

STATE OF MARYLAND

Department of Health and Mental Hygiene

BOARD OF PHARMACY



FISCAL YEAR 2019 ANNUAL REPORT

July 1, 2018

through

June 30, 2019

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 2019 BOARD COMMISSIONERS

President

Kevin Morgan

Chain Drug Store Representative

Secretary

Kristopher Rusinko

Home Infusion Representative

Treasurer

Jennifer Hardesty

Long Term Care Representative

Surinder Singal

Independent Pharmacist Representative

Neil B. Leikach

Independent Pharmacist Representative

Efstratios (Steve) Bouyoukas

Chain Drug Store Representative

Karla Evans

Acute Care Hospital Representative

Brenda Oliver

Consumer Representative

Daniel Ashby

Acute Care Hospital Representative

Ellen H. Yankellow

At-Large Representative

BOARD COUNSEL

Linda Bethman, AAG

Brett Felter, Staff Attorney

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Maryland Board of Pharmacy

FY 19 Year in Review



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DEENA SPEIGHTS-NAPATA
EXECUTIVE DIRECTOR

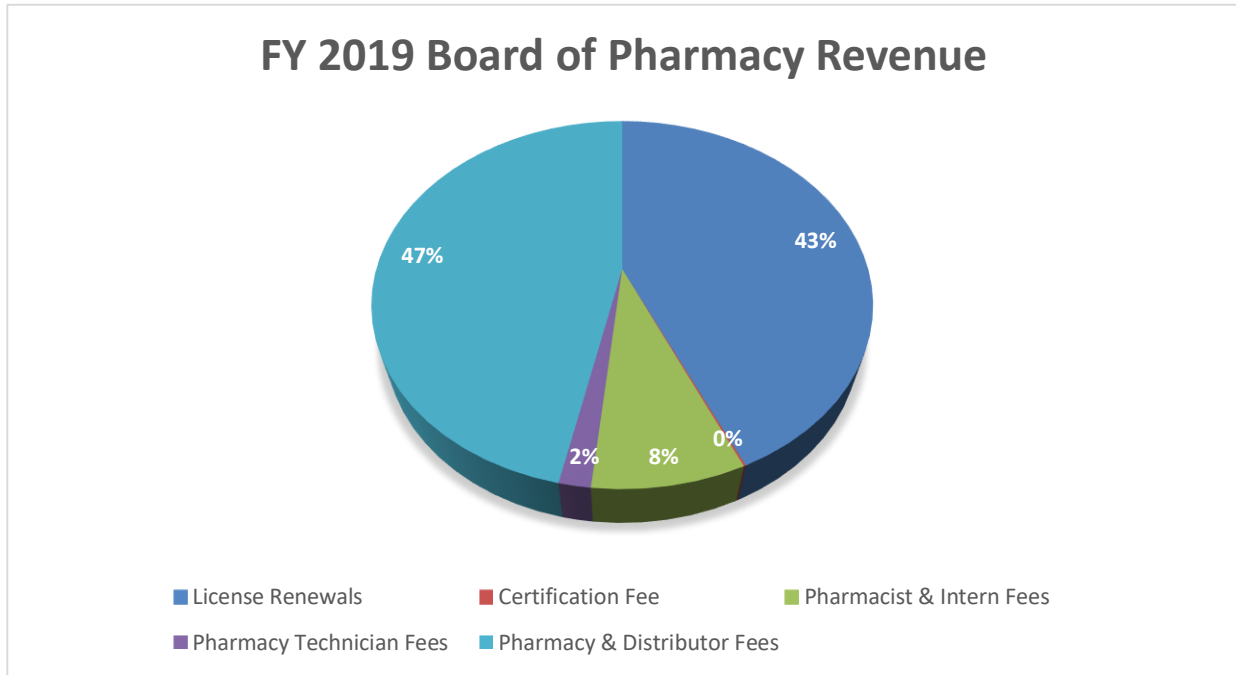
OPERATIONS UNIT REPORT

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



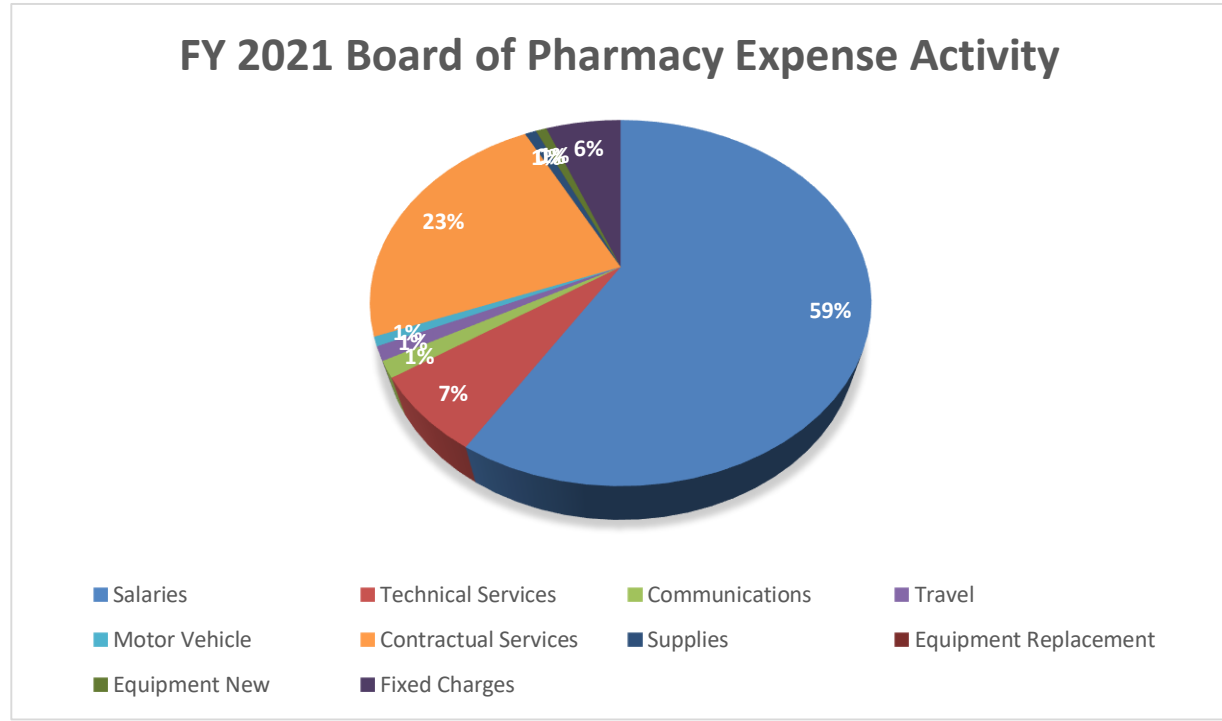
Revenue	Amount	Percent
License Renewals	\$1,919,732.02	43.23%
Certification Fee	\$5,420.00	0.12%
Pharmacist and Intern Fees	\$367,580.00	8.28%
Pharmacy Technician Fees	\$76,559.00	1.72%
Pharmacy & Distributor Fees	\$2,071,110.25	46.64%
Revenue FY 2021	\$4,710,449.78	100%

Board Revenue

The above chart reflects the revenue collected for license renewals for: Distributors, Pharmacies Pharmacists and Technicians. The majority of the revenue is derived from either Distributors or Pharmacies which renew biannually. In FY 2021, the Distributors renewed their licenses during the March through May renewal period.

