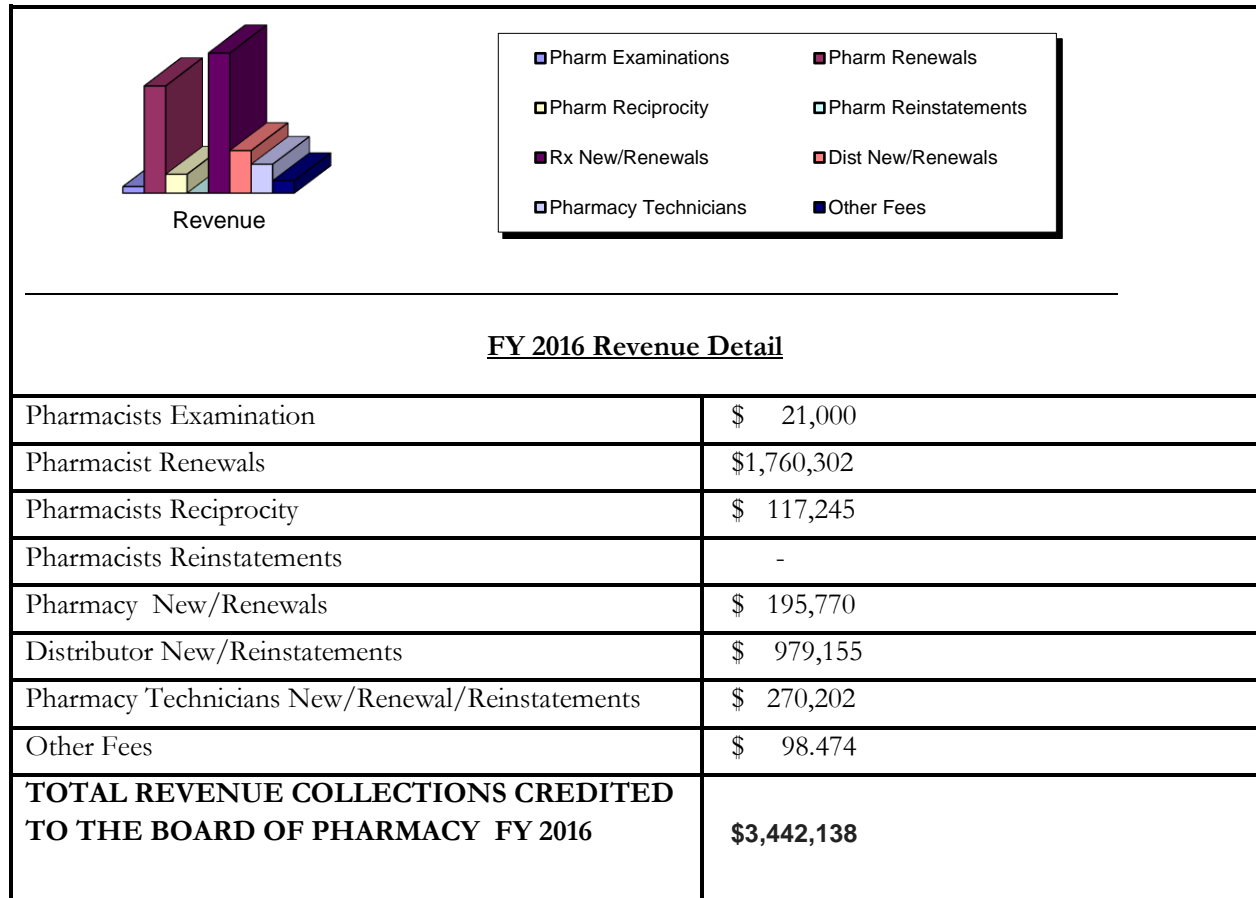
**Happy New Year Everyone!**

## OPERATIONS UNIT REPORT

### Overview

The Operations Unit (OU) of the Maryland Board of Pharmacy (Board) consists of three professional staff persons: a Manager; an Assistant to the Manager and a Secretary/Receptionist. The Unit is responsible for managing three key administrative functions at the Board, which include: fiscal; personnel; and procurement. OU 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.

The unit's fiscal functions include collection of fees and revenue and budget reconciliation activities. Also, the OU unit is responsible for procuring equipment and supplies, paying invoices and travel requests, processing expense reports and vehicle mileage reports, and inventorying and archiving documents for the Board. Administration activities include reviewing proposed legislation and preparing fiscal notes. All approved training requests for Board employees are processed by the unit, including: communicating personnel policies; preparing personnel documents; retaining confidential personnel records; processing personnel timesheets and training development.



### **Board Revenue**

The above chart reflects changes in the renewal periods for pharmacy and distributor establishments during the previous legislative session. Effective FY 2013, pharmacy and wholesale distributor establishment applications expire biennially on the last day of May. Wholesale distributor permits expired in fiscal year 2015 and pharmacy permits expired in fiscal year 2016.

### **Training Related Travel**

During FY 2016 the Board Staff participated in various trainings. Key training courses taken by staff members addressed supervisory management, use of MIS various software applications, and sterile compounding inspection techniques. National and District Conferences training from NABP, National Citizens Advocacy Center training, and regulatory (FARB) training.

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

The many new responsibilities undertaken by the Board in recent years have contributed the need for the Board to begin reorganization planning. In addition to its current personnel the Board anticipates requiring additional funding to support the reorganization initiative as well as to fully implement the new sterile compounding mandate. The plan is to attend more professional and community events across the State to enhance the mission of the Maryland Board of Pharmacy.



## **PUBLIC RELATIONS**

### **Overview**

The Public Relations Unit (PR) of the Maryland Board of Pharmacy (Board) is implemented by one person, but is driven by the Board's Public Relations Committee. This Unit is responsible for managing three key functions at the Board, which include: public relations; communication; and training. PR represents the Board at professional and community events throughout the state. This unit makes recommendations regarding the Board's marketing, media, educational, and awareness campaign endeavors.

PR staff promotes the Board by consistently focusing on the Board's mission statement.

### **Accomplishments**

Public Information staff in the unit coordinated responses to all requests made to the Board under the Public Information Act (PIA). The PIA defined what information may be released to the public upon request. Unit staff was assigned to assure that information released does not violate state and federal confidentiality rules.

