

STATE OF MARYLAND

Department of Health and Mental Hygiene

BOARD OF PHARMACY



FISCAL YEAR 2017 ANNUAL REPORT

July 1, 2016

through

June 30, 2017

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 student interns, 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 2017 BOARD COMMISSIONERS

President

Mitra Gavgani

Home Infusion Representative

Secretary

Zeno St. Cyr II

Consumer Representative

Treasurer

Kevin Morgan

Chain Drug Store Representative

Daniel Ashby

Acute Care Hospital Representative

Efstratios (Steve) Bouyoukas

Chain Drug Store Representative

Karla Evans

Acute Care Hospital Representative

Jennifer Hardesty

Long Term Care Representative

Neil B. Leikach

Independent Representative

Brenda Oliver

Consumer Representative

Roderick Peters

Independent Pharmacist Representative

Rhonda M. Toney

At-Large Representative

Ellen H. Yankellow

At Large Representative

BOARD COUNSEL

Linda Bethman, AAG

Brett Felter, Staff Attorney

Fiscal Year (FY) 2017 BOARD STAFF 410-764-4755

EXECUTIVE

<p>Speights-Napata, Deena - Executive Director Logan, Brian – Legislative Liaison Vacant - Management Associate</p>	<p>Board Operations, Board Units, Board Members and Board Minutes, PIA requests</p>
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DATA INTEGRITY PROCESSING AND ASSESSMENT

<p>Johnson, Nakia – Call Center/Data Input & Analysis Manager Burnham, John - Customer Service Specialist Chew, Christine - Customer Service Specialist Goodman, Kimberley - Customer Service Specialist Goodman, Rhonda – Customer Service Lead Specialist Jackson, Leroy - Customer Service Specialist Lane, Joy - Customer Service Specialist Seeds, Janet - Public Info/Education/Communication/Training Coordinator Tates, Lawrence – Customer Service Specialist</p>	<p>Scans all documents into licensee files. Answers Incoming Calls and Emails</p>
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COMPLIANCE

<p>Evans, Thomas – Compliance Officer Sanderoff, Lisa – Investigator Supervisor Collins, Jada – Administrative Specialist Kracke, Sandra - Investigator Heather McLaughlin - Compliance Coordinator Thomas-Gray, Vanessa - Investigator West, Shiela - Investigator</p>	<p>Complaints, Pharmacy Practice, Disciplinary, Investigations and Pharmacists Rehabilitation</p>
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INSPECTION

<p>Richard, Nancy – Lead Pharmacy Inspector Barefield, Amanda - Pharmacy Inspector Johnson, Cheryl - Pharmacist Inspector Lin, Emory – Pharmacy Inspector Weigley, Kerri - Pharmacy Inspector Young, Shanelle - Pharmacy Inspector</p>	<p>Inspections, Pharmacy Practice</p>
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LICENSING

<p>Brand, Etzion – Licensing Manager Ayers, Christopher - Licensing Specialist James, Doris – Licensing Specialist Lanteon-Edmonds, Darchelle - Licensing Specialist Lead Wise, Keisha - Licensing Specialist</p>	<p>Licensing, Permits, and Registration, Reciprocity, and Scores</p>
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MANAGEMENT INFORMATION SERVICES

<p>Fields, Edward – Deputy Director of Operations Bozek, John - Computer Specialist Green, Jacqueline - Database Specialist Partin, Janey - Web Design / Computer Network Specialist Trainee</p>	<p>Computer, Database and Website and On-line Renewals</p>
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MESSAGE FROM THE EXECUTIVE DIRECTOR

Deena Speights-Napata

As the end of CY 2017 has arrived, it seems like a good time to reflect on our achievements this year. We have been involved in many different aspects of public health, fulfilling our mission and vision of protecting the public and setting a standard for pharmaceutical services that ensure safety and quality health care for our citizens. We've worked toward achieving our mission and vision primarily through being responsive to the public through our call center and customer service initiative, through establishing internal and external collaborations, continuing to be on the cutting edge of information technology development, and working with others on legislative initiatives and regulatory development.



For example, let's take a look at the call center and customer service initiative. The board this calendar year, based on year to date numbers, is projected to respond **to over 20,000 Inquiries and Data requests from Pharmacists and Stakeholders, including public and licensee inquiries (phone calls, faxes, and emails)** WOW!!!

Other areas of significant achievement include:

Information/Technology Development

- An electronic Distributor application was developed to ensure an easy distributor application process.
- An electronic inspection form was developed which cut by 50% the time needed to conduct and document an inspection
- Development of Fraud Detection protocol to increase efforts at protecting personal identifier information of licensees

Board of Pharmacy Collaborations

- Montgomery County Office of Legislative Affairs
- MDH new centralized licensing system discussion
- Maryland Governor's Opioid Operational Command Center member
- UMES and Howard University pharmacy student presentations
- Internship/preceptor agreement with UMES established University of Baltimore Law School internship agreement in progress
- Participation in the National Boards of Pharmacy Task Force on the Definition of a Patient-Pharmacist Relationship
- Participation in the Pharmacy Technician Certification board conference on technician certification requirements
- Maryland Society of Health-System Pharmacy member
- Maryland Office of Controlled Substances Administration
- Maryland Medicaid
- MDH Career Day

- MDH Office of Infectious Disease in promotion of syringe sales in pharmacies
- DEA Annual Drug Take Back Day promotion
- Regional Opioid 7 Substance Abuse Summit—Meeting with Washington DC, Virginia, and MD opioid epidemic strategists
- National boards of pharmacy annual regional and national meetings
- USP 800 Director of Compliance certification
- Maryland Hospital Association—Naloxone Prescribing and Dispensing and Hospital Role in Addressing The Opioid Crises, Overdose Survivors Outreach Project, and Alcohol and Drug Use Screening webinar series
- Pharmacists Prescribing Contraceptives Workgroup
- Maryland Behavioral Health Administration, Prescription Drug Monitoring Program
- East Coast Regional Controlled Substances Coalition
- FDA Annual meeting

Procurements

- Software engineering contract to develop and monitor digital inspection form
- New Rehabilitation Committee contract developed and posted for bid. The new contract expands the scope of work, increases funding, and extends the term of service to up to 5 years.