Board Expenses

FY 2021 Board of Pharmacy Expense Activity



Expense Category	Amount	Percent
Salaries	\$2,109,021.15	58.78%
Technical Services	\$242,391.79	6.76%
Communications	\$51,757.52	1.44%
Travel	\$44,227.12	1.23%
Motor Vehicle	\$28,690.98	0.80%
Contractual Services	\$840,741.50	23.43%
Supplies	\$31,619.51	0.88%
Equipment Replacement	\$409.97	0.01%
Equipment New	\$29,917.31	0.83%
Fixed Charges	\$209,309.56	5.83%
Total	\$3,588,086.41	100%

Board Expenses

The above chart reflects the ten (10) expense categories for expenditures by the Board in FY 2018. 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 Licensing application.

- **Fixed Charges** – Rental costs for Board of Pharmacy space

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 and Database Specialist.

Current Year Accomplishments

The Board continued to develop a hybrid work model that allowed employees to work in the office and remotely. This included the ability to trouble shoot and assist remotely as necessary.

Security features were increased by incorporating Multi Factor Authorization methods for various logins.

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 and Drop-Off Programs, pharmacy 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, three (1) licensing specialists, (1) Administrative Officer II, (2) Administrative Officer III and one (1 vacant) office secretary.

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
- 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 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 FY2019, the Licensing Unit processed 5,094 licenses, permits, and registrations for pharmacists, pharmacy interns, pharmacy technicians, pharmacies, prescription drug drop-offs and repositories and

WSDs.

This number includes new applications, renewals and reinstatements, and represents an increase of approximately 40% over the previous fiscal year.

In FY2019, the Licensing Unit processed 213 new distributor permits, an increase of 36% from FY2018. Additionally, the Unit processed 174 distributor renewals during the renewal period which occurred in FY2017/FY2018.

In FY2019, the Licensing Unit processed 1,813 pharmacist licenses (initial and renewal, including vaccine certifications), a 45% increase compared to FY2018.

In FY2019, the Licensing Unit issued 39 Pharmacy Intern Graduate and 426 Pharmacy Intern Student registrations (initial and renewal), an increase from the previous fiscal year.

In FY2019, the Licensing Unit processed 387 WSD permits (213 new permits and 174 renewals) compared to 380 permits in FY2018 (193 new permits and 187 renewals).

In FY2019, the Licensing Unit issued 2,107 technician registrations (initial, renewal, and reinstatement).

Figure 1. Licenses/Permits/Registrations (New applications, Renewals, Reinstatements) Processed

FY 2019	
Pharmacists	1,301
Pharmacy Intern	465
Pharmacy Technician	2,151
Pharmacies	209
Distributors	387
Vaccinations	524
VAEIA	0

2019				
New	Renewals	Reinstatements	Totals	
871	418	12	1,301	
315	150	0	465	
1,434	707	10	2,151	
207	2	0	209	
213	174	0	387	
456	68	0	524	
0	0	0	0	

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 Pharmacist Investigations Supervisor, a Compliance Pharmacist, four (4) Compliance Investigators, a Compliance Coordinator/Investigator, two (2) Laboratory Scientist Surveyor, a Pharmacy Technician Compliance Inspection Supervisor, two (2) full-time and one (1) contractual Pharmacy Technician Compliance Inspectors.

Compliance Investigators 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

Compliance Inspectors perform the following functions:

- inspect pharmacies and wholesale distributors
- forward inspection infractions for investigation

The Unit hired a new Investigator Supervisor in 2019 and created a new Compliance Pharmacist position. The Unit also lost two (3) inspectors due to retirement and wanting to explore new pharmacy opportunities.

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 seven fiscal years. There were 406 complaints filed in FY19, compared to 389 complaints in FY18. 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 from July 1, 2018-June 30, 2019**