Two other important public information responsibilities included monitoring and coordinating responses to pharmacy-related news media and planning. Unit personnel were 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 were 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 2016 Summary of Public Relations Activities**

- Exhibit at ASCAP Convention, Alexandria, VA - August 2016
- Exhibit at MPhA Convention, Ocean City, MD, - June 2016

### **FY 2016 Summary of Pharmacist Training & Education**

- Continuing Education Breakfast, Maritime Institute, Linthicum, MD, October 2015

### **FY 2015 Summary of Emergency Preparedness Activities**

- Participated monthly in the State SNS Partners meeting.
- Worked with DHMH on the RSS operations.
- Coordinated with DHMH and other State agencies in preparing state emergency management plans that included pharmacists as active participants in protecting the citizens of Maryland during emergency situations.
- Conducted emergency preparedness exercises at school of pharmacy

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

With the Board's re-evaluation of responsibilities and tasks, PR has inherited some new tasks as well as continuing those already established. These will certainly continue into next year:

- assuming more support services for the Executive Director,
- continuing to offer support to the Public Relations Committee;
- continuing to provide Emergency Preparedness Task Force support;
- creating written publications, brochures, and notifications;
- providing e-mail blasts to licensees, staff, and constituents;
- incorporating social media into communication with licensees; and
- planning on-going conferences and trainings..

PR also plans to partner with more Maryland agencies that could benefit from pharmaceutical legislation and from which the Board can also benefit.

## **LICENSING UNIT REPORT**

### **Overview**

The Licensing Unit is responsible for all activities related to the issuance of new, renewal, and reinstatement of licenses, registrations, and permits to qualify pharmacists, pharmacy technicians, pharmacy interns, pharmacies and wholesale distributors that operate in Maryland. The Unit also processes applications for the prescription Drug Repository Program, Technician Training Programs, and Pharmacist Vaccine Certifications for those pharmacists who wish to administer Influenza, Herpes Zoster, Pneumococcal Pneumonia, and other vaccines.

The Unit staff consists of a manager and two (2) licensing specialists. They perform the following functions:

- receive and enter applications;
- process, analyze, and review applications;
- contact applicants for any missing information;
- refer certain applications to the Licensing Committee for further review; and
- approve and issue licenses/registrations/permits.

The Licensing Committee is responsible for reviewing all applications submitted that may not meet certain licensure requirements or that indicate an applicant/licensee has had problems with their licenses/permits/registrations in other states. This Committee also reviews requests from applicants/licensees to waive requirement or fees due to special circumstances. Another important responsibility of the Committee is the review and development of licensure requirements and/or applications resulting from the promulgation of new laws or regulations or changes to the existing laws or regulations.

The Unit experienced several personnel concerns that affected certain operations, as detailed below. Specifically, the entire Licensing Unit was comprised of only two (2) staff members. Fiscal Year 2016 is the renewal period for all pharmacies; in addition, the Board started issuing Pharmacy Intern registrations for the first time. The workload increase, coupled with the drastic decrease in staff members, made it extremely difficult to ensure that all types of applications (including the ordinary renewals as well as new applications for all the different licensing types) were processed timely. The two licensing staff members worked diligently and tirelessly to process all applications received by the Board. Under the direction of the new Executive Director, the Board actively recruited and trained additional temporary staff and transferred a staff member from another unit to work in the Licensing Unit.

### **Licensing Processing Statistics**

The Licensing Unit processed applications along with other required documents for a total of 15,882 licensees during FY2016; this is a 28.9% increase over the last fiscal year. This number includes pharmacy, wholesale distributor, pharmacist, pharmacy intern, and pharmacy technician applications.

FY2016 was the year for pharmacy permit renewals and, as a result, the Board renewed a total of 1,920 permits, as compared to only 7 renewals in FY2015. In addition to renewal applications, the Board also processed 216 new pharmacy permits, bringing a total of 6,823 pharmacy applications processed.

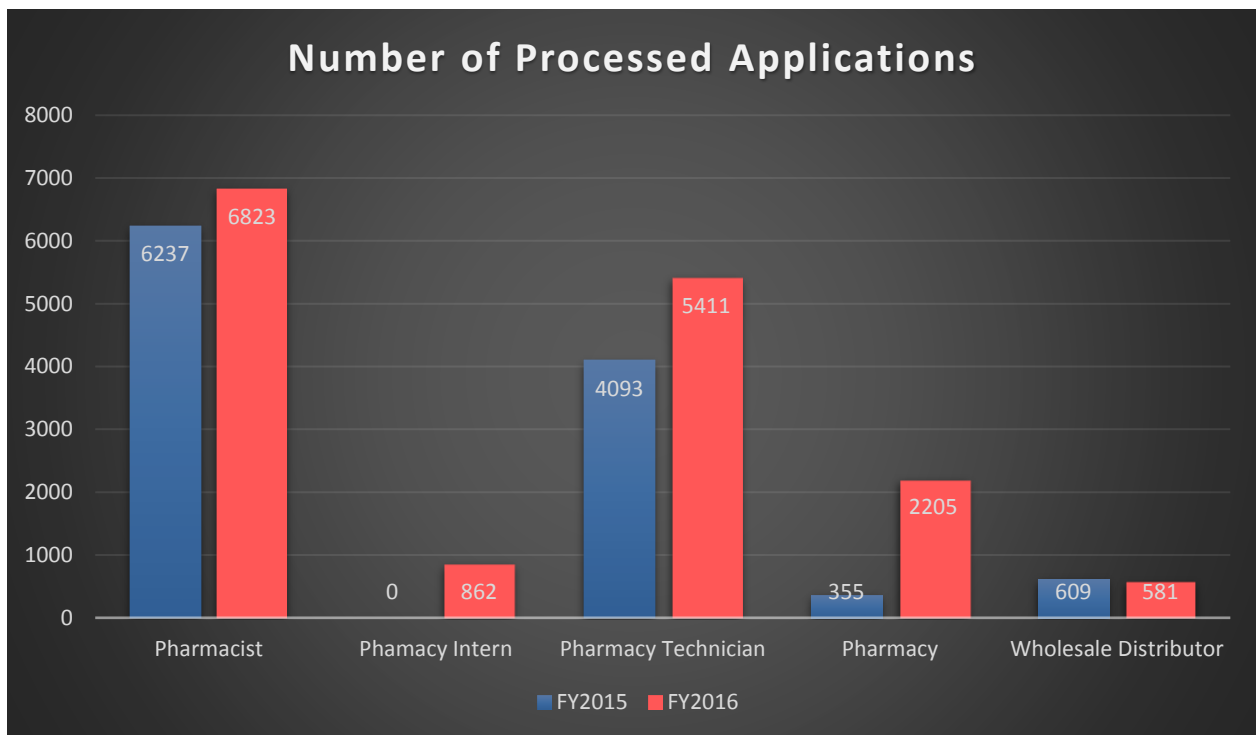
The Board processed 6,823 pharmacist applications, including Vaccine Certifications, resulting in an 8.6% increase compared to FY2015.

