

STATE OF MARYLAND

Department of Health and Mental Hygiene

BOARD OF PHARMACY



FISCAL YEAR 2014 ANNUAL REPORT

July 1, 2013

through

June 30, 2014

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 2014 BOARD COMMISSIONERS

President

Lenna Israbia- Jamgochian

Chain Drug Store Representative

Secretary

Harry Finke, Jr.

Independent Representative

Treasurer

Mitra Gavvani

Home Infusion / Home Care Representative

Lynette Bradley-Baker

At Large Representative

Bruce Zagnit

Acute Care Hospital Representative

Daniel Ashby

Independent Representative

Sajal Roy

Acute Care Hospital Representative

David Jones

Long Term Representative

Chairmaine Rochester

Consumer Representative

Zeno St. Cyr, II

Consumer Representative

Jermaine Smith

Chain Drug Store Representative

Trinita Robinson

Consumer Representative

BOARD COUNSEL

Linda Bethman, AAG

Brett Felter, Staff Attorney

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REMARKS FROM THE BOARD PRESIDENT

Lenna Israbian-Jamgochian, RPh, Pharm.D

As President on the Maryland Board of Pharmacy (Board), I want to thank you for the continued opportunity to serve the citizens of Maryland. It has been another busy year as usual. As a result, I am pleased to highlight some of the new legislation and regulations that were recently enacted impacting the profession of pharmacy and the patients we serve. 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 through developing and enforcing regulations and legislation; resolving complaints; and educating the public.”

A number of Board legislative initiatives were successful in Annapolis during the 2014 Legislative Session resulting in better quality healthcare and protecting consumers. The major initiatives included registration of pharmacy interns; repealing the requirement that officers of the Board may only be pharmacists; and notification by wholesale distributors to pharmacies when the wholesale distributor limits the quantity of available drugs.

The registration of pharmacy interns requires students enrolled in pharmacy school seeking employment in a pharmacy; individuals who have graduated from an ACPE accredited Doctor of Pharmacy program and have applied for licensure with the Board; and individuals who have graduated from a foreign school of pharmacy to register and be approved by the Board before practicing pharmacy as a pharmacy intern. The Board sought sponsorship of this important legislative proposal for several reasons, including the fact that many foreign graduates were working in pharmacies beyond 10 months continually circumventing requirements for pharmacy technicians and pharmacists that practice in Maryland. Pharmacy interns will work under the direct supervision of a licensed pharmacist, as had been previously required of students participating in a school of pharmacy sanctioned experiential learning rotation. A registered pharmacy intern may administer vaccinations in accordance with regulations adopted by the Board and may not delegate a pharmacy act or perform final verification of a prescription drug or device before dispensing. Included in this legislative initiative is the requirement that a licensed pharmacist would only be allowed to supervise two pharmacy interns at one time.

The Board also worked with the State Legislature to amend the Maryland Pharmacy Practice Act related to the election of Board of Pharmacy officers. The new law repealed the requirement that the election of a president, secretary and treasurer of the State Board of Pharmacy may only be pharmacist members and not consumer members of the Board. A consumer member of the Board suggested this change and the Board overwhelmingly supported it since it supported the notation that the Board should have the ability to elect the best qualified individuals from among all of its members to serve in leadership roles.

The Board, working with durable medical equipment and prescription device providers, supported legislation to exempt entities that dispense only prescription devices (containing no prescription drugs) and prescription durable medical equipment (DME) from the Maryland Pharmacy Practice Act. It became clear to the Board and the stakeholders that requiring a pharmacy permit did not provide any additional public protection over devices and DME. These entities are accredited by national organizations and provide devices and DME to

participants of the Centers for Medicare and Medicaid Services (CMS). CMS has stringent requirements for these providers and a Maryland pharmacy permit would not add additional public protection. These entities will no longer be required to obtain a Maryland pharmacy permit.

Another important law that passed relates to Wholesale Distributors – Notification to Pharmacy. This new law requires a wholesale distributor to notify a pharmacy at least 30 days before the wholesale distributor imposes a limit on the quantity of a prescription drug or prescription device distributed to the pharmacy. While the limit is in effect, the wholesale distributor must provide a pharmacy with an update (at least weekly) on the quantity of the prescription drug or prescription device available to the pharmacy. This law was passed due to patient complaints to the Board that patients were unable to obtain their pain medications. Upon review the Board learned that many pharmacies were no longer filling prescription for new patients as the pharmacies did not want to deplete their inventory for their existing patients. It made it very difficult for patients released from the emergency rooms, who may not have an existing controlled dangerous substance prescription, to obtain the pain medications they need.

The Board also updated several regulations. One of them was the regulation of Inpatient Institutional Pharmacy. The revision was made to assure that all decentralized pharmacies located in hospitals were known to the Board and could be inspected to assure appropriate operations and patient safety requirements were being followed. The revisions now require separate licensure for pharmacy areas not located in the same building or pavilion as the main hospital pharmacy. See other revisions made to this regulation in the Legislative and Regulations Unit section of this Annual Report.

Another new regulation relates to the Opening and Closing of Pharmacies and Change to Permit – Pharmacy or Wholesale Distribution Permit Holder. The Board learned that some permit holders were not notifying both the Board and the Division of Drug Control (DDC) when they planned to close. This caused concern because permits were not retrieved timely and there was potential for unauthorized activities while they were still in the permit holders' possession. The updated regulations clarify that a permit holder is required to notify the Board and the DDC when closing a pharmacy and included permit holders to give notification to the Board when hours of operation are changed. This was included to assist the Board's inspectors in scheduling establishment inspections.

I also want to introduce four new Board Commissioners that joined this year: Trinita Robinson, *Consumer Representative*; Charmaine Rochester, *At-Large Representative*; Bruce Zagnit, *Independent Representative*; and Daniel Ashby, *Acute-Care Representative*. I also want to thank outgoing Board Member, Harry Finke, for his dedicated service.

The many legislative and regulatory changes over the past few years have greatly expanded the Board's responsibilities, staffing and operational processes. The Board also has many new members who are eagerly looking forward to examining its organizational structure in FY 2015 and proposing changes to accommodate the Board's substantial growth.



MESSAGE FROM THE EXECUTIVE DIRECTOR

LaVerne Naesea

The Board of Pharmacy (Board)'s regulatory responsibilities have been quickly expanding since the beginning of the 21st Century and FY 2014 was no different from previous years. The number of licenses issued and the number of complaints investigated have correspondingly increased over the same 13 year period. To give perspective, there were close to 13,000 total licensees (pharmacists, pharmacies and distributors) licensed in FY 2001. At the end of FY 2014 there were 25,534 total licensees (pharmacists, pharmacies, wholesale distributors, pharmacy technicians, pharmacy students, pharmacists authorized to administer vaccines). Much of the work of the Board and staff during FY 2014 focused on systematically examining and making plans to address operational challenges and the changes required to accommodate the growth in licensees and regulatory oversight.

Growth in regulated licensees, changing practice trends and new types of specialty practices, (e.g., hospital satellite sites, drug therapy management, vaccine administration and sterile compounding) led to a Board review of regulatory definitions in FY 2014. Consequently, the definitions of a permit waiver, sterile products and terms were revised.