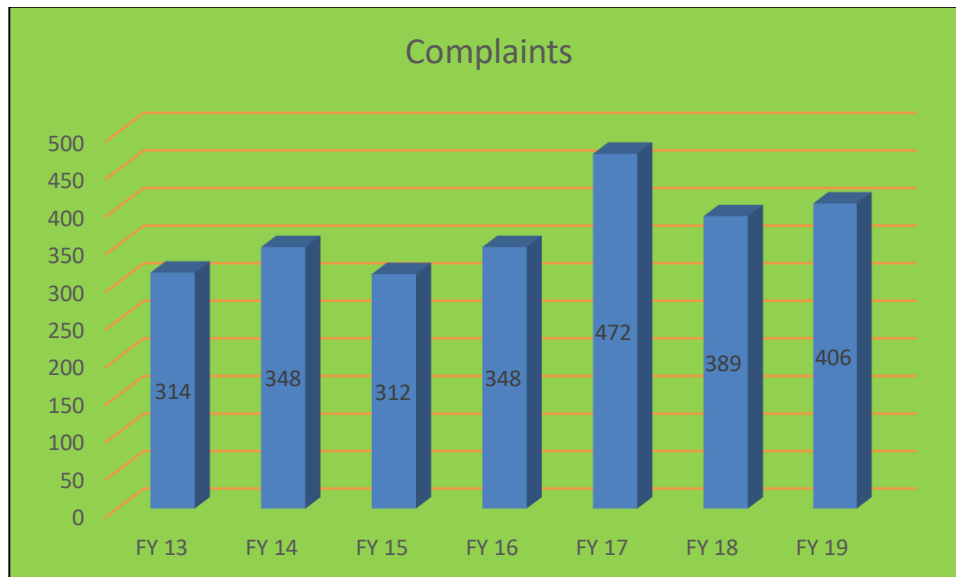
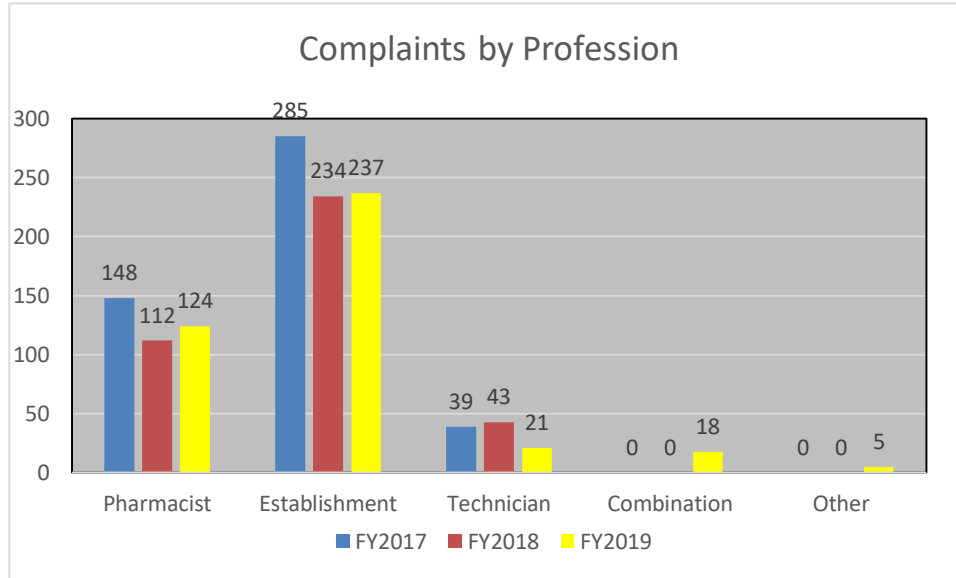


Figure 2, below, reveals that for FY 2019, the greatest number of complaints is still attributed to the establishments followed by complaints against pharmacists. There is an increase in the number of complaints this year, which is reflected in number of complaints for the pharmacists and establishments; however, the number of complaints against technicians decreased significantly compared to the last fiscal year.

Figure 2

Complaints against Licensees, Registrants, and Permit Holders



The types of complaints received are broadly categorized (see Figure 3). The majority of complaints are violations noted on annual inspection. The types of violations most commonly seen on inspection are related to vaccinating pharmacists not having valid CPR certification and unlicensed personnel working in the pharmacy. Other examples of inspection violations noted in FY18 are improper labeling, food in the refrigerator, CII discrepancies, failure to notify the Board of remodel or relocation, not having a licensed pharmacist on duty during posted hours. Other types of complaints commonly seen are dispensing errors, FDA 483/sterile compounding violations, refusal to fill, and communication/customer service complaints.