FY2016 was the first time that pharmacy students currently enrolled and having completed one year of professional pharmacy education in a Doctor of Pharmacy program (accredited by the Accreditation Council of Pharmacy Education) and/or pharmacy school graduates, were able to apply for an intern registration. The Board issued 44 Pharmacy Intern Graduate and 818 Pharmacy Intern Student registrations.

Although FY2016 was not a renewal period for wholesale distributors, the Board processed 380 renewals. This could be attributed to the fact that these wholesale distributors submitted a substantially completed application in the previous year, however, the Board received the results of the criminal background checks for the designated representatives and their immediate supervisors during FY16.

Just like FY15, the Board processed more technician renewal applications than new applications. There is an increase by 24.4% in the total number of technician applications processed in FY2016 bringing a total of 5,411 applications

**Figure 1 Applications Processed from July 1, 2015-June 30, 2016**



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

For Fiscal Year 2017, the Licensing Unit plans to:

- acquire additional staff members as well as finding a licensing manager and cross train staff members;
- reduce the application processing time; and
- update application forms.

## **COMPLIANCE UNIT REPORT**

### **Overview**

The Compliance Unit protects the public health of Maryland's citizens by enforcing compliance with state laws and regulations regarding the practice of pharmacy. Unit staff consists of a pharmacy compliance officer, one (2) half-time pharmacist inspector supervisors, four (4) compliance inspectors, three (3) compliance investigator, and a compliance coordinator. 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 actions to national databases; and
- inspect pharmacies and wholesale distributors..

The Unit experienced several personnel concerns that affected certain operations, as detailed below. Specifically, the Board was functioning with only one investigator until November 2015 and extended medical leave taken by a number of compliance staff. Under the direction of the new Executive Director, the Board actively recruited and trained two new Investigators, a Laboratory Scientist Surveyor, additional temporary staff, and continued to train the newly hired Compliance Coordinator.

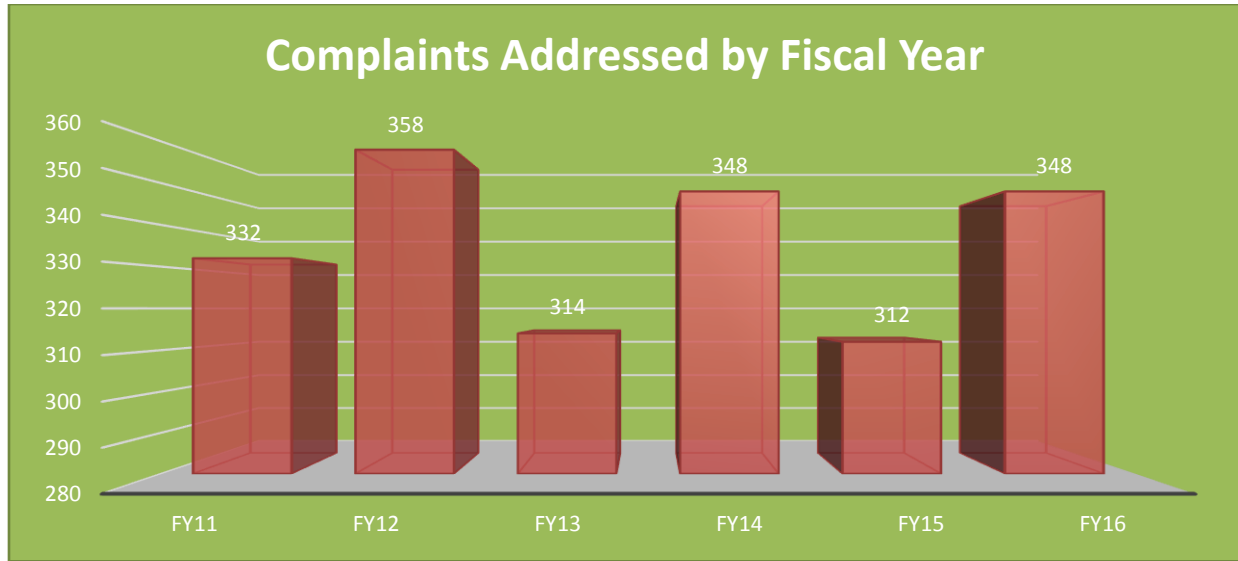
### **Complaints**

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's website at [www.dhmh.maryland.gov/pharmacy](http://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 and/or to the full Board for further review and vote. If the nature of the complaint is outside the Board's purview, then it is referred to the appropriate authority.

Figure 1 below, provides the number of complaints received in the past six fiscal years. Compared to previous years, FY2016 has received 348 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 from July 1, 2015-June 30, 2016**