During the latter part of FY 2014, the Board began evaluating how its staff and operational resources were being utilized. It examined various approaches to fulfilling recent mandates, while addressing immediate operational concerns such as processing backlogs, staff turnover and absences and excessive telephone complaints from licensees about delayed application statuses. A Management Information System (MIS) Steering Committee was also assigned to review the Board's database software and recommend actions to increase processing efficiencies. The committee determined that the system required too many manual manipulations to enter and retrieve data or reflect annual changes in laws, regulations and/or business workflows.

Following its assessment, the Board concluded that its organizational structure had outlived the ability to accommodate growth since its last reorganization in 2001. Short-term measures to address concerns during the year included temporary recruitment of staff, and the creation of a pilot customer service call center. The Board further resolved that it would reorganize the Board's operational units. Also long-range planning began to replace the Board's MIS software product. The pilot Customer Service Call Center helped to better support anxious licensee applicants. A Data Integrity Unit is under study to also help expedite license data and information processing. The Board also voted to create two new Deputy Director positions: one to manage Operations (Administration, MIS, and Data Integrity); and the second to manage Programs (Licensing, Compliance and Customer Service). The full reorganization proposal was submitted to the DHMH Office of Human Resources and Department of Budget and Management for consideration in FY 2015.

Two key pieces of legislation passed in FY 2014 expanded the types of vaccines that pharmacists can administer, and amended Board regulation related to compounding pharmacists, physicians, dentists, veterinarians, and other practitioners that engage in sterile compounding in Maryland. The latter initiative resulted in legislative approval for six new positions. Also, the Board initiated specialized sterile compounding training for its compliance inspectors and worked on related sterile compounding regulations, permit applications, and inspection forms.

A few of the many other Board initiatives in FY 2014 included hosting two public meetings off-site at the University of Maryland School of Pharmacy Shady Grove campus, and Western Maryland Hospital Center in Cumberland, Maryland; issuance of a survey to assess the working conditions for personnel in pharmacies; and working with the National Association of Boards of Pharmacy to enhance regulation of sterile compounding pharmacies across the country. The last initiative led to the development and use of a centralized pharmacy inspection portal that allows state boards to exchange inspection reports about regarding non-resident pharmacies licensed by their states. The Board also recruited consultant experts to help develop review protocols for inspection reports involving sterile compounding.

Much of the Board's effort over the past fifteen years has been to focus on strengthening laws to protect Maryland citizens as trends in pharmacy practice have evolved. Though successful, significantly increased regulatory responsibilities led Board members and staff to the realization in FY 2014 that their operational (MIS) systems and organizational structures were no longer efficient nor effective to meet the Board's current and future expanded authority. Joint efforts by Board and staff members to review and fix broken systems during FY 2014 are admirable and timely, but the Board's work is far from over. The Board's proposed reorganization is expected to come to fruition over the next two fiscal years. Continued infrastructure revamping during that period should position the Board to successfully meet the many unknown pharmacy challenges and trends during this new century.

ADMINISTRATION AND PUBLIC SUPPORT UNIT REPORT

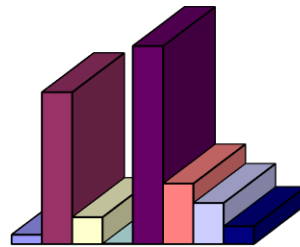
Overview

The Administration and Public Support Unit (APS) of the Maryland Board of Pharmacy (Board) consists of four professional staff persons, a Manager, a Public Information Officer, an Assistant to the Manager and a Secretary/Receptionist. The Unit is responsible for managing four key administrative functions at the Board, which include: fiscal, personnel, procurement, and public information and educational activities. APS also makes recommendations regarding the Board's annual budget and audit functions. The Board derives its revenue through payments for licenses, permits and other applicable fees. Expenditures are made based on submission of an annual budget request that must be approved by the Secretary of the Department of Health and Mental Hygiene, the Governor's office and subsequently by the State Legislature. Funding to support new program areas, personnel, purchases and/or purchases contract procurements are routinely included in the Board's budget request.

The unit's fiscal functions include collection of fees and revenue and budget reconciliation activities. Also, the APS unit is responsible for processing contractual agreements; 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. Public Information activities conducted through the APS Unit include the provision of information and education about the Board to the public and pharmacist community.

Board Revenue

A total of \$3,510,395.50 was collected in fiscal year 2014. The below 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. Pharmacies permits expired in fiscal year 2014 and wholesale distributors expired in FY 13. The approximate \$200,000 thousand decrease in revenue from 3,713,014 in FY 2013 was primarily due to no renewal fees collections from wholesale distributors in FY 2014. This amount would have been a few thousand less, however, several wholesale distributors that expired in FY 2013 reinstated in FY 2014. Also, the number of new non-resident pharmacists continued to increase in response to the new non-resident pharmacies laws that became effective in FY 2013.



Revenue

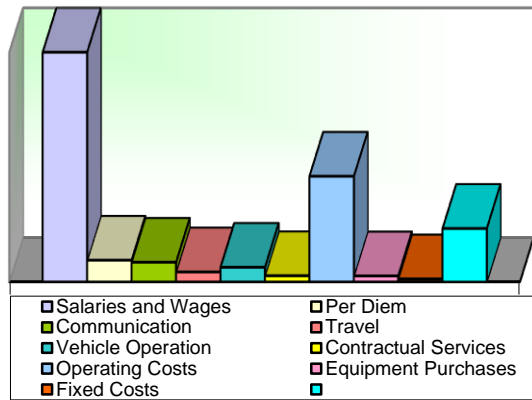


FY 2014 Revenue Detail

Pharmacists Examination	64,455
Pharmacist Renewals	1,054,547
Pharmacists Reciprocity	186,150
Pharmacists Reinstatements	1,650
Pharmacy New/Renewals	1,375,750
Distributor New/Reinstatements	419,750
Pharmacy Technicians New/Renewal/Reinstatements	284,783
Other Fees	123,310
TOTAL REVENUE COLLECTIONS CREDITED TO THE BOARD OF PHARMACY FY 2014	\$3,510,395

Expenditures

Based on the Board's annual budget request funds are appropriated by the Legislature to meet the Board's operational expenses. The FY 2014 appropriation was \$2,917,529. The Board expended \$2,761,355. Much of the approximate \$156,174 difference in the projected versus actual expenditures can be attributed to staff vacancies. Also, the slower than expected implementation of the Sterile Compounding program caused certain projected expenditures to be deferred to FY 2015.



FY 2014 Expenditure Detail

<u>Salaries and Wages</u>	\$1,725,056
<u>Technical & Special Service</u>	93,556
<u>Per Diem</u>	84,544
<u>Communication</u>	42,420
<u>Travel</u>	62,548
<u>Vehicle Operation</u>	25,843
<u>Contractual Services</u>	459,350
<u>Operating Costs</u>	24,934
<u>Equipment Purchases</u>	11,738
<u>Fixed Costs</u>	231,366
<u>TOTAL EXPENDITURES</u>	\$2,761,355

Personnel

The Board had 22 permanent positions by the end of FY 2014. It experienced two manager vacancies in addition to two other staff vacancies during part of the year. However, expenditures for salary and wage exceeded the approved \$1,155,917 for this category because several long term staff illnesses along with the mentioned vacancies required the Board to recruit temporary and contractual staff to meet operation needs. Also, a consultant pharmacist was recruited to support implementation of the new sterile compounding laws.