Staffing

- Call Center Director position created to oversee the call center, licensing data input, supports staff operations, and customer service
- Inspection and Investigative staff received nationally recognized CLEAR basic and advanced certification
- Naloxone Administration certification training for Board of Pharmacy staff
- NABP Sterile Compounding Certification for Inspection Supervisor

Legislation and Regulation

- Facilitator of Maryland Contraceptive Work group regulation development
- Investigational Drugs, Biological Products, and Devices - Right to Try Act
- Licensed Pharmacists - Risks of Opioid Addiction - Notifications
- State Board of Pharmacy - Registered Pharmacy Technicians - Exemption for Pharmacy Students
- Oncologists – Dispensing and Insurance Coverage of Orally Administered Cancer Chemotherapy
- Health Care Providers - Opioid Prescriptions - Limitations and Requirements
- Pharmacists - Administration of the Influenza Vaccination - Age Requirement
- Pharmacists - Substitution and Dispensing of Biological Products

- Courts - Criminal and Civil Immunity - Prescribing, Dispensing, and Administering Opioid Antagonists
- Public Health - Expedited Partner Therapy - Trichomoniasis and Pharmacist Dispensing
- Health Insurance - Specialty Drugs - Authority to Dispense
- Health Insurance - Prescription Drugs - Dispensing Synchronization

Events

- Annual Continuing Education Breakfast—Record number of over 300 pharmacists receiving continuing education credits
- Annual reception for departing board commissioners
- Annual staff appreciation luncheon

I'm looking forward to FY 2018 as another great year of outstanding achievement!

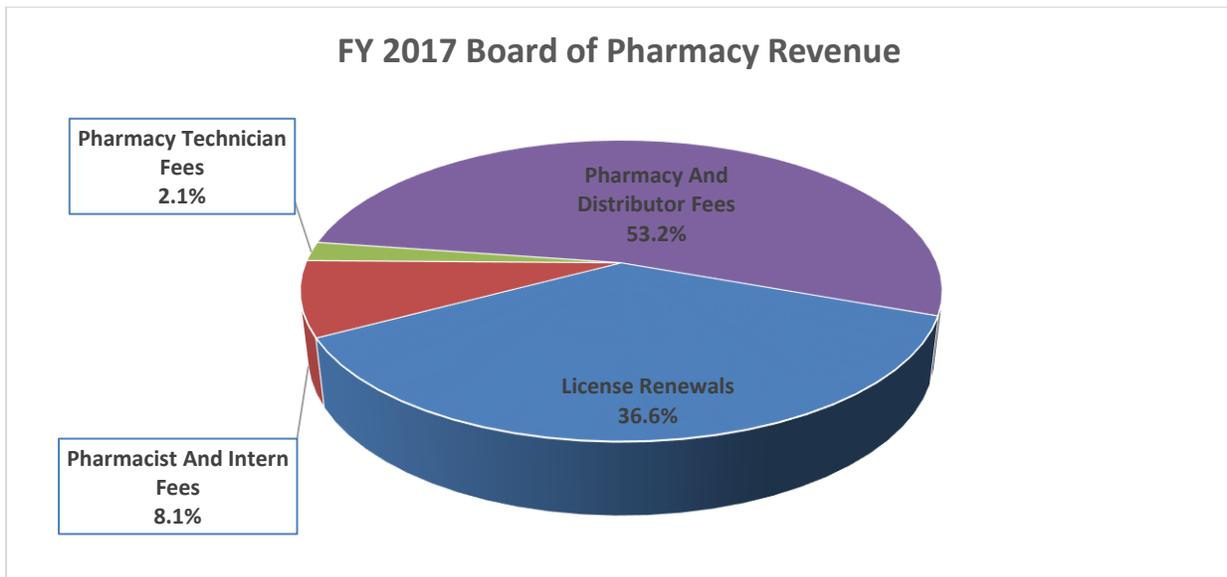
OPERATIONS UNIT REPORT

Overview

The Operations Unit (OU) of the Maryland Board of Pharmacy (Board) is responsible for managing the fiscal and procurement key administrative functions at the Board. 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 Maryland Department of Health, 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 management of revenue, expenses 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.

Board Revenue



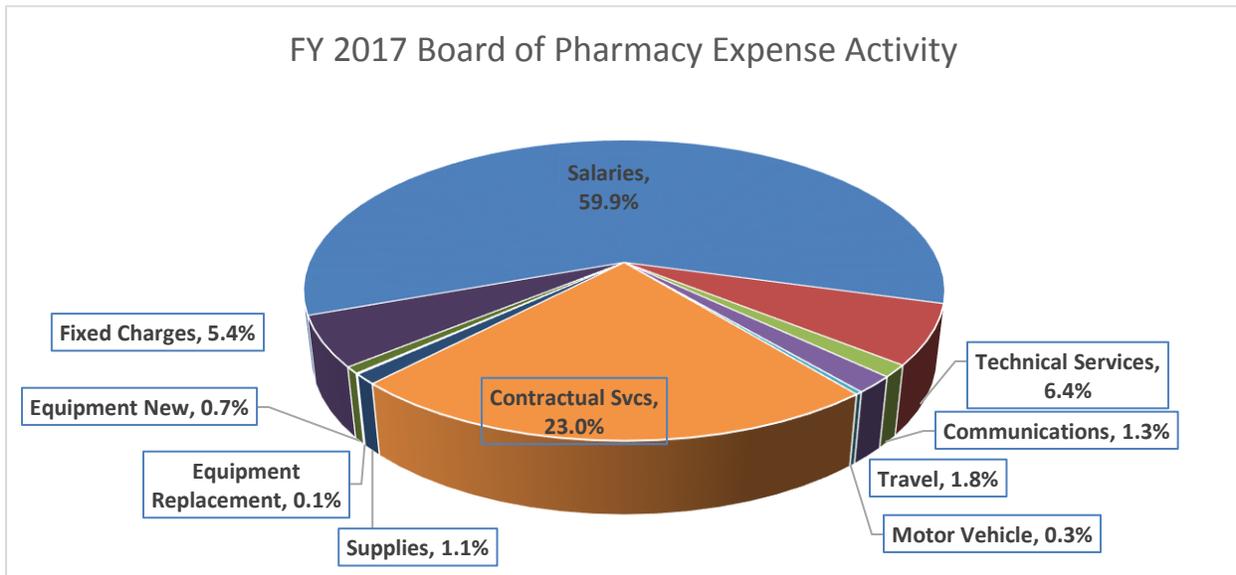
Revenue	Amount	Percent
License Renewals	1,559,479.00	36.6%
Pharmacist And Intern Fees	343,687.90	8.1%
Pharmacy Technician Fees	88,048.99	2.1%
Pharmacy And Distributor Fees	2,267,336.71	53.2%
Revenue 2017	4,258,552.60	100.0%