**Figure 2**

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

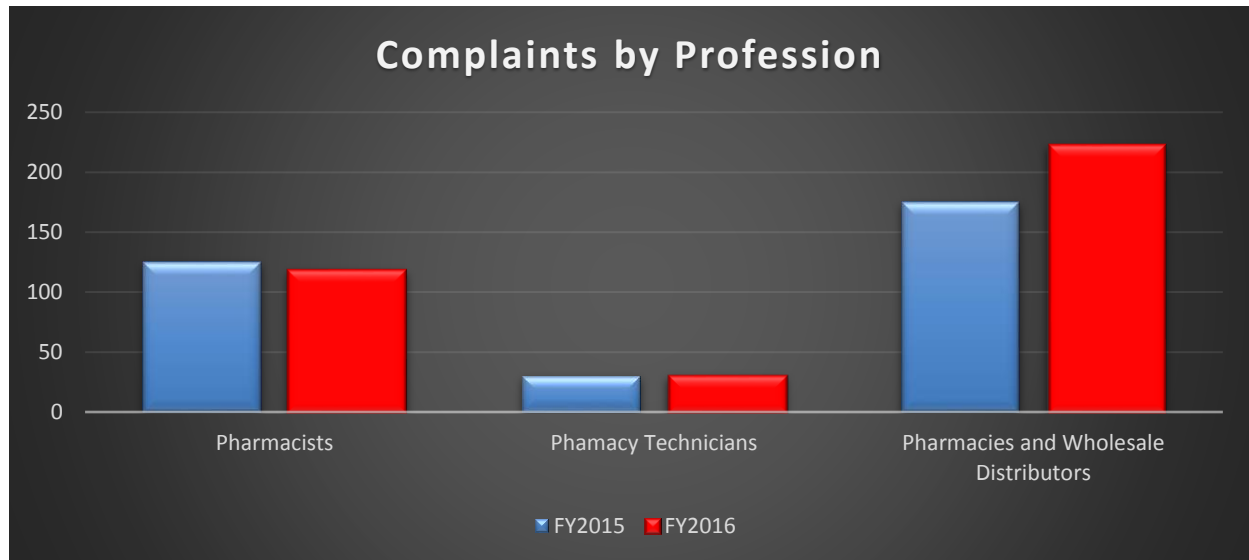
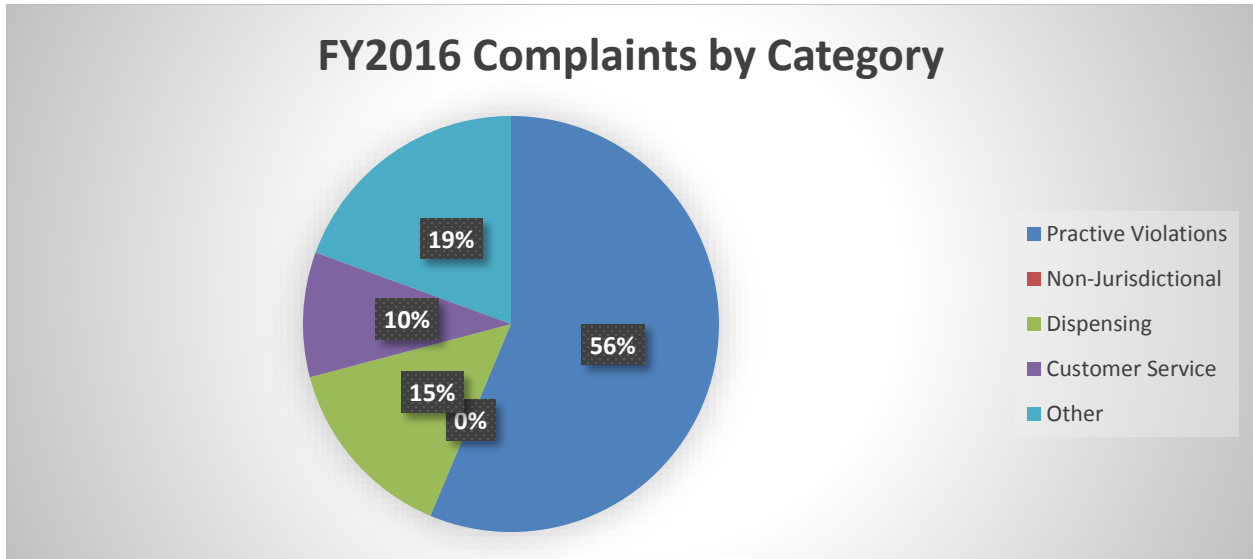


Figure 2 above reveals that for FY 2016, the greatest number of complaints is still attributed to the establishments followed by complaints against pharmacists. There is an increase in the number of complaints received against establishments this year compared to FY 2015. Number of complaints against technicians seems to be comparable to last fiscal year's.

Figure 3

Types of Complaints from July 1, 2015-June 30, 2016



The types of complaints received are broadly categorized (see Figure 3). The majority relates to practice violations. 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 the types of complaints in this category. This fiscal year, the number of practice violation complaints is comparable to last year's as it relates mostly to establishments resulting from deficiencies found during annual inspections as well as self-reports, reports from sister agencies notifying the Board of establishments' acquisitions or sales of prescription drugs without being duly licensed by this Board, medication errors, and theft or significant loss of drugs.

### **Disciplinary Cases**

All complaints are investigated by Board staff members. For the current fiscal year, the Board has taken formal or informal actions on 282 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, informal deficiency letters, and closures. Examples of formal actions include a license or permit being placed on probation, suspension, revocation, as well as fines. Approximately 71% of the complaints remained open, pending more investigation. This is due to the back log from the previous fiscal year, insufficient investigators, as well as the unforeseen extended medical leave taken by many compliance staff. Figure 4 shows the number of formal and informal actions taken for Fiscal Year 2016, compared to the previous 5 years.