Procurement

The Board's project to scan over 100,000 licensees' records so the hard copies can be sent to State Archives began in late FY 2014. The delayed start created a surplus of approximately \$300,000 in the contractual services category. The Board continued its long-standing Pharmacist Rehabilitation Services contract with PEAC to support impaired practitioners under Board orders and practitioners who voluntarily (and anonymously) entered into treatment. The Board also continued its contracts with Maryland State Archives to provide service web hosting and web statistics and the National Association of Boards of Pharmacy (NABP) to perform inspections a few out of state pharmacy establishments. The Board's newsletter and annual report printing was performed by the Maryland Correctional Enterprises (MCE).

Public Information

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 in the APS Unit 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 2014 Summary of Public Relations Activities

Exhibit at ASCAP Convention, Solomon's Island, MD, and August 2013

Exhibit at Baby Boomer Senior Expo, Timonium Fair Grounds, MD, October 2013

Exhibit at Baltimore Flower Mart, Mt. Vernon Place, Baltimore City, May 2014

Exhibit at MPhA Convention, Ocean City, MD, - June 2014

FY 2014 Summary of Pharmacist Training & Education

Continuing Education Breakfast, Maritime Institute, Linthicum, MD, October 2013

FY 2014 Summary of Emergency Preparedness Activities

- Participated monthly in the State SNS Partners meeting.
- Worked with DHMH on the RSS operations.

· Worked in coordination 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.

Training Related Travel

During FY 2014 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.

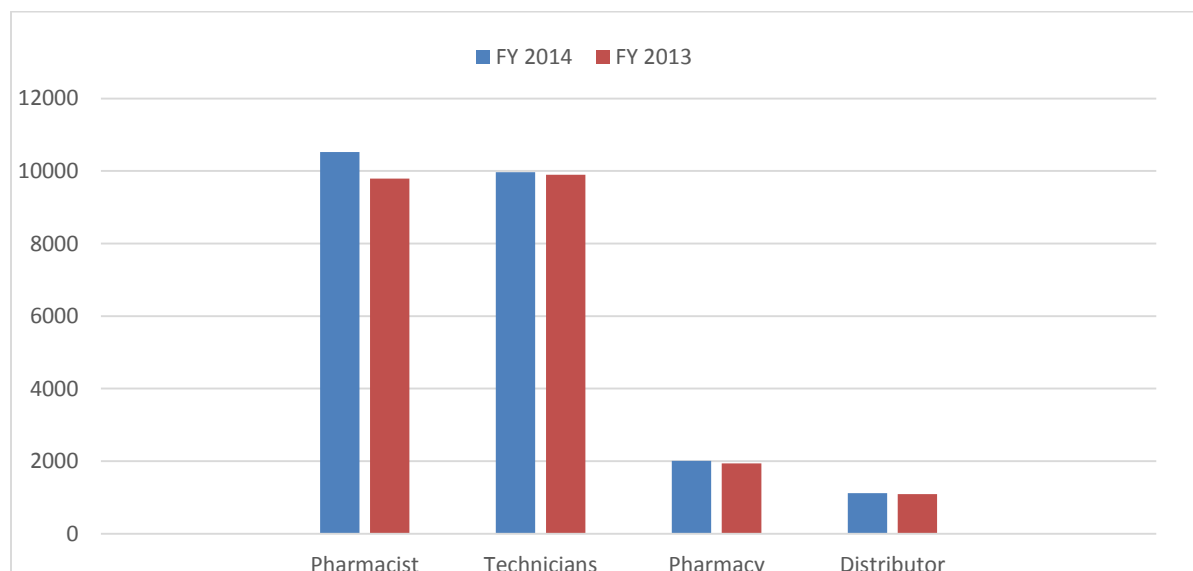
LICENSING UNIT REPORT

Overview

The Licensing Unit (Unit) of the Maryland Board of Pharmacy (Board) is responsible for all activities related to the issuance of new and renewed licenses, permits and registrations to qualified pharmacists, pharmacy technicians, pharmacy owners and pharmaceutical distributors that operate or practice in Maryland. The Unit also processes applications for the Prescription Drug Repository Program and from pharmacists to who wish to administer Influenza, Herpes Zoster, and Pneumococcal Pneumonia and other Vaccines. The Unit consists of five professional licensing staff persons: a Manager, three (3) Licensing Specialists and a Secretary. The Unit also staffs the Licensing Committee (Committee) which is responsible for reviewing all applications submitted that may not meet licensure requirements or that indicate that a licensee has had problems with their licenses or permits in other states. The Committee also reviews request from licensees to waive fees, or fines because of special circumstances. Another important responsibility of the Committee is to review or develop new licensure requirements or applications in order to accommodate new laws or changes to existing laws.

Licensing Processing Statistics

The Unit processed applications and other required documents for a total of 23,629 licensees during FY 2014 in comparison with FY2013. (See below chart). Nearly eleven thousand pharmacists (10,528) were included in the number of licensees, reflecting an increase of (733) from the previous fiscal year. This substantial increase is likely related to the fact that three schools of pharmacies in Maryland graduated students for the first time in FY 2014. Pharmacies licensed in Maryland also increased by 70, bringing the total to 2011 permit holders in FY 2014. This increase was partially a result of the law change which requires decentralized or satellite pharmacies within hospitals to be licensed in Maryland as an individual pharmacies. Wholesale distributor permits increased by 30 bringing the total number of distributors to 1119 at the end of FY14. The total number of registered pharmacy technicians, 9971, also slightly increased from FY2013.



Accomplishments

The Unit implemented cross-training of all unit staff members who had previously specialized in processing one of the four key license application types. This helped to refine processes and eliminate time lost during peak application periods because of staff absenteeism and/or vacancies. Unit staff also worked with the Licensing Committee in updating all Unit applications to reflect new and projected changes to Board statutes and regulations. The Unit also worked closely with the MIS Team in preparing more than 20,000 licensee file for the Board's canning and archiving project. This project was completed in preparation for moving the Board offices to another floor in its current building. The project was also tedious and detailed, but allowed all licensee files to be viewed in the Board's database system.

Next Year at a Glance

The Licensing Unit plans to work closely with Board members and the management team during Fiscal 2015 in reviewing current operational practices and determining methods to organize the Board for better efficiency. It will also begin to develop applications and the application review process for the new the Sterile Compounding and Pharmacy Interns regulations. These projects, as well as the on-going Committee work and application review processes, promise another active year in the Licensing Unit.

COMPLIANCE UNIT REPORT

Overview

The Compliance Unit of the Maryland Board of Pharmacy (Board) protects the public health of Maryland's citizens by ensuring compliance with state laws and regulations regarding the practice of pharmacy. Unit staff consists of a pharmacy compliance officer, two (2) half-time pharmacist inspector supervisors, four (4) compliance inspectors, a compliance coordinator, a compliance investigator, and a unit secretary. They perform the following functions:

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

The Unit experienced several personnel concerns and computer software issues that affected certain operations, as detailed below. Specifically, the Board lost one full time inspector around January 2014, the loss of a part time pharmacist inspector around June 2014, trained 2 newly hired inspectors, and extended medical leave taken by a number of Compliance staff. Due to all these setbacks, the Board petitioned and was granted the recruiting of emergency temporary Investigators and Administrative Specialist II in order to support the Board's daily functions.