Board Revenue

The above chart reflects the four (4) revenue types collected by the Board. The Board was directed by the Legislative Auditors to discontinue directly processing checks or money orders. In FY 2017 payments of these types were made directly to a bank lockbox which reduced the number of categories license fees are distributed to. Payments made by check or money order via the lockbox are segregated in the categories of Pharmacists & Interns, Technician or Pharmacy and Distributors. Payments made by credit card for license renewals are reflected as License Renewals for Pharmacists, Interns, Technicians or Distributors.

The Board collected \$124,750 of fines related to inspections that are transferred directly to the State of Maryland General Fund and not utilized for operation of the Board. The Board also transferred \$182,844 related to the Pharmacists license renewal fee to the Maryland Health Care Commission, which represented \$36 of the \$261 license renewal fee.

Board Expenses



Expense Category	Amount	Percent
Salaries	2,319,749.14	59.8%
Technical Services	247,697.81	6.4%
Communications	51,771.23	1.3%
Travel	68,818.52	1.8%
Motor Vehicle	13,176.40	0.3%
Contractual Svcs	893,388.46	23.0%
Supplies	42,823.57	1.1%
Equipment Replacement	4,424.00	0.1%
Equipment New	26,466.05	0.7%
Fixed Charges	208,014.82	5.4%
Totals	3,876,330.00	100.0%

Board Expenses

The above chart reflects the ten (10) expense categories for expenditures by the Board in FY 2017. Most of the categories of expense are self-explanatory but we would be providing additional information related to some of the major expenses incurred by the Board:

- **Technical Services** - Contractual employees costs and Per Diem payments to Board Members
- **Contractual Services** - Attorney General legal cost share from the Maryland Department of Health for legal expertise related to Board decisions, Bank account charges for Lockbox activity related to license payments, Software Maintenance contract for licensing software, Indirect costs from the Maryland Department of Health for centralized costs, Printing costs for Maryland Pharmacy Law Book, Software updates for Mobile application for inspectors and Distributor online renewal application.
- **Fixed Charges** – Rental costs for Board of Pharmacy space

Next Year at a Glance

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 Maryland Department of Health.

PUBLIC RELATIONS

Overview

The Public Relations Unit (PR) of the Maryland Board of Pharmacy (Board) is implemented by staff, 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

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 2017 Summary of Pharmacist Training & Education

- Continuing Education Breakfast, Maritime Institute, Linthicum, MD, October 2016

FY 2017 Summary of Emergency Preparedness Activities

- Participated monthly in the State SNS Partners meeting.
- Worked with MDH on the RSS operations.
- Coordinated with MDH 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 schools 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 (WSD) 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 four (4) licensing specialists. They perform the following functions:

- process, analyze, and review applications;
- contact applicants for any missing information;
- refer certain applications to the Licensing Committee for review
- approve and issue licenses/registrations/permits; and
update applications, forms and the content of the Board's website.

The Licensing Unit works closely with the Licensing Committee. The Licensing Committee is responsible for reviewing applications that may not meet certain licensure requirements or that indicate an applicant/licensee has had problems with their license/permit/registration in another state. The Committee also reviews requests from applicants/licensees to waive requirements or fees due to special circumstances. Another important responsibility of the Committee is the review and development of licensure requirements and procedures resulting from the promulgation of new laws or regulations or changes to the existing laws or regulations.

The Licensing Unit experienced several personnel changes this year. A new licensing manager was hired. In addition, two (2) specialists were added to the staff. As a result of the staff increase, applications were handled more quickly and efficiently. The Licensing Unit staff responded to applicants within one (1) day of receipt of application more than 95% of the time. In instances where applications were complete, licenses/permits/registrations were issued on the same day. Additionally, the Licensing Unit replaced several forms, made significant improvements in applications and forms, and updated the content of the Board's website to ensure accurate information.

Licensing Processing Statistics (see Figure 1)

In FY2017, the Licensing Unit issued 12,625 licenses, permits, and registrations to pharmacists, pharmacy interns, pharmacy technicians, pharmacies and WSDs. This number represents an increase of approximately 10.4% over the previous fiscal year. The processing of adjudicating licenses, permits, and registration applications requires careful review of documentation submitted along with the applications.

In FY2017, the Licensing Unit processed 222 new pharmacy permits. This number reflects an 18.9% decrease from FY2016.