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

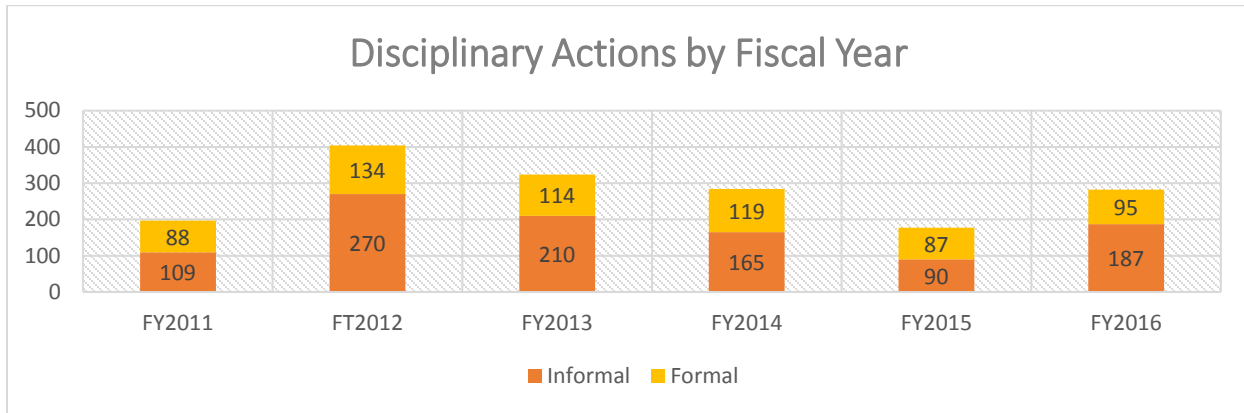
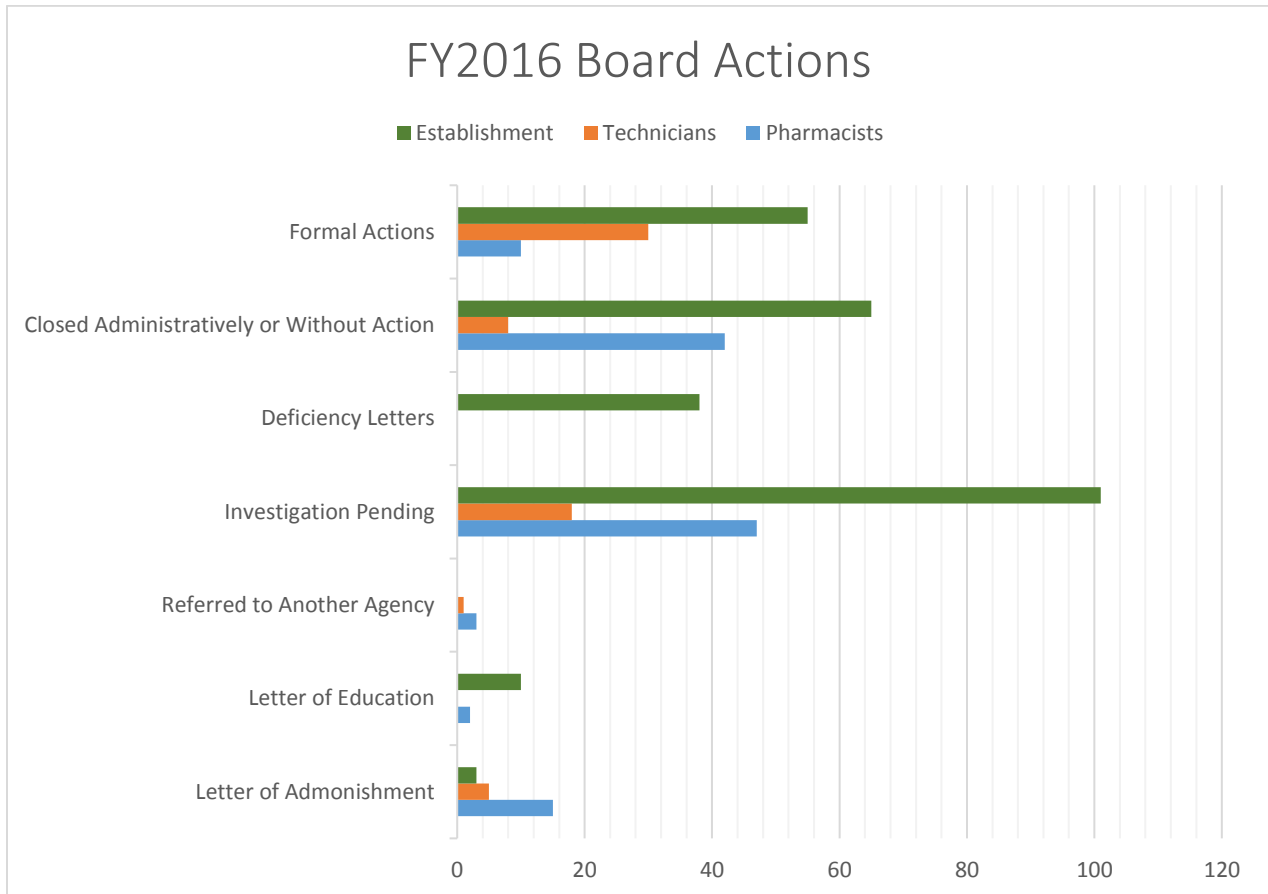


Figure 5 represents a categorical description of the various types of formal and informal actions taken against pharmacists, pharmacy technicians, and establishments in the most recent fiscal year.

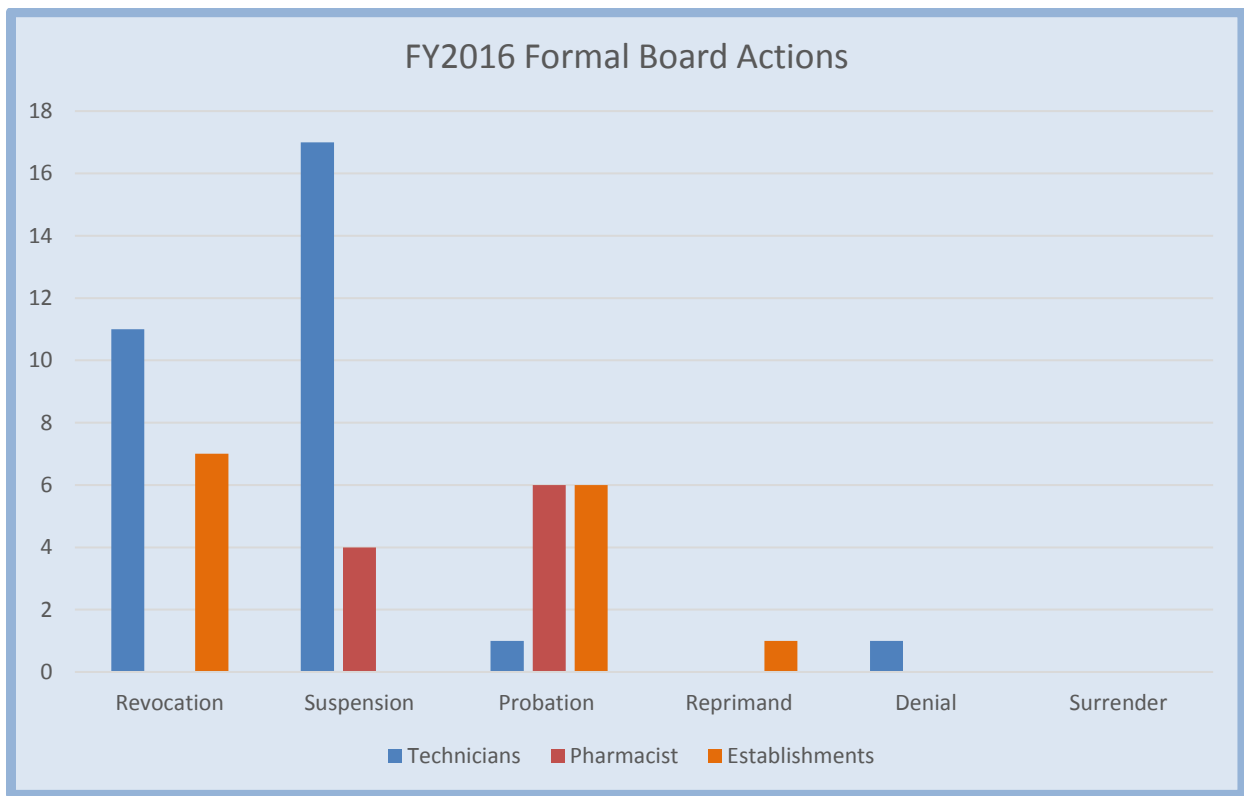
**Figure 5** Board Action taken from July 1, 2015-June 30, 2016