Inspectors attended additional training on Sterile Compounding Training offered by NABP and along with investigators, attended an investigator training offered by CLEAR-NCI), and supported the MBOP in developing more uniform complaint reviews.

Complaints

The Unit receives complaints from a variety of sources and is charged with addressing each complaint. Individuals may obtain a complaint form by mail or from the Board of Pharmacy website at www.dhmh.maryland.gov/pharmacy and submit the completed form via fax, mail, email, or in person. All information related to each complaint is investigated and the results presented to the Board's Disciplinary Committee for review and recommended action for follow-up by Compliance Unit staff or to the full Board for further review and vote. If an issue is outside the Board's scope or jurisdiction, the complaint will be referred to the appropriate authority.

Figure 1 below, provides the number of complaints received in the past six fiscal years. Compared to previous years, FY2014 has received 348 complaints which is 10 complaints shy of that in FY2012, the year which the highest number of complaints were processed. Due to the high volume of complaints received by the Board and the unforeseen extended medical leave of many compliance staff during the middle of the fiscal year, the Board felt compelled to request emergency investigators and administrative specialist in order to continue to carry out the Board's mission in protecting Maryland consumers. Complaints received by the Board may

include, but are not limited to, an actual complaint made by the public, referrals from other state or federal agencies, or deficiencies found during inspections.

Figure 1 **Complaints Processed July 1, 2013-June 30, 2014**

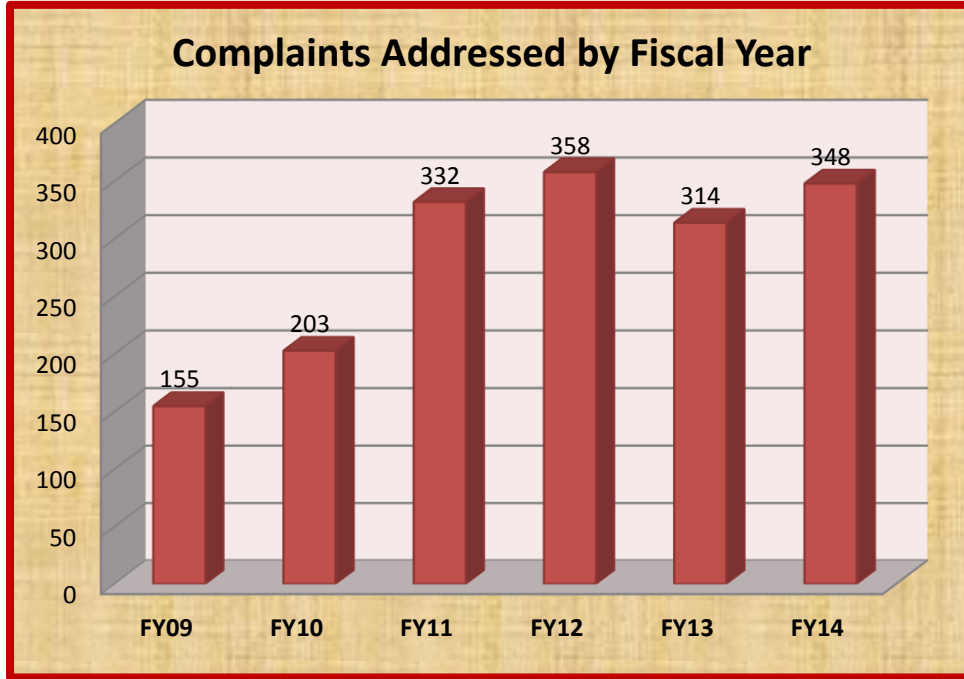
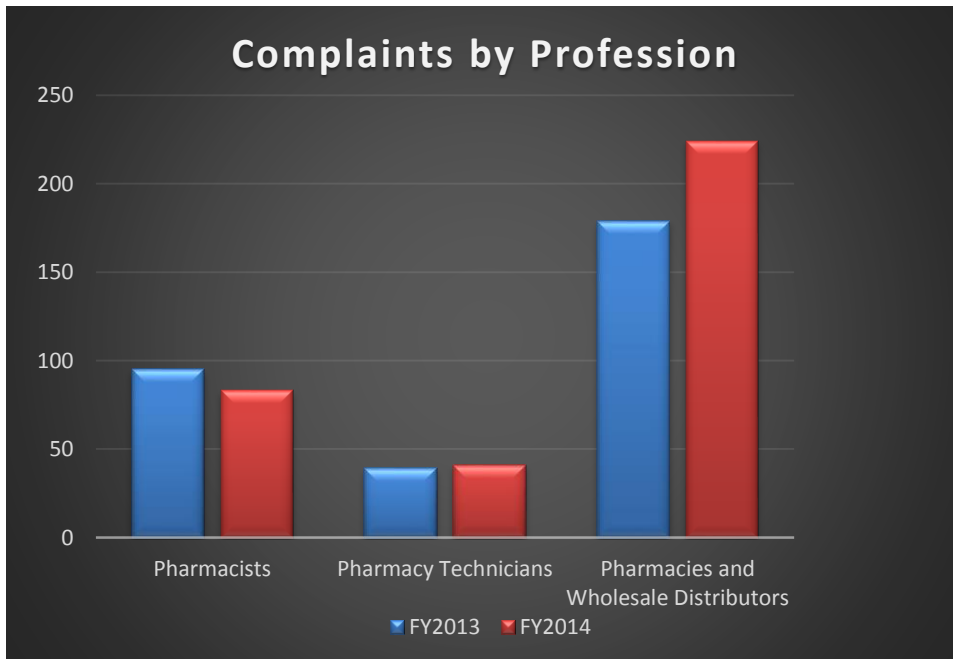
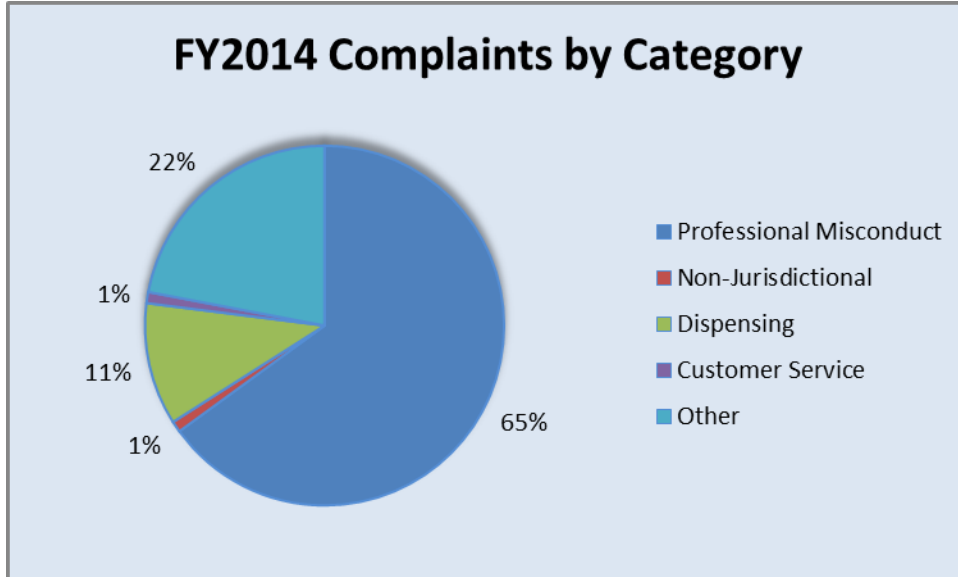


Figure 2 **Complaints against Licensees, Registrants, and Permit Holders**



This is the 6th year that the Board has registered pharmacy technicians. As a result, technician compliance monitoring is also part of the Board's purview. Figure 2 above reveals 12% of the complaints filed in this fiscal year were against pharmacy technicians. This is three times higher compared to fiscal year 2009, during the early implementation of pharmacy technician registration, but comparable to fiscal year 2013. There is; however, an increase in the number of complaint against establishments compared to other fiscal years.