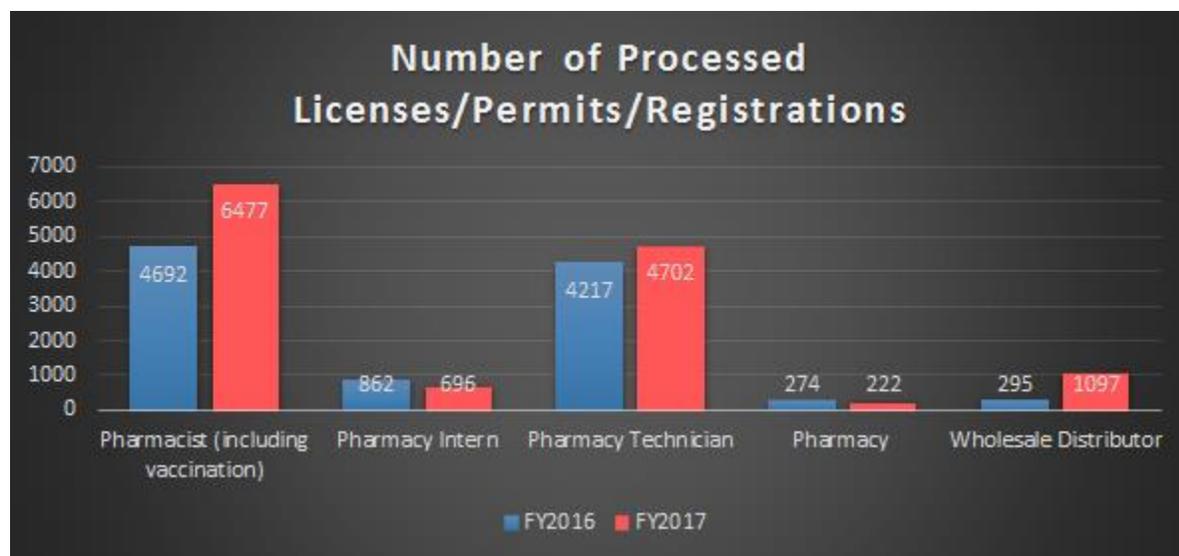
In FY2017, the Licensing Unit processed 6,477 pharmacist licenses (initial and renewal, including vaccine certifications), a 35.1% increase compared to FY2016.

In FY2017, the Licensing Unit issued 39 Pharmacy Intern Graduate and 657 Pharmacy Intern Student registrations (initial and renewal); a decrease of 19.2% from FY2016, which was the first time that pharmacy students were eligible to apply for intern registration.

In FY2017, the Licensing Unit processed 1,097 WSD permits (864 renewals and 233 new permits), compared to 295 permits in FY2016 (94 renewals and 201 new permits). The large disparity in renewals is attributable to the WSD renewal period which occurred in FY2017.

In FY2017, as in previous years, the Licensing Unit processed more technician renewal applications than initial applications. The Licensing Unit issued 4,702 technicians registrations (initial, renewal, and reinstatement), an increase of 11.5% from the number of technician registrations issued in FY2016.

Figure 1 Licenses/Permits/Registrations Processed in FY2016/FY2017



Next Year at a Glance

For Fiscal Year 2018, the Licensing Unit plans to:

- update applications and other forms;
- update the content of the Board's website; and
- increase the efficiency and improve the application process.

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 Pharmacist Compliance Director, a Lead Compliance Inspector, two (2) half-time Pharmacist Compliance Inspectors, four (4) full-time Compliance Inspectors, a Pharmacist Investigator Supervisor, three (3) Compliance Investigators, a Compliance Coordinator, and a Laboratory Scientist Surveyor. 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
- inspect pharmacies and wholesale distributors

The Unit experienced several personnel changes in FY17. The Unit added a Pharmacist Investigator Supervisor, saw one Compliance Investigator retire, hired a new Compliance Director and Laboratory Scientist Surveyor, and promoted an administrative position to an investigative position.

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.health.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, 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, FY2017 has received 472 complaints. 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. The increase in complaints is due to a variety of factors, including the effects of the opioid crisis on the industry, an increase in the scrutiny of sterile compounding facilities, an increase in thefts and employee pilferage, and growing consumer frustration surrounding the instability in the insurance industry.

Figure 1 **Complaints Processed from July 1, 2016-June 30, 2017**

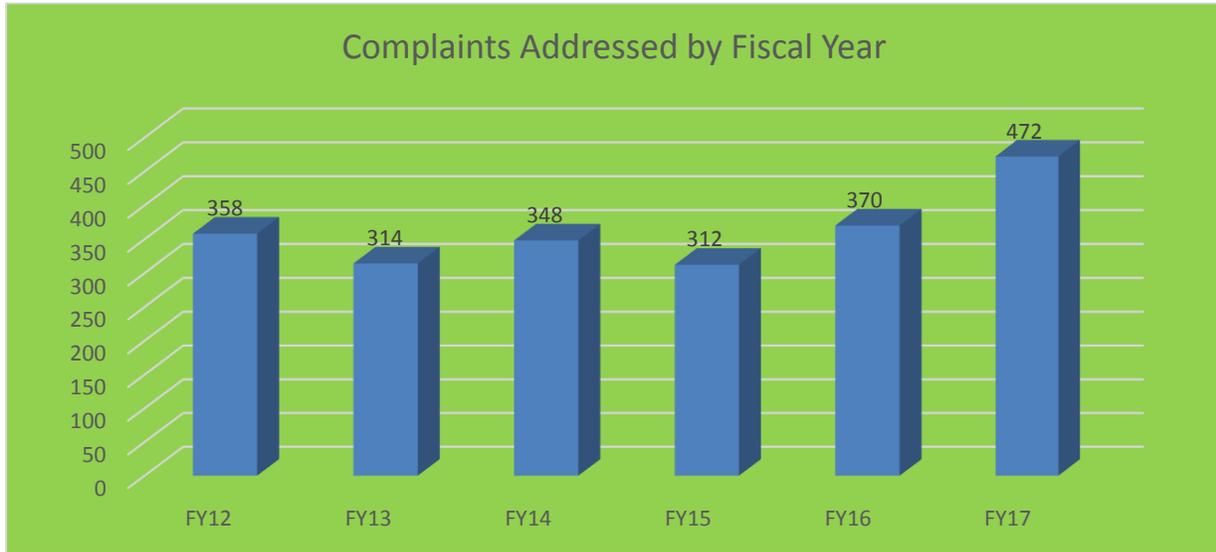


Figure 2, below, reveals that for FY 2017, the greatest number of complaints is still attributed to the establishments followed by complaints against pharmacists. There is an increase in the number of complaints received against establishments this year compared to FY 2016. The number of complaints against technicians rose compared to last fiscal year as well.