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 2016. Some formal actions against licensees or permit holders included fines which are excluded from figure 6. Formal actions, including some of the fines issued are published in the Board of Pharmacy newsletter along with name of the licensee, registrant, and permit holder.

**Figure 6** Formal Board Actions Taken from July 1, 2015-June 30, 2016



**Inspections**

The Compliance Unit continues to work closely with the Office of Controlled Substances Administration (OCSA), formerly known as 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 in-state pharmacies, while OCSA 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 2016. The Board completed 100% of annual inspections for all the facilities permitted in Maryland.

This year, the Board had a markedly increased number of Miscellaneous Inspections compared to last year. This is due change of ownership inspections performed for the changes of ownership for some chain pharmacies

**Figure 7**

Annual Inspections	1447
Opening Inspection	54
Miscellaneous Inspection	130
Distributors	1
Total Inspections	1632

As the Board continues to find software to accommodate and incorporate the mobile inspection component into its current software system, inspections continue to be manually scanned into the data base with the help of an administrative specialist.

**Practitioner, Substance Abuse and Compliance Monitoring**

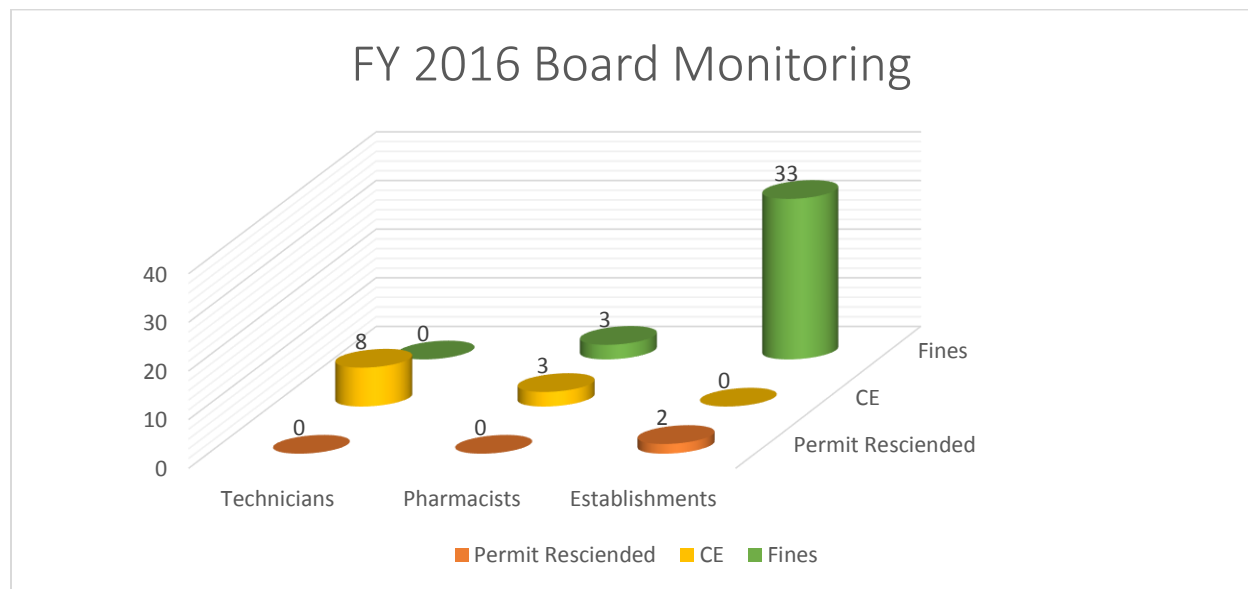
Chemical dependence among health care professionals has been observed over the years to be at least as prevalent as with the plague in society. In addressing disciplinary actions, the Maryland Board of Pharmacy may opt to mandate substance abuse treatment. If treatment is so ordered, Compliance Unit 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; and
- 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. Not only does the Board monitor pharmacists, but it also monitors registered pharmacy technicians who are issued public orders for actions involving substance abuse. In Fiscal Year 2016, the Board monitored 13 pharmacists and 3 pharmacy technician who were under Orders that involved substance abuse

In addition to consent order, the Board monitors pharmacists, pharmacy technicians, and establishments for compliance from the formal and informal disciplines sanctioned by the Board to include consent fines, CE requirements through Letter of Admonishment or Education, and rescission of permits/licenses. This year, the Board rescinded the permit for two pharmacies for which permit were issues as the pharmacies were not opened and operational within 60 days of the issuance of the permit. Figure 8 below, depicts FY2016's Board monitoring

**Figure 8 Board Monitoring from July 1, 2015-June 30, 2016**



The Maryland Board also contracted 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. Although individual assistance provided by PEAC is confidential, monthly aggregate reports are 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 2016, PEAC monitored a combined total of 19 clients, all of which were pharmacists

Per PEAC's request, PEAC's contract with the Board ended on December 31, 2015. However, PEAC continues to provide its services to individuals whom anonymously and voluntarily request substance abuse assistance.

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

For Fiscal Year 2017, 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;
- update/review inspection forms;
- hire more inspectors and investigators;
- provide additional training to staff on performing investigations;
- identify and procure a software system that is conducive to the business operations of inspections and investigations

## **LEGISLATION/REGULATIONS UNIT REPORT**

### **Overview**

The Legislative and Regulations Unit (the “Unit”) plays an active role in supporting the Board by evaluating, developing and drafting Board-directed legislative and regulatory proposals that protect the public and promote quality health care in the pharmaceutical profession. The Unit, is also responsible for supporting the Board and its various committees in the areas of legislative review, health policy research, regulatory evaluation and a variety of special assignments. The standing committees staffed by the Unit in FY 2016 included Pharmacy Practice and Legislative.