Figure 3 **Types of Complaints July 1, 2013-June 30, 2014**



The types of complaints received are broadly categorized (see Figure 3). The majority relate to professional misconduct. Violations from annual inspections, unlicensed personnel engaged in the practice of pharmacy, unauthorized dispensing, theft or loss of drugs, employee pilferage, and sexual harassment are among a few examples of professional misconduct. This fiscal year, there is a significant increase in professional misconduct as compared to previous years. These relate mostly to establishments resulting from deficiencies found during annual inspections, as well as self-reports or reports from sister agencies notifying the Board of establishments that brought or sold prescription drugs without being duly licensed by the Board.

Disciplinary Cases

All complaints are investigated by the Board staff members. For the current fiscal year, the Board has taken formal or informal actions on 284 complaint cases including the opened complaints that were carried over from the previous fiscal year. Examples of informal actions include letters of education, letters of admonishment, and letters of agreement, deficiency letters, and consent order issued to certain technicians to submit to a criminal background check upon their first renewal. Examples of formal actions include a license or permit being placed on probation, suspension, revocation, as well as fines issued. Approximately 42% 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 2014, compared to the previous 5 years.

Figure 4 Disciplinary Actions-Fiscal Year Comparison

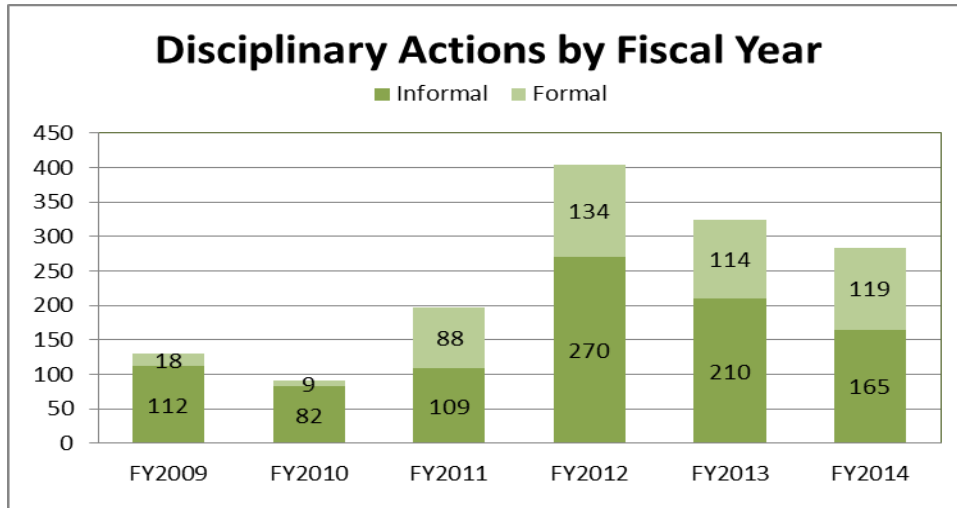
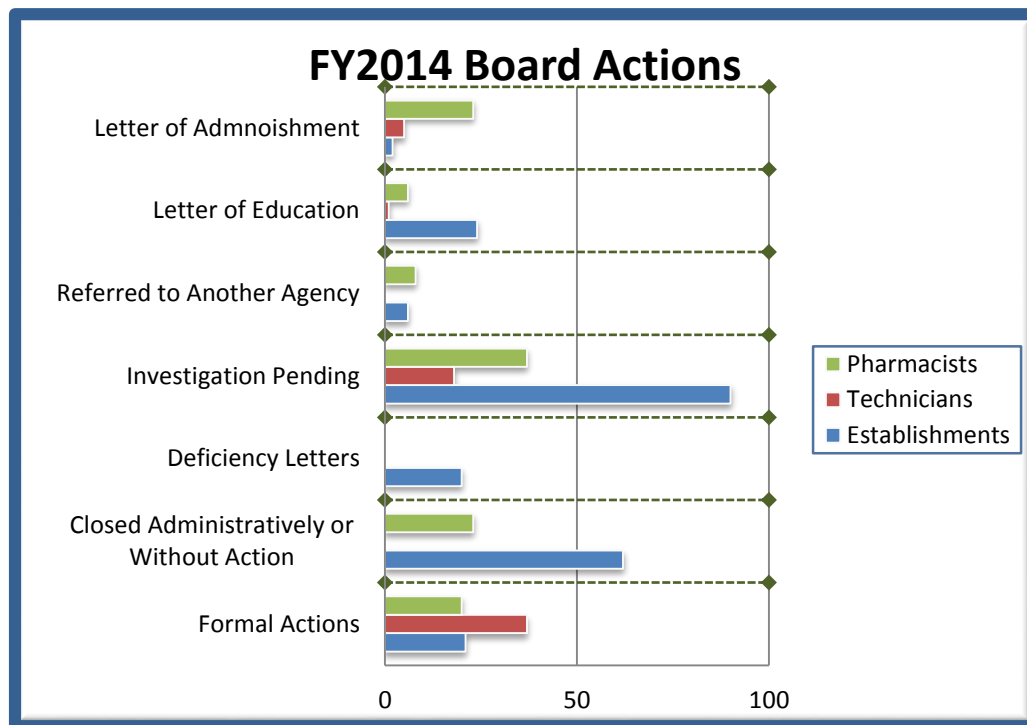


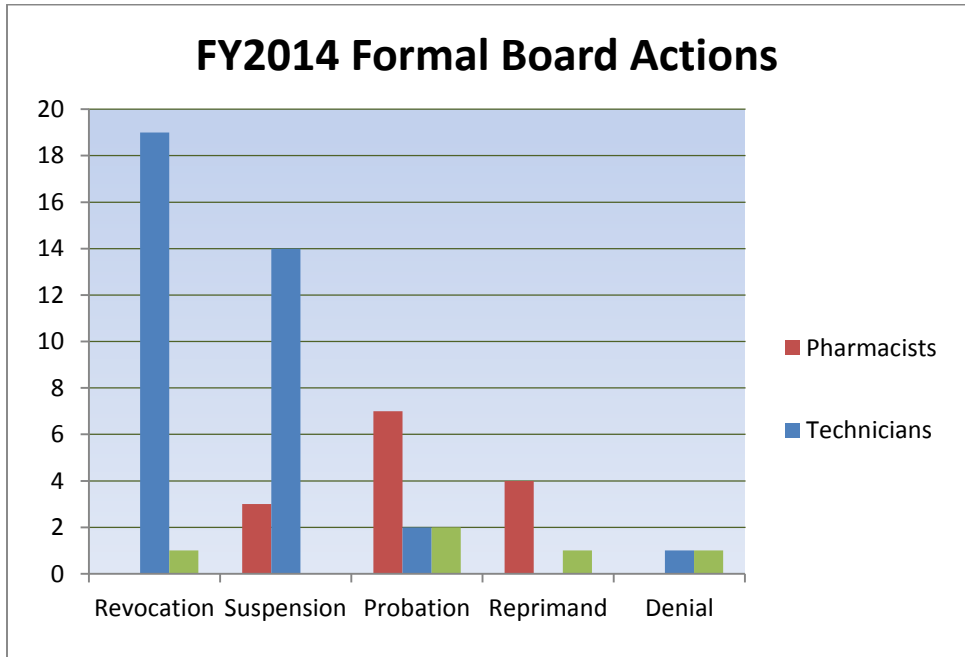
Figure 5 represents a categorical description of the various types of formal and informal actions taken against pharmacists, pharmacy technicians, and establishments in the most recent fiscal year.