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

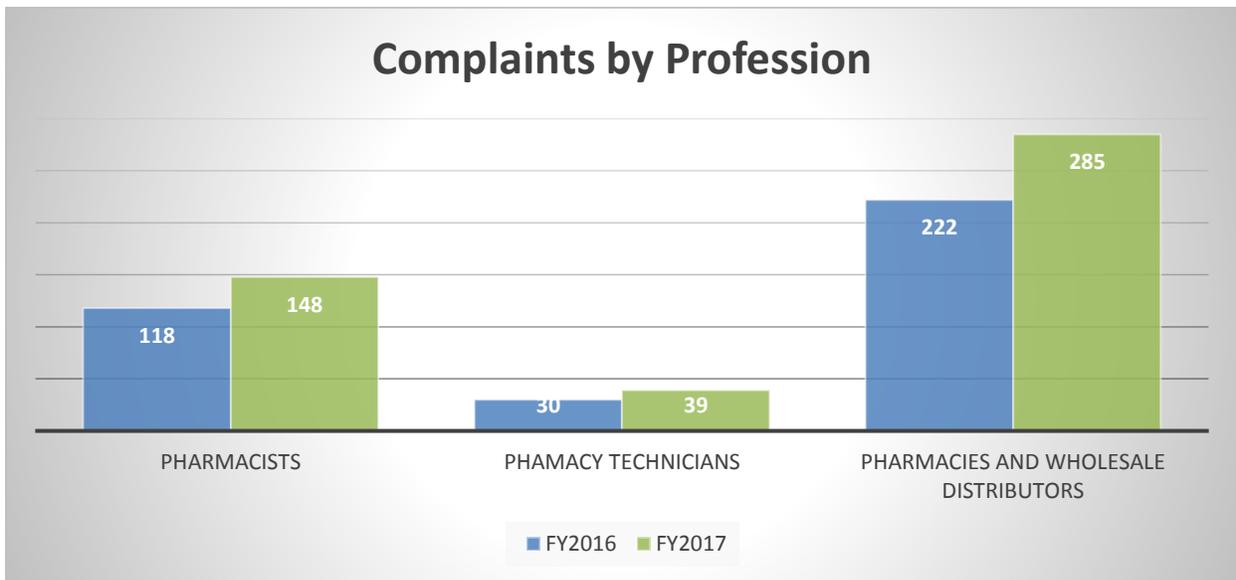
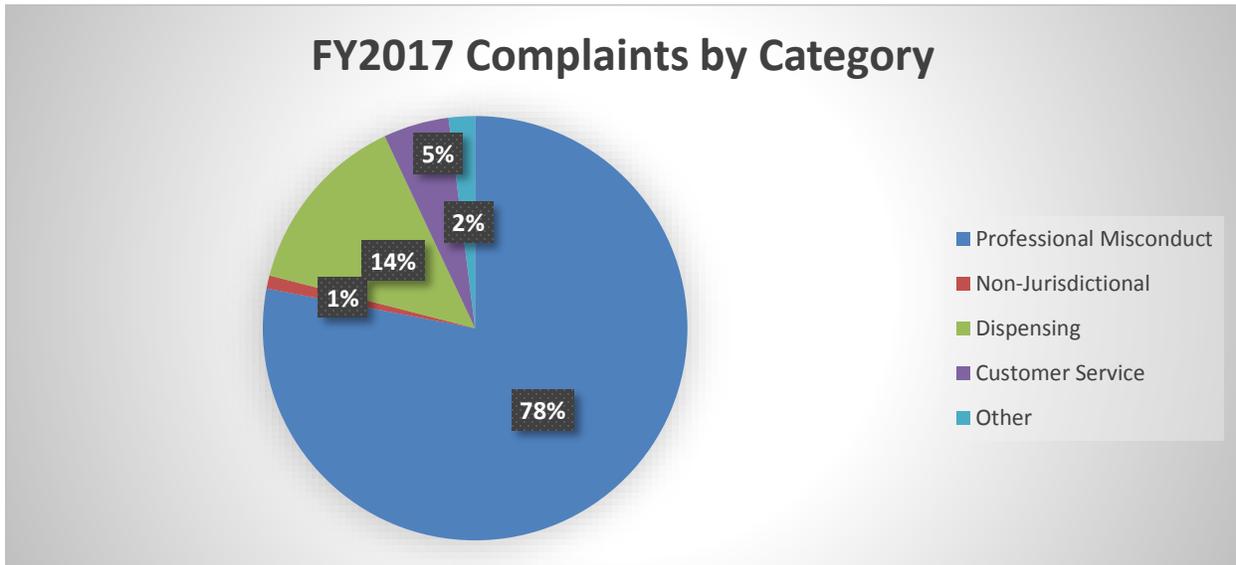


Figure 3

Types of Complaints from July 1, 2016-June 30, 2017



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 has increased compared to last year. It relates mostly to deficiencies found in establishments 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 342 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, or revocation, and deficiency fines. Approximately 74% of the complaints remained open. This is due to investigations still pending, those pending action from the attorney general's office, outstanding fines, suspensions pending revocation, probation and formal actions which involve licensee monitoring. Figure 4, below, shows the number of formal and informal actions taken for Fiscal Year 2017, compared to the previous 5 years.