The Board revises regulations routinely 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 took more than one fiscal year to complete the promulgation process.

During Fiscal Year 2016 the Unit has been diligently working on responses from: 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. Practice questions that required Board interpretation or involved controversial issues were presented at the monthly Practice Committee meeting and as necessary, the Committee’s recommended responses are submitted to the Board at its Public meetings for final consideration.

### **Legislative Initiatives**

During the interim period before the Maryland Legislative Session begins, the Unit assists the Board in determining whether changes to the Maryland Practice Act are appropriate. The Unit prepares legislative proposals for review by the Department’s Office of Governmental Affairs. Additionally, the Unit coordinates meetings to apprise the Chairs of the Senate Education, Health, and Environmental Affairs (EHE) and the House Health and Government Operations (HGO) Committees of Board proposed legislative initiatives. These meetings help garner early support and identify potential sponsors of 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. The Unit is most active during the session communicating Board legislative proposals to health professional boards, local and national health associations and the regulated industry.

The Unit tracked and drafted position papers and/or letters to various legislative committees. Below is provided a chart of the some of the bills.

<b>Bill #</b>	<b>Bill Name</b>	<b>Result</b>
SB 217	State Board of Physicians - Distribution of Fees by Comptroller - Loan Assistance Repayment for Physicians and Physician Assistants	<b>PASSED</b>
HB245/SB310	Child Abuse and Neglect - Failure to Report	<b>PASSED</b>
HB752/SB647	Physicians - Prescriptions Written by Physician Assistants or Nurse Practitioners - Preparing and Dispensing	<b>PASSED</b>
HB1482/SB898	Health Occupations - Board of Pharmacy - Pharmacist Rehabilitation Committee - Definition	<b>DID NOT PASS</b>
HB1362	Crimes - Robbery, Burglary, or Theft of Property - Controlled Dangerous Substances	<b>DID NOT PASS</b>
HB1418/SB898	Public Health - Auto-Injectable Epinephrine - Certification for Emergency Administration	<b>DID NOT PASS</b>
HB1462/SB614	Veterinarians, Pharmacies, and Pharmacists - Dispensing Compounded Preparations for Use by Nonfarm Animals	<b>PASSED</b>
SB17	Open Meetings Act - Retention of Minutes and Recordings - Revision	<b>PASSED</b>
HB1193/SB67	State Government - Administrative Procedure Act - Effective Date of Adopted Regulations	<b>DID NOT PASS</b>
SB1083	Secretaries of Principal Departments - Supervision and Review of Decisions and Actions by Units Within Department	<b>DID NOT PASS</b>

**Summaries of the most relevant bills from the 2016 Legislation Session are provided below:**

**SB 469/HB 117 Health Occupations – State Board of Pharmacy - Proof of Proficiency in English**

This legislation establishes alternate means of determining proficiency in the oral communication of the English language for purposes of the examination and licensing procedures. Prior to the bill, the Board would require an applicant for a pharmacist license to demonstrate oral competency in the English language by passing a board-approved standardized test of oral competency. This bill requires the board to accept as proof of proficiency graduation from a recognized English-speaking professional school accredited by the Accreditation Council for Pharmacy Education. This bill makes English proficiency requirements for pharmacists similar to those required by the State Board of Nursing and the State Board of Physicians for their licensees. It also allows pharmacists to have an alternative method for demonstrating competency other than the current test, which requires applicants to pay a fee.

- **Revisions Effective 10/1/16**

**SB 537/HB 4371 Department of Health and Mental Hygiene – Prescription Drug Monitoring Program - Modifications**

This legislation requires certain prescribers and pharmacist to register with the Prescription Drug Monitoring Program by July 1, 2017. The Bill requires prescribers and pharmacists to request and access prescription monitoring data. Prescribers and Pharmacists are subject to disciplinary action by their respective licensing Board for failure to comply with the bill's mandatory registration and use requirements. This Bill also allows the Prescription Drug Monitoring Program to review prescription monitoring data for indications of a possible violation of the law or possible breach of standards by a prescriber or dispenser. This bill also requires the Department of Health and Hygiene to develop outreach and education plan regarding registration with the Prescription Drug Monitoring Program.

- **Revisions Effective 10/1/16**

**SB614- Veterinarians, Pharmacies, and Pharmacists - Dispensing Compounded Preparations for Use by Nonfarm Animals**

This Legislation authorizes a licensed veterinarian to dispense compounded nonsterile preparations or compounded sterile preparations to a “nonfarm animal” under specified circumstances. This Legislation also allows a licensed pharmacist to provide compounded nonsterile preparations or compounded sterile preparations without a patient-specific prescription to a licensed veterinarian.

- **Revisions Effective 10/1/16**

**Regulatory Initiatives**

The Unit assists in revising the Board's regulations as needed. Below is provided a chart of the regulatory revisions and accomplishments for FY 2016.

Maryland Board of Pharmacy Regulations, COMAR 10.34.01 - .38, revisions effective during Fiscal Year 2016:

<b>COMAR Citation</b>	<b>Title</b>	<b>Effective Date</b>
10.34.10	Pharmacist, Pharmacy Intern and Pharmacy Technician Code of Conduct	February 1, 2016
10.34.19	Sterile Pharmaceutical Compounding	February 1, 2016
10.34.29	Drug Therapy Management	March 28, 2016
10.34.33	Prescription Drug Repository Program	May 9, 2016
10.34.37	Pharmacy Permit Holder – Wholesale Distribution	Pending resolution
10.34.39	Pharmacist Administration of Self-Administered Drugs	May 9, 2016

**Year at a Glance (Projections for FY 2017)**

The Unit anticipates another busy legislative session as the Board continues to strengthen protection for Maryland citizens who are dispensed prescription medications from a variety of entities including, in-state and out-of-state pharmacists and pharmacies, physicians, dentists, podiatrist, and nurses.

The Board will also continue to review laws and regulations that govern the settings and practices of the professions it regulates during FY 2017.



## **MANAGEMENT AND INFORMATION SYSTEMS UNIT REPORT**

### **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 full-time staff members, including a Supervisor/Manager, Computer Network Specialist, and Database Specialist.