Figure 5 Board Action July 1, 2013-June 30, 2014



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 2014. 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 newsletter along with name of the licensee, permit holder, or applicant.

Figure 6 Formal Board Actions Taken July 1, 2013-June 30, 2014



Inspections

The compliance unit continues to work closely with the Division of Drug control (DDC) in performing inspections. The Board of Pharmacy conducts opening, some closing, relocation, change of ownership, and annual inspections of in-state pharmacies, while DDC performs most closing inspections on behalf of the Board and the Department. The Board has a goal of inspecting all in-state pharmacies annually. The chart in Figure 7 reflects the total number of annual, opening inspections, miscellaneous inspections (relocation, change of ownership, investigative inspections), and distributor inspections performed in Fiscal Year 2014. Despite set back from not being fully staffed and the training a full time pharmacy technician inspector and a part-time pharmacist inspector, the Board completed 93% of annual inspections for all the 1315 facilities permitted in Maryland.

Figure 7

Annual Inspections	1215
Opening Inspection	123
Miscellaneous Inspection	49
Distributors	6
Total Inspections	1393

Although FY 2014 is not the year that the Board performed its wholesale distributor inspections, 6 wholesale distributor inspection were performed in order to satisfy the permit holder's renewal requirements in other states.

From the end of FY2013 to the beginning of FY2014, the Board licensed Durable Medical Equipment (DME) facilities and 42 opening inspections were performed during this fiscal year. These are included in Figure 7 under Opening Inspections.

The new computer software system, My License Office (MLO), acquired by the Board did not have a mobile inspection component that was conducive to the operations of inspection. As result, the Board had to hire a temporary administrative specialist to help scan all the inspections into the data base in addition to help support the compliance unit in other tasks.

Practitioner, Substance Abuse and Compliance Monitoring

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

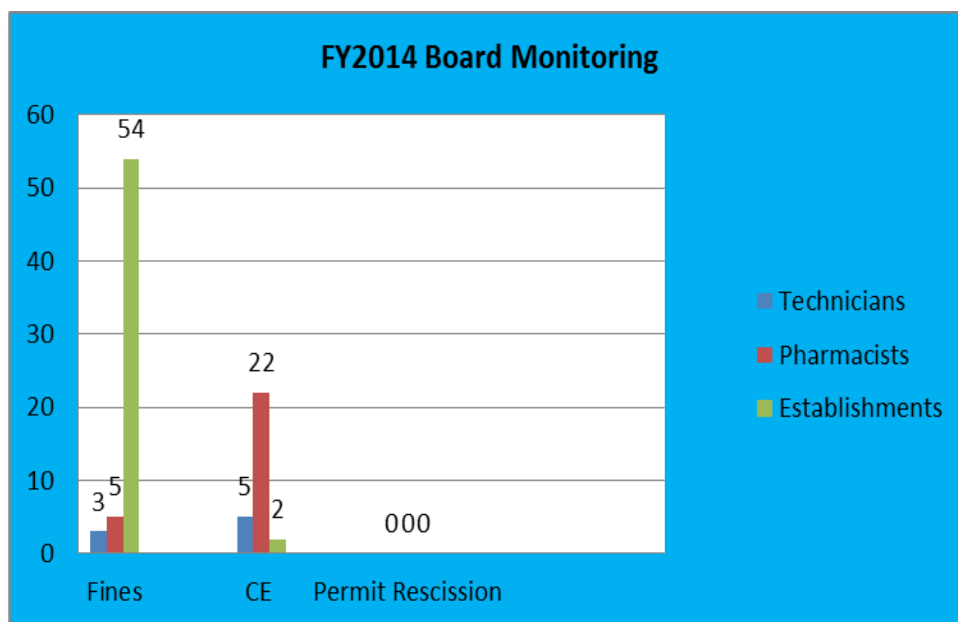
- random drug testing
- substance abuse treatment or psychotherapy
- participation in local NA/AA programs
- psychiatric evaluations
- employer reports
- continued education (CE) requirements
- any exams or courses as deemed necessary by the MBOP

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 2014, the Board monitored 15 pharmacists and 3 pharmacy technicians who were under Orders that involved substance abuse.

In addition to consent orders, 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 Letters of Admonishment or Education, and rescission of permits/licenses. This year; however, there was no permit rescission. Figure 8, below, depicts FY2014's Board monitoring.

Figure 8 Board Monitoring July 1, 2013-June 30, 2014



The 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 was confidential, monthly aggregate reports were submitted to the Board. Each client served by PEAC was required to sign a contract indicating that he or she understood that the Board would be notified if the terms of their contracts were violated. In Fiscal Year 2014, PEAC monitored a combined total of 19 clients: 18 pharmacists and 1 pharmacy technician.

As part of the requirements, PEAC made presentations about the Pharmacists Rehabilitation Committee as described in HO § 12-317, the Duty-To-Report requirement described in COMAR 10.34.10.05, and its role and its monitoring program to receive confidential assistance and as a public safety state service at the following Pharmacy Schools in Maryland:

- UMB presented to 110 pharmacy students
- UMES presented to 60 pharmacy students
- Notre Dame presented to 90 pharmacy students
- Notre Dame presented to 120 pharmacy students

PEAC was present at both the Maryland Pharmacist Association (MPhA) annual meeting exposition and the mid-year meeting where they engaged the participants in one-on-one conversations and provided specific referral information upon request.

Next Year at a Glance

For Fiscal Year 2015, 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.

MANAGEMENT AND INFORMATION SYSTEMS UNIT REPORT

Overview

The Management and Information Systems (MIS) Unit of the Maryland Board of Pharmacy (Board) is responsible for implementing and maintaining automated systems that support 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 began developing scopes of work for two projects in FY 2014. The first major project was a document management and scanning project to digitize the Board's paper documents that have been accumulating for decades. The Board anticipates relocating to another floor in its current building and is planning to save storage space by sending the paper documents to MD State Archives after the project is completed. The second project scope was to hire a software engineer to begin programming to update a mobile inspection program for our Compliance Inspectors.

Accomplishments

The Board awarded the contract to a vendor in FY2014 to complete the document management project. Also, during FY2014, disaster-recovery procedures were updated to include "bare-metal" restores to fully restore any one of the production computers in case of hardware or software failure. The Board has a remote disaster-recovery site at the Maryland State Archives facility that houses the Board's network licensing servers. MIS staff also continued evaluation and replacement of older computer equipment at the board, updating desktop software/hardware to meet DHMH policy standards.

Next Year at a Glance

During FY 2015, the MIS Team will begin the process of creating a mobile inspection program for the Field Compliance Inspectors to better accommodate their needs while performing pharmacy and wholesale distributor facility inspections.