Figure 4

Disciplinary Actions-Fiscal Year Comparison

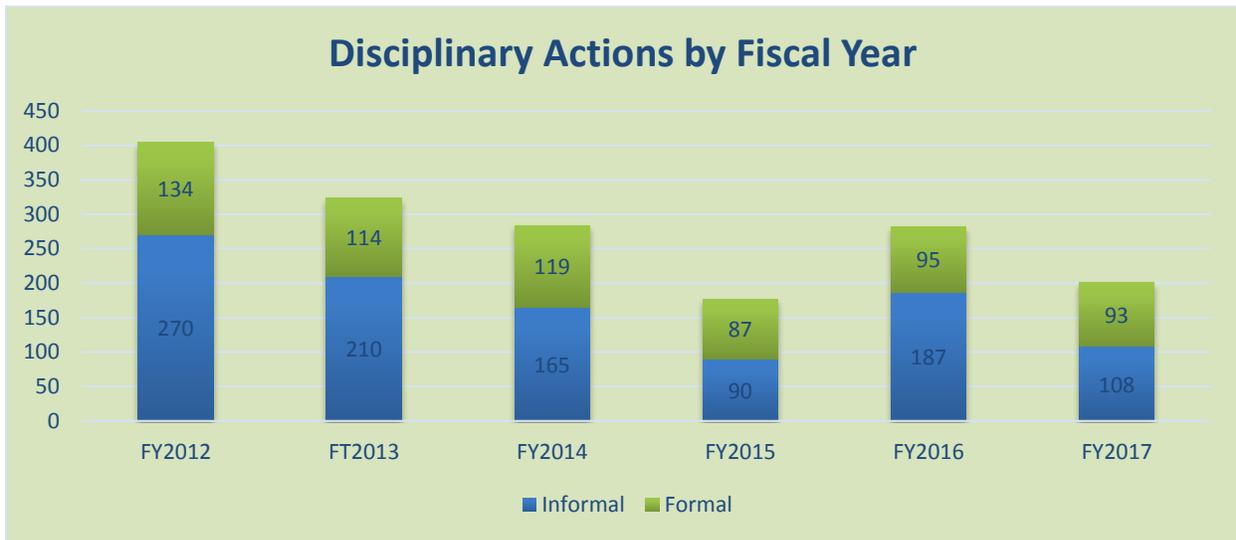


Figure 5 represents a categorical description of the various types of formal and informal actions taken against pharmacists, pharmacy technicians, and establishments in the most recent fiscal year.

Figure 5

Board Action taken from July 1, 2016-June 30, 2017

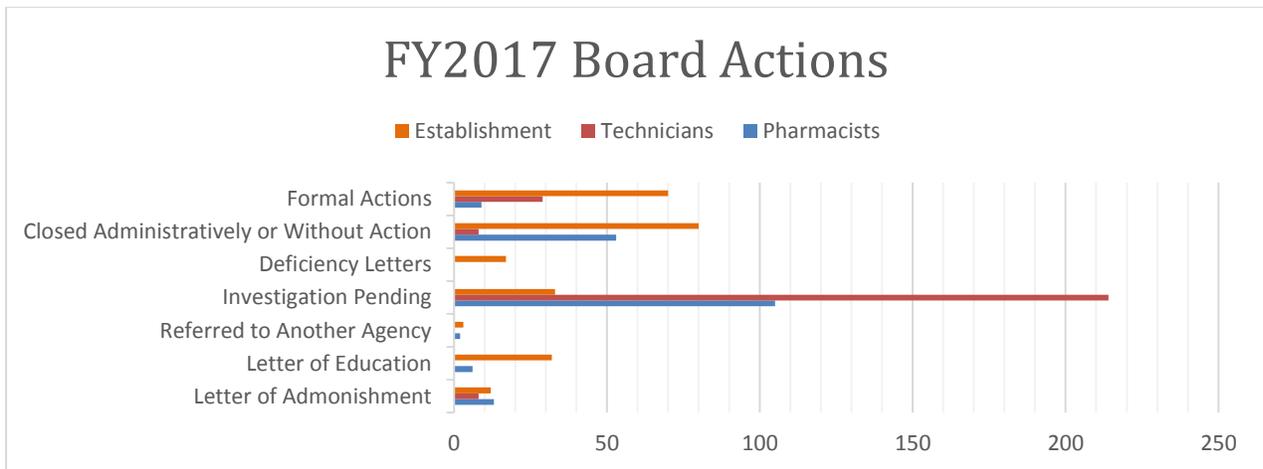
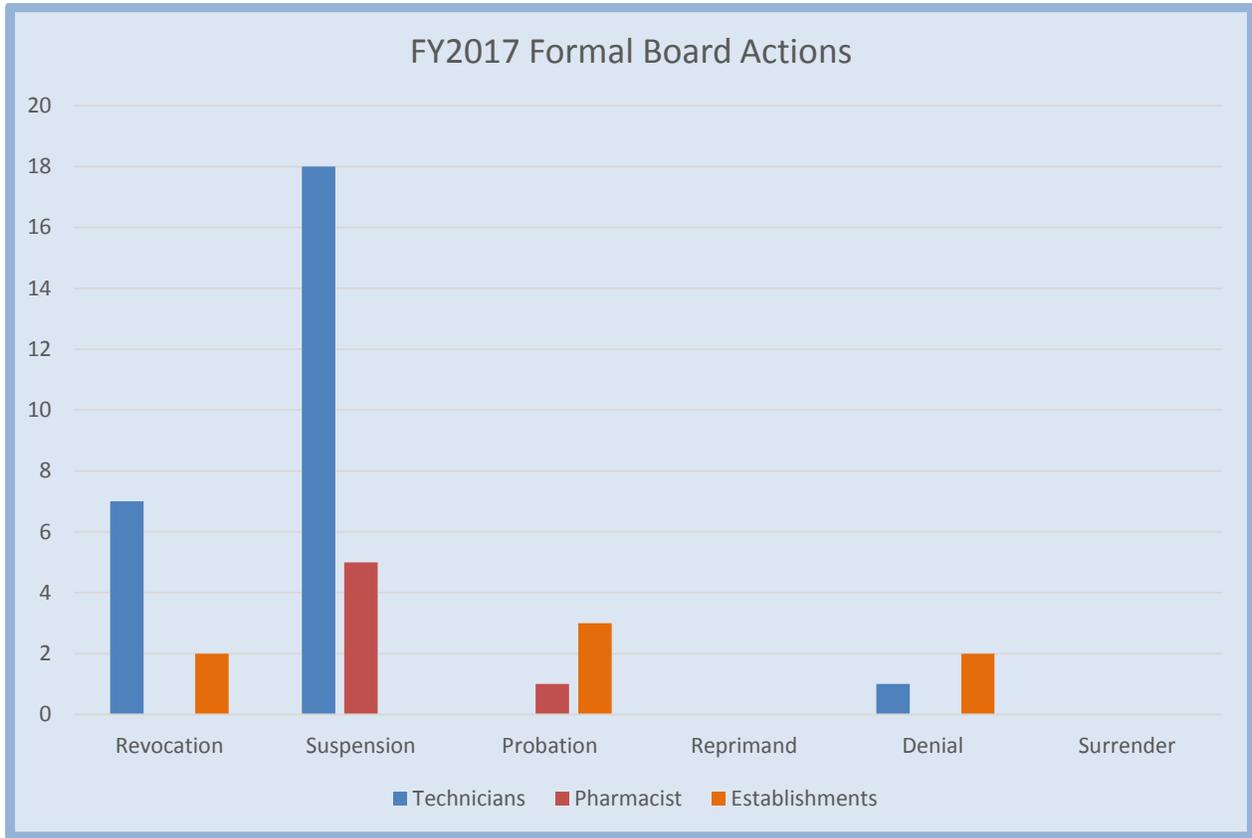


Figure 6, below, reflects the formal actions taken against pharmacists and pharmacy technicians in Fiscal Year 2017. Formal actions, including deficiency fines, issued are published in the Board of Pharmacy newsletter along with name of the licensee, registrant, and permit holder as well as posted on the Board of Pharmacy website.