### **New Developments**

An IT Business Consultant was contracted to help analyze and propose improvements to the agency's business procedures and mission. The Board also, through a joint effort with a business consultant, did a full assessment of our customer service procedures. This will allow the board to do a complete re-engineering of our Customer Service unit to better serve our licensees and citizens of Maryland as it relates to the Pharmacy profession.

The Board will be implementing a new customer service system to log and keep track of license related issues. This will help the Board improve its customer service to the community and the licensing profession.

To further improve our distribution of Board information, we will be implementing social media pages (facebook and twitter) to create digital community outreach to provide information about news, updates, and other important announcement from our agency's website. It will also be an avenue to provide emergency alerts to the public.

### **Accomplishments**

In FY16 the Board was able to implement online renewals for our Pharmacy license types and significantly cut down on the amount of paper that was mailed into the Board's offices. Previously we only had two other license types available for online renewal. The Board also implemented a Lockbox procedure to process all checks and money orders sent to the board. This also served to decrease the amount of paper being mailed to the Board, which also contributed to faster processing times of paper correspondence.

The Board also began the process of revamping its IT infrastructure which involves acquiring an IT business consultant to document and analyze the Board's business rules and procedures, recommend changes that would help the Board's workflow, and recommend language that could eventually be used to include in any Request for Proposals for any new Licensing Software. These joint efforts between the Board and the consultant have resulted in decreased licensing processing times.

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

The Board will implement and make online renewals for Distributors available online. This should further speed up the processing times for the renewal of licenses and reduce the amount of paper applications that the Board will have to process.

A re-vamped mobile inspection software program will be developed to assist the Board's facility inspectors when performing inspection visits.

The Board is a part of the State's new initiative to combine the needs of multiple State licensing agencies, to find a single vendor for new licensing systems for each agency. The Board has submitted an extensive system requirements list that will provide the Board with the best possible outcome for our system needs. This is being curated by the State's Office of Information & Technology (DOIT).

## PROGRAM INTAKE ASSESSMENT AND EVALUATION

### Overview

The data entry section of the Program Intake Assessment and Evaluation unit of the Maryland Board of Pharmacy (Board) has been created to provide a smoother transition for licenses needing to be processed. Rather than licenses coming directly into the Board, a new system has been created whereby the licenses are processed through a lock-box system and then sent to the Board. This alleviates the Board handling large sums of money.

The Board now only accepts credit card transactions; all other transactions (checks and money orders) have to be sent to the lock-box address. This makes for a smoother operation here at the Board office.

The mail goes through the Department of Health mailroom at 4201 Patterson Avenue, then comes up to the 5<sup>th</sup> floor Board office where it is separated for input into individual files by the staff in the data entry section.. All documents are scanned into licensee files and forwarded to the Licensing unit for processing.

The Board has devoted a significant amount of time and energy this year to systems improvement and personnel training and productivity. In order to fulfill our mission to serve the public we realized the importance of also improving services to our stakeholder community, so that they would be empowered to better serve the citizens of Maryland. Achievements have resulted in improved response times, a better informed stakeholder population, improved relationships with stakeholders, and more effective customer service.

### Systems Improvements

- ✓ **New computer software system for phone calls, emails, and faxes** that records every incoming query and response. This new system has helped us to improve our response time and create a permanent record that can be used to verify queries and update responses
- ✓ **Additional phone lines** have been added to our call center to respond to calls more quickly during peak license renewal periods
- ✓ **Call Center and Data Entry staff have been cross-trained** creating a more knowledgeable staff to be able to respond to the areas needing increased resources
- ✓ A contract was established with a national vendor to process license renewals **using a lock box system**. The use of the system has significantly reduced the number of processing errors and has improved our rate of speed in creating and mailing licenses
- ✓ **Weekly staff customer service trainings** using a nationally recognized on line library of training modules has produces a well trained staff focused on providing quality customer service. Call center in person and phone surveys administered to callers have indicated customer satisfaction rates with Board of Pharmacy customer service at excellent or good levels 99% of the time.
- ✓ Procurement of **software engineering services that will create a hand held data entry tool** that will create an environment for the real time entry of inspection data directly into the boards licensing database by board inspectors. This will improve the board's ability to share data with the national pharmacy board as well as other state boards; and it will improve follow up to pharmacies requiring **additional staff hired to improve services**: 1 laboratory scientist to conduct sterile compounding inspections and follow up technical assistance; 2 additional pharmacists on our compliance team (one already hired, one currently in interview process); 1 new social media specialist; 1 new call center lead

employee to train and assign tasks; 2 new licensing staff to process applications and 1 new licensing manager(interviews in process)

- ✓ **Addition of board lobby information kiosk and two renewal kiosks**, allowing technician renewals.
- ✓ **Development of distributor renewals on line** to be available for use in March of 2017
- ✓ **Restored exchange of information with the National Boards of Pharmacy (NABP)** resulting in improved speed in processing reciprocity and license verification requests

#### **Public Relations/Communications**

- ✓ **Improved quarterly newsletter** that includes NABP articles, new Frequently Asked Questions column, and increased pharmacy articles of interest
- ✓ **New Facebook and Twitter Access**
- ✓ **First Continuing Education event offered in person and by web access**
- ✓ **Increased use of surveys**
- ✓ **Increased involvement in pharmacy conferences and events**

#### **Licensing and Compliance**

- ✓ **Increased training** in inspection and investigation techniques
- ✓ **Staff certification** in sterile compounding
- ✓ Inspection staff now verifying licensing data at inspections and sharing with data entry staff to ensure the accuracy of licensee data

None of these achievements would have been possible without the hard work and dedication of a staff of professionals that work hard for the Board of Pharmacy every day, and a smart and dedicated group of Board Commissioners that provide guidance and support.

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

This unit is only going to continue to get more efficient by:

- reestablishing internships with pharmacy school students;
- partnering with stakeholders on legislative initiatives;
- obtaining additional training;
- continuing to evaluate our client response rate;
- cross-training so that the transfer of calls will become less necessary;
- growing our pharmacy community by enabling them to practice innovative programs that have been successful in other states;
- increasing our ability to monitor prescription drug repository programs; and
- implementing an expanded rehabilitation committee across the entire state of Maryland.



# STATE OF MARYLAND BOARD OF PHARMACY



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