Additionally, the MIS Team also plans to develop more automated reporting for the Board units to better track licensing and disciplinary trends, provide more consistent reporting, and to better forecast future regulatory and operational needs.

A major initiative planned in FY 2015 entails the Board initiating a bid process to secure a Business Analyst to document and analyze the Board's business rules and procedures and recommend changes to make the Board's workflow more efficient. A new software system is required by the Board to expand online services available to licensees including the ability to apply for initial applications online, extending online renewals capabilities to pharmacy and wholesale distributor establishments, and printing/receiving licenses via the internet. The MIS Unit staff will use the recommendations received from the Business Analyst to begin identifying a licensing software program that reflects the ever expanding needs of an innovative body such as the Maryland Board of Pharmacy.

LEGISLATION/REGULATIONS UNIT REPORT

Overview

The Legislative and Regulations Unit of the Maryland Board of Pharmacy (Board) 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. This Unit, which consists of a manager and part-time administrative assistant, is also responsible for supporting 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 2014 included Pharmacy Practice and Legislative. During FY 2014 the Unit also staffed the Pharmacist Working Conditions Subcommittee and began staffing the SB 257 Task Force to Study Access to Pharmacy Services in Maryland.

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. Revisions to regulations for **Sterile Pharmaceutical Compounding** were begun in FY 2013 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). The Notice of Final Action was published on June 27, 2014 at the end of the FY 2014 with an effective date of January 1, 2015.

The revisions to **Pharmacist Administration of Vaccinations**, pursuant to 2013 Legislation, was published in December 2013 and became effective April 28, 2014. These regulations allow pharmacists to administer vaccinations listed in the Centers for Disease Control and Prevention's (CDC) recommended immunization schedule to children between 11 and 17 years old who possess a prescription from an authorized prescriber. It allows pharmacists to administer vaccines to adults that are listed in the CDC recommended immunization schedule or CDC's Health Information for International Travel. DHMH established the criteria for the protocols for adult immunization and that criteria was included in the proposal. Reporting requirements were also included for a pharmacist reporting administration of all immunizations to the ImmuNet Program established under §18-109 of the Health-General Article. Additionally, the revised regulations require pharmacists to report back to authorized prescribers that when they administered a vaccine to their patients. If the vaccination has not been administered in accordance with a prescription the revised regulations require pharmacists to inform the individual's primary care provider or other usual source of care that the vaccine has been administered. Finally, the fee that a pharmacist may charge for the administration of vaccinations was increased from a cap not to exceed the Medicare reimbursement rate of \$50 in addition to the cost of the vaccine.

During Fiscal Year 2014 the Unit revised or amended five other sets of regulations. The amendments are described later. Staff also responded to 1,347 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. 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 the Board’s legislative proposals to health professional boards, local and national health associations and the regulated industry.

The Unit identified 45 bills to present to the Board of Pharmacy’s Legislative Committee for consideration during FY 2014. The Unit tracked and drafted position papers and/or letters to various legislative committees for 21 of the 45 bills. Below is provided a chart of the 21 bills (companion bills are counted as one bill) and the results.

Bill #	Bill Name	Result
SB 228 HB 398	State Board of Pharmacy - Election of Officers	Passed
SB 257	Task Force to Study Access to Pharmacy Services in MD	Passed
HB 301 SB 413	Health Occupations - Dentists With Permits to Dispense Dental Products - Exclusion from Maryland Pharmacy Act	Passed
HB 303 SB 412	Health Occupations - Licensed Dentists Who Dispense Antibiotics - Exclusion from Maryland Pharmacy Act	Passed
HB 761 SB 874	Health Insurance - Specialty Drugs	Passed
SB 852	Health Occupations - Dispensers of Devices and Equipment - Exclusion from the Maryland Pharmacy Act	Passed

HB 1029		
SB 854 HB 1218	Board of Pharmacy - State Registered Pharmacy Interns	Passed
SB 884 HB 1127	Health Insurance - Incentives for Health Care Practitioners	Passed
HB 1088	Health Occupations - Compound Drugs - Provision to Ophthalmologists for Office Use	Passed
SB 1108	Sterile Compounding Permits - Definition of “Compounding”	Passed
HB 106	Senior Prescription Drug Assistance Program - Sunset Extension	Passed
SB 215 HB 280	Workers’ Compensation - Payment for Physician-Dispensed Prescriptions – Limitations	Unfavorable
SB 217 HB 281	Workers’ Compensation - Payment for Controlled Dangerous Substances Prescribed by Physicians - Limitations	Unfavorable
HB 368 SB 482	Workers’ Compensation - Prescription Drugs - Choice of Pharmacy	Did not cross
SB 607	Child Abuse and Neglect - Failure to Report and Training	Unfavorable
HB 596	Board of Pharmacy - Wholesale Distributors - Notification to Pharmacy	Unfavorable
SB 825 HB 875	Pharmacy Benefits Managers - Specialty Drugs	Unfavorable
SB 915 HB 1333	Public Health - Emergency Use Auto-Injectable Epinephrine Program	Unfavorable

SB 969 HB 1343	Department of Veterans Affairs - Opioid Time Lock	Unfavorable
HB 1166	Maryland Second Chance Act of 2014	Failed
HB 1137 SB 1048	Crimes - Robbery or Theft of Property - Controlled Dangerous Substances	Failed

Summaries of major bills from the 2014 Legislation Session are provided below:

SB 228/HB 398 State Board of Pharmacy – Election of Officers

Amended the Maryland Pharmacy Act to allow for consumers members appointed to State Board of Pharmacy to be elected to as Board officers. This proposed amendment to the Maryland Pharmacy Act is consistent with the practice acts of the other health occupations boards.

- **Revisions Effective 10/01/14**

SB 852/HB 1029 Health Occupations – Dispensers of Devices and Equipment – Exclusion from the Maryland Pharmacy Act

Exempts from the Maryland Pharmacy Act entities that dispense only prescription devices or prescription durable medical equipment (DME). These entities will no longer be required to obtain a Maryland pharmacy permit. Entities that dispense only prescription devices containing no prescription drugs or oxygen are exempt. If a prescription device contains a prescription drug, then the entity is still required to be licensed as a pharmacy. Oxygen providers are regulated by the Office of Health Care Quality as Residential Service Agencies.

- **Revisions Effective 06/01/14**

SB 854/HB 1218 Board of Pharmacy – State Registered Pharmacy Interns

Requires three types of individuals to register and be approved by the Board of Pharmacy before practicing pharmacy as a pharmacy intern under the direct supervision of a licensed pharmacist: 1) students enrolled in pharmacy school seeking employment in a pharmacy; 2) individuals who have graduated from an ACPE accredited Doctor of Pharmacy program and have applied for licensure with the Board; and 3) individuals who have graduated from a foreign school of pharmacy, have established educational equivalency as determined by the Board, passed an examination of oral English approved by the Board, and working on completing 1,560 hours of work experience in a Maryland pharmacy.

Pharmacy interns will be required to submit to a criminal history records check upon application. The new law provides for expiration and renewal of a registered pharmacy intern who is only allowed to practice pharmacy

under the direct supervision of a licensed pharmacist. A licensed pharmacist would only be allowed to supervise two pharmacy interns at one time.