Figure 6

Formal Board Actions Taken from July 1, 2016-June 30, 2017



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, most closing, relocation, change of ownership, and annual inspections of in-state pharmacies, while OCSA performs some 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 2017. The Board completed 100% of annual inspections for all the facilities permitted in Maryland.

Figure 7

Annual Inspections	1474
Opening Inspection	85
Miscellaneous Inspection	75
Distributors	78
Total Inspections	1712

The Board contracted and developed new software to accommodate and incorporate the mobile inspection component into its current software system. Inspections now have an electronic inspection tool with software that allows real time access to data and the upload of inspection reports. This has streamlined the inspection process and increased the level of customer service and satisfaction for permit holders and licensees.

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 the following:

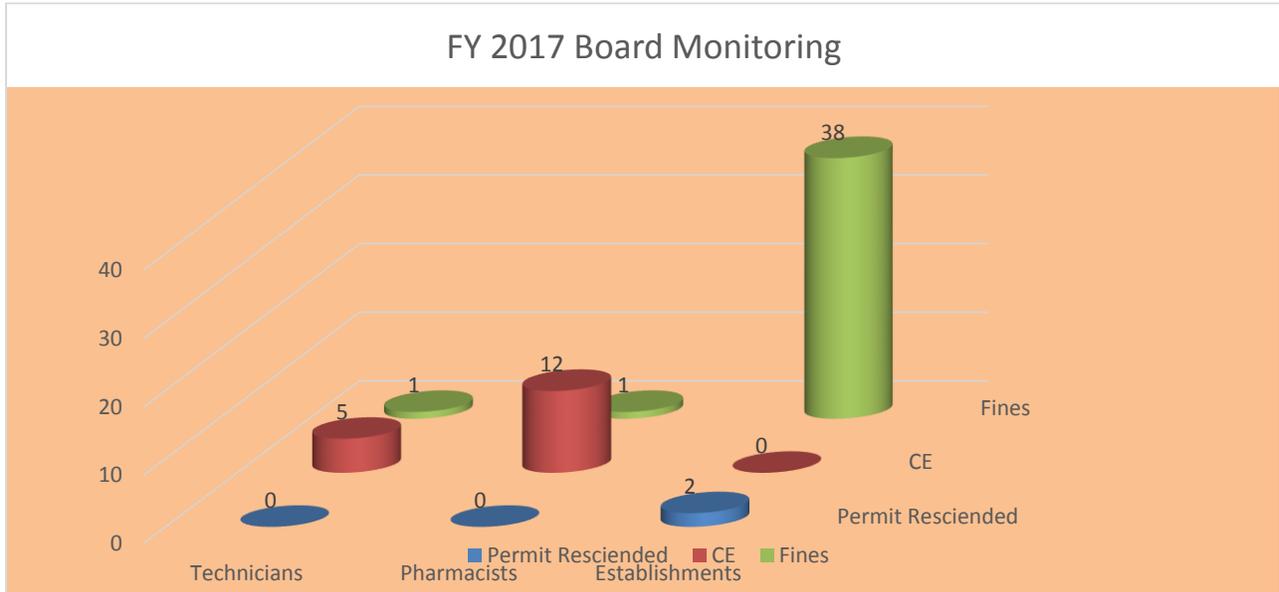
- random drug testing
- substance abuse treatment or psychotherapy
- participation in local NA/AA programs
- psychiatric evaluations
- employer reports
- continued education (CE) requirements
- any exams or courses as deemed necessary by the Board

Once disciplined, the licensee's information is reported to NABP, who in turn reports the information 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 2017, the Board monitored 33 pharmacists and 11 technicians, which includes 6 pharmacists and 2 pharmacy technician who were under Orders that involved substance abuse.

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 five pharmacies for which permits were issued due to the pharmacies not being opened and operational within 60 days of the issuance of the permit. Figure 8, below, depicts FY2017's Board monitoring.

Figure 8

Board Monitoring from July 1, 2016-June 30, 2017



The Maryland Board is temporarily using a few services to provide assessments, treatment referrals, and monitoring of pharmacists and pharmacy technicians that anonymously and voluntarily request substance abuse assistance. Contract negotiations are under way to replace the services of the Pharmacist Education and Advocacy Counsel (PEAC), a pharmacist rehabilitation committee, which ceased operations in the fall of 2016.

Although the individual assistance provided to licensees is confidential, monthly aggregate reports are submitted to the Board. Each client monitored 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.

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 the policies and procedures for the investigative unit
- 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. This unit responds to public information requests. 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.