- **Revisions Effective 10/01/14**

SB 1108 Sterile Compounding Permits – Definition of “Compounding”

Establishes a specific exemption from a sterile compounding permit for oncology, hematology, and rheumatology practices. In the legislation the term “Compounding” no longer included mixing, reconstituting, or other similar acts routinely performed by, or under the supervision of, and oncologist, a rheumatologist, or a hematologist who administers chemotherapy, biologic therapy, supportive care medication, rheumatology therapy, or another therapy in the treatment of cancer, a rheumatology condition, or a blood condition when prepared in accordance with the:

- 1) Directions contained in approved labeling provided by the product’s manufacture;
- 2) Other manufacturer directions consistent with the labeling; and
- 3) Other direction or guidance from the U.S. Food and Drug Administration relating to the Acts described in this paragraph.

In an uncodified section of the law, the Secretary of Health and Mental Hygiene was required to:

- (1) convene a workgroup, including representatives of the Maryland Board of Physicians, the State Board of Pharmacy, the Maryland Society of Clinical Oncology, MedChi, and other interested parties, to study appropriate national safety standards for mixing, reconstituting, and other similar acts routinely performed by, or under the supervision of, an oncologist, a rheumatologist, or a hematologist who administers chemotherapy, biologic therapy, supportive care medication, rheumatology therapy, or any other therapy in the treatment of cancer, a rheumatology condition, or a blood condition; and
- (2) on or before December 15, 2014, report to the Governor and the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee on: (i) the results of the study; and (ii) the Secretary’s recommendations for appropriate oversight

- **Revisions Effective 07/01/14**

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HB 596 Board of Pharmacy – Wholesale Distributors – Notification to Pharmacy

Requires a wholesale distributor to: (1) notify a pharmacy at least 30 days before the wholesale distributor imposes a limit on the quantity of a prescription drug or prescription device distributed to the pharmacy; and (2) while a limit is in effect, provide a pharmacy with an update, at least weekly, on the quantity of a prescription drug or prescription device available to the pharmacy. Also provides that the notification is not required if: 1) due to circumstances beyond the control of the wholesale distributor, the wholesale distributor is not aware of the quantity limit at least 30 days before a limit is imposed on the pharmacy; or 2) a limit is imposed on the pharmacy due to suspected illegal activity and the wholesale distributor provides documentation of the circumstances or suspected illegal activity during any inspection by the Board. Documentation of circumstances or suspected activity is not be required if, due to circumstances beyond the control of the wholesale distributor, the wholesale distributor is not aware of the quantity of a prescription drug or device available to the pharmacy or a limit is imposed on the pharmacy due to suspicion of illegal activity. The wholesale distributor is required to provide documentation of the circumstances or suspected illegal activity during any Board inspection.

- **Revisions Effective 10/01/14**

HB 1088 Health Occupations – Compound Drugs – Provision to Ophthalmologists for Office Use

Allows ophthalmologist to store in the office and administer to a patients, without a patient-specific prescription, the following prescription compounds:

1. Compounded antibiotics for the emergency treatment of bacterial endophthalmitis and viral retinitis; and
2. Compounded antivasular endothelial growth factor agents for the emergency treatment of neovascular glaucoma, wet macular degeneration, and macular edema.

Under existing law, pharmacies may only perform sterile compounding pursuant to a patient-specific prescription. The ophthalmologist may obtain these compounds, without a patient-specific prescription, from an outsourcing facility that is registered with FDA and holds a Maryland wholesale distributor permit. The ophthalmologist may also prepare these medications themselves as long as they follow USP 797 guidelines and obtain, when it becomes available, a Maryland Sterile Compounding Permit. The ophthalmologist shall then inform the pharmacy or sterile compounding facility, from where the compounds were acquired, of the identity of any patient to whom the drugs are administered.

- **Revisions Effective 07/01/14**

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 2014.

Maryland Board of Pharmacy Regulations, COMAR 10.34.01 - .37, revisions effective during Fiscal Year 2014:

COMAR Citation	Title	Effective Date
10.34.03	Inpatient Institutional Pharmacy	May 31, 2014
10.34.14	Opening and Closing of Pharmacies	July 8, 2013
10.34.23	Pharmaceutical Services to Patients in Comprehensive Care Facilities	September 16, 2013
10.34.30	Change to Permit - Pharmacy or Wholesale Distribution Permit Holder	July 8, 2013
10.34.32	Pharmacist Administration of Vaccinations	April 28, 2014

Summaries of regulatory changes that became effective in FY 2014 are provided below.

10.34.03 Inpatient Institutional Pharmacy

Revisions require separate licensure for pharmacy areas not located in the same building or pavilion as the main hospital pharmacy, includes definitions for a “decentralized pharmacy” and “pavilion,” and includes specific requirements for decentralized pharmacies located in hospitals. They were revised to address the numerous decentralized pharmacies in hospitals that operate under a single hospital pharmacy permit. Many times these outlying pharmacy areas, or decentralized pharmacies, were not inspected; the Board did not know that they existed. Additionally, many of the outlying pharmacy areas functioned as independent pharmacies.

10.34.14 Opening and Closing of Pharmacies and 10.34.30 Change to Permit – Pharmacy or Wholesale Distribution Permit Holder

Revised:

(1) COMAR 10.34.14 Opening and Closing of Pharmacies to:

(a) Clarify that a permit holder is required to notify the Board and the Division of Drug Control when closing a pharmacy;

(b) Clarify that the Board performs closing inspections, or designates a Board agent to perform the closing inspection, instead of specifically designating the Division of Drug Control (DDC); and

(c) Make additional revisions for clarity and consistency; and

(2) COMAR 10.34.30 Change to Permit – Pharmacy or Wholesale Distribution Permit Holder to include a new regulation requiring notification to the Board of changes to a permit holder’s hours of operation which will assist the Board’s inspectors in scheduling inspections of pharmacies and wholesale distributors.

10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities

The purpose of this action was to amend Regulations .03 and .09 to require a pharmacist to perform the final check on the contents of an interim box.

10.34.32 Pharmacist Administration of Vaccinations

Revised COMAR 10.34.32 to comply with statutory requirements as amended by Chapters 255 and 256, Acts of 2013 (SB 401/HB 179 Pharmacists – Administration of Vaccinations – Expanded Authority and Reporting Requirements). See summary of revisions above.

Legislative Reports

The Unit drafted annual legislative reports including: 1) Annual Report on the Implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act; 2) Annual Report on the Operation of the Prescription Drug Repository Program; and 3) State Board of Pharmacy Report on the Implementation of Title 12, Subtitle 4A of the Health Occupations Article as enacted by HB 986 State Board of Pharmacy – Sterile Compounding – Permits, 2013, Chapter 397.

New Year at a Glance

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. Beginning in Fiscal Year 2015, the Unit will prepare legislative reports due January 1, 2015. 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;
- Report to the Governor and the General Assembly on Changes to The Drug Quality and Security Act, and Federal Guidance Provided under the Act, As Those Changes Relate to the Authority of a Sterile Compounding Facility to Provide Prescription Drugs to Ophthalmologists For Office Use; and
- Report of the SB 257 Task Force to Study Access to Pharmacy Services in Maryland

The Board will also continue to review laws and regulations that govern the settings and practices of the professions it regulates during FY 2015.

STATE OF MARYLAND BOARD OF PHARMACY



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