Bill Number	XFile Bill Number	Sponsor	Synopsis	Title	Effective
HB0584	SB0572	Delegate Young, K.	Authorizing a manufacturer of an investigational drug, biological product, or device to make available the investigational drug, biological product, or device to eligible patients; requiring a manufacturer of an investigational drug, biological product, or device to notify a specified patient and a specified health care provider of specified side effects or risks; requiring the Office of the Attorney General to develop an informed consent form that meets specified requirements; etc.	Investigational Drugs, Biological Products, and Devices - Right to Try Act	1-Oct-17
HB0613	SB0363	Delegate Hettleman	Authorizing a pharmacist who meets the requirements of State Board of Pharmacy regulations to prescribe and dispense specified contraceptives; requiring the State Board of Pharmacy, on or before September 1, 2018, and in consultation with the State Board of Physicians, the State Board of Nursing, and specified stakeholders to adopt regulations establishing the conditions under which pharmacists may prescribe and dispense contraceptives; etc.	Pharmacists - Contraceptives - Prescribing and Dispensing	7/1/2017
HB0628	SB0517	Delegate Barron	Requiring the Secretary of Health and Mental Hygiene and the Office of Administrative Hearings, in consultation with stakeholders and other interested parties, to adopt regulations for the supervision of each board or commission that is composed of individuals participating in the occupation or profession regulated by the unit in order to prevent anticompetitive actions and to determine whether the actions further a clearly articulated State policy to displace competition; requiring the Office to establish a specified process; etc.	Secretaries of Principal Departments - Supervision and Review of Decisions and Actions by Units Within Departments	6/1/2017
HB1031	SB0815	Delegate Pena-Melnyk	Providing that a specified provision of law requiring an individual to be registered and approved by the State Board of Pharmacy as a pharmacy technician before performing delegated pharmacy acts does not apply to a specified pharmacy student currently completing the first year of a professional pharmacy education program and performs, under the direct supervision of a licensed pharmacist, delegated pharmacy acts in accordance with specified regulations; etc.	State Board of Pharmacy - Registered Pharmacy Technicians - Exemption for Pharmacy Students	10/1/2017
HB1273	SB0997	Delegate Cullison	Authorizing a pharmacist to substitute an interchangeable biological product for a prescribed product under specified circumstances; requiring a pharmacist or the pharmacist's designee, except under specified circumstances, to inform specified consumers of the availability of an interchangeable biological product and the approximate cost difference as compared to a specified drug; requiring the State Board of Pharmacy to maintain on its Web site a link to specified lists of biological products; etc.	Pharmacists - Substitution and Dispensing of Biological Products	10/1/2017

HB1432		Chair, Health and Government Operations Committee	Requiring health care providers to prescribe the lowest effective dose of an opioid and in a quantity no greater than the quantity needed for the expected duration of specified pain unless the opioid is prescribed to treat a specified disorder or specified pain; requiring the dosage, quantity, and duration of specified prescribed opioids to be based on an evidence-based clinical guideline for prescribing controlled dangerous substances; authorizing specified disciplinary action by health occupations boards; etc.	Health Care Providers - Prescription Opioids - Limits on Prescribing (The Prescriber Limits Act of 2017)	5/25/2017
SB0110		Senator Conway	Authorizing, notwithstanding any other provision of law, a licensed pharmacist to dispense antibiotic therapy prescribed to sexual partners of patients diagnosed with specified sexually transmitted infections without making a personal physical assessment.	Public Health - Expedited Partner Therapy - Trichomoniasis and Pharmacist Dispensing	10/1/2017

Regulatory Initiatives

The Unit assists in revising the Board's regulations as needed.

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.

The Board will also continue to review laws and regulations that govern the settings and practices of the professions it regulates during FY 2018.

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 Computer Network Specialist, Database Specialist and Administrative Specialist.

New Developments

Systems Automation was contracted with to develop an online distributor renewal application for the biannual renewal cycle starting in March and ending in May 2017.

The Board contracted with a technical services company to provide a software engineer to develop 11 online applications for the inspectors to utilize in the annual inspections of licensees.

Accomplishments

In FY 2017 the Board implemented online renewals for the Distributor Licenses which are renewed on a biannual cycle. The online renewals for these licenses were available for the March to May 2017 renewal cycle.

The technical services company provided a software engineer to work with the inspection staff from January through July 2017 to develop the following forms:

1. Community Pharmacy
2. Hospital
3. Supplemental Sterile Processing
4. Comprehensive Care Pharmacy
5. Pharmacy Opening
6. Opening Inspection for Sterile Processing
7. Wholesale Distributor of Prescription Drugs and Devices
8. Wholesale Distributor Closing
9. Pharmacy Closing
10. Repository/Drop Off
11. Supplemental Form for Assisted Living

The inspection staff is utilizing these electronic forms which can be directly uploaded to the licensing database to decreasing the amount of time to perform the inspections. These forms directly link to data necessary to be accessed while performing the inspections.

Next Year at a Glance

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 Maryland Department of Health.

CUSTOMER SERVICE

Overview

The Customer Service Unit of the Maryland Board of Pharmacy (Board) is constantly a work in progress. Responding to concerns from the licensees and the public, the Board created a call center to address the phone concerns. The consensus was that questions were not being responded to in a timely manner and/or that the answers were not correct.

In the beginning of 2015, the Board chose staff that they considered to be highly qualified to start a call center. This was gradually implemented with changes along the way. Perceptions among the licensees began to change as their concerns were being addressed.

It soon became evident, though, that more staff were needed since staff members had originally been taken from other areas to 'share' call center duties on a part time basis. There was a list of guidelines written for the call center staff to follow, but they basically learned as they went. They constantly shared with each other in order to enable to make things run smoothly. As they learned more, new guidelines were addressed so that they would all be on the same page.

The first thing the Call Center implemented was that most calls coming into the Board are routed through the call center. Those staff are the ones that respond to questions and/or refer to other staff. This has greatly reduced the number of calls distracting employees throughout the workday. Emails coming into the Board are answered in a few days. Frequently Asked Questions, derived from the Call Center, are placed on the Board's website; that greatly reduces the number of calls that come into the Board.

Then, towards the end of 2015 BITHGROUP Technologies was contracted to do an assessment of the Board. A final report was printed in September of 2016 that summarized the findings of the consultant tasked with this assignment, based on her findings from March – September 2016. After doing an evaluation of the Board's current business rules, workflow, licensure types and applications, inspections and complaint reports, fee collection, customer service and other tasks, and vendor solicitation, recommendations were made. Suggested recommendations included digital analysis, a system for on-going updating of policies and procedures, training manual development, training program management, systems analysis, and a new document management process as well as HR and change management.

In 2017, a manager was hired to oversee the Call Center and continually evaluate services. This has greatly improved morale among the employees which has resulted in greater service to the public.

Next Year at a Glance

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

- obtaining more training;
- learning more about the operation of other units;
- responding accurately to clients; and
- communicating with applicants when necessary.

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 5th 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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