Figure 3

Types of Complaints from July 1, 2017-June 30, 2018

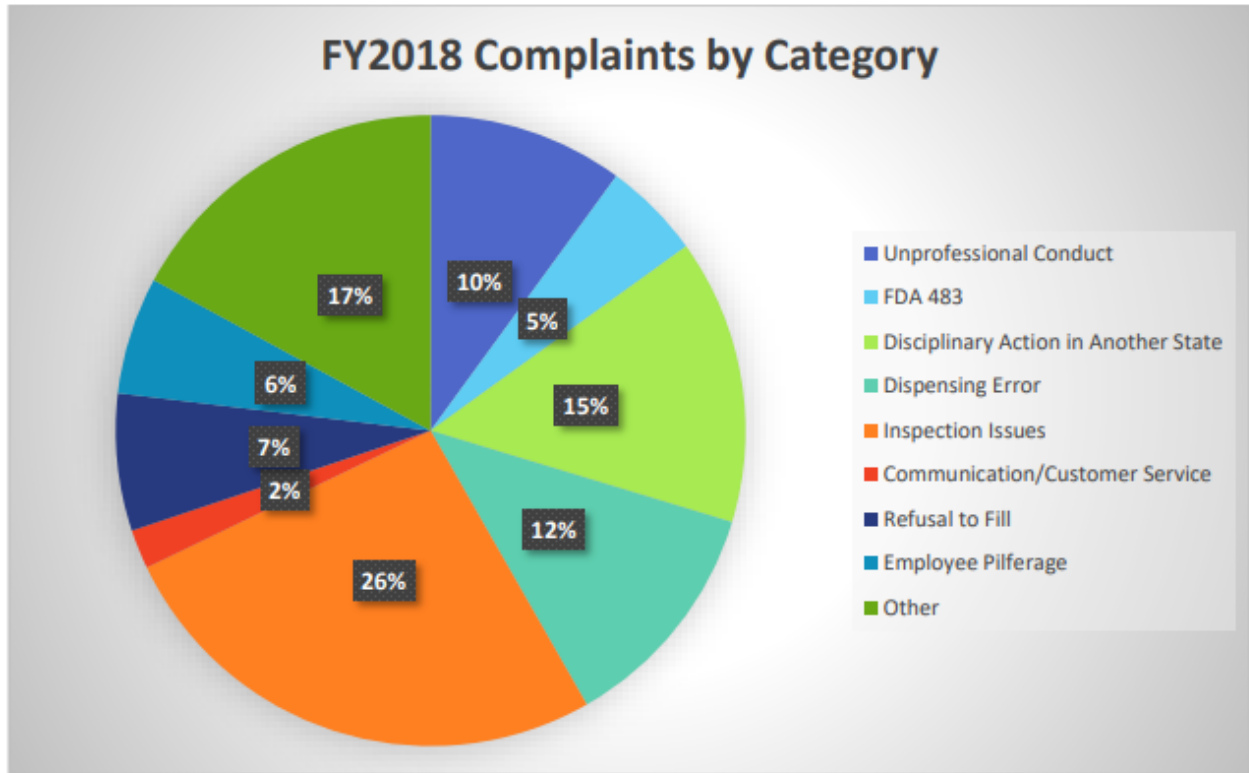


Figure 3

Types of Complaints from July 1, 2018-June 30, 2019

FY19 Types of Complaints

July 1, 2018 - June 30, 2019

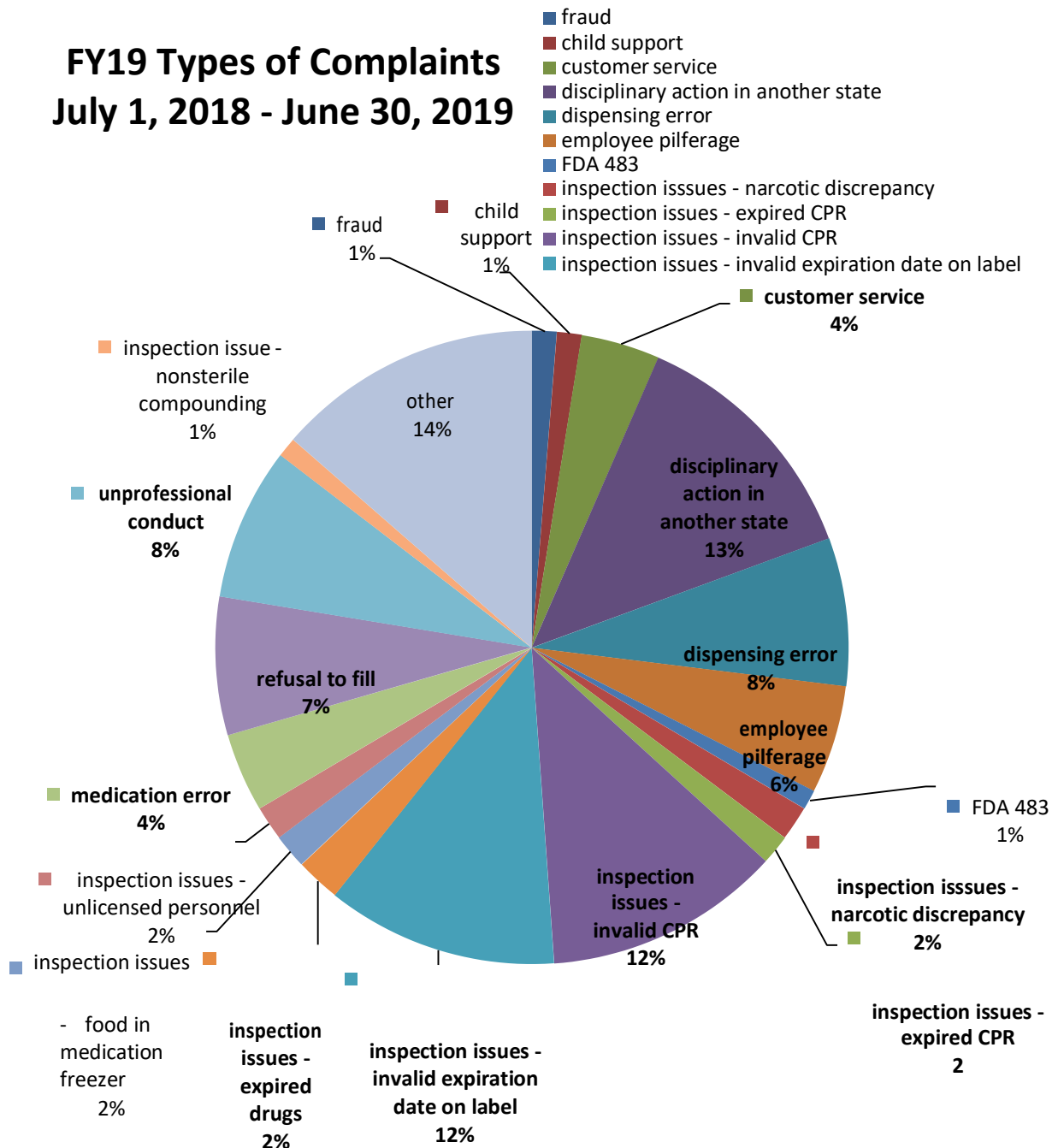


Figure 5 represents a categorical description of the various types of formal and informal actions taken against pharmacists, pharmacy technicians, and establishments in fiscal years 2018 and 2019.

Figure 5 Board Action taken from July 1, 2017-June 30, 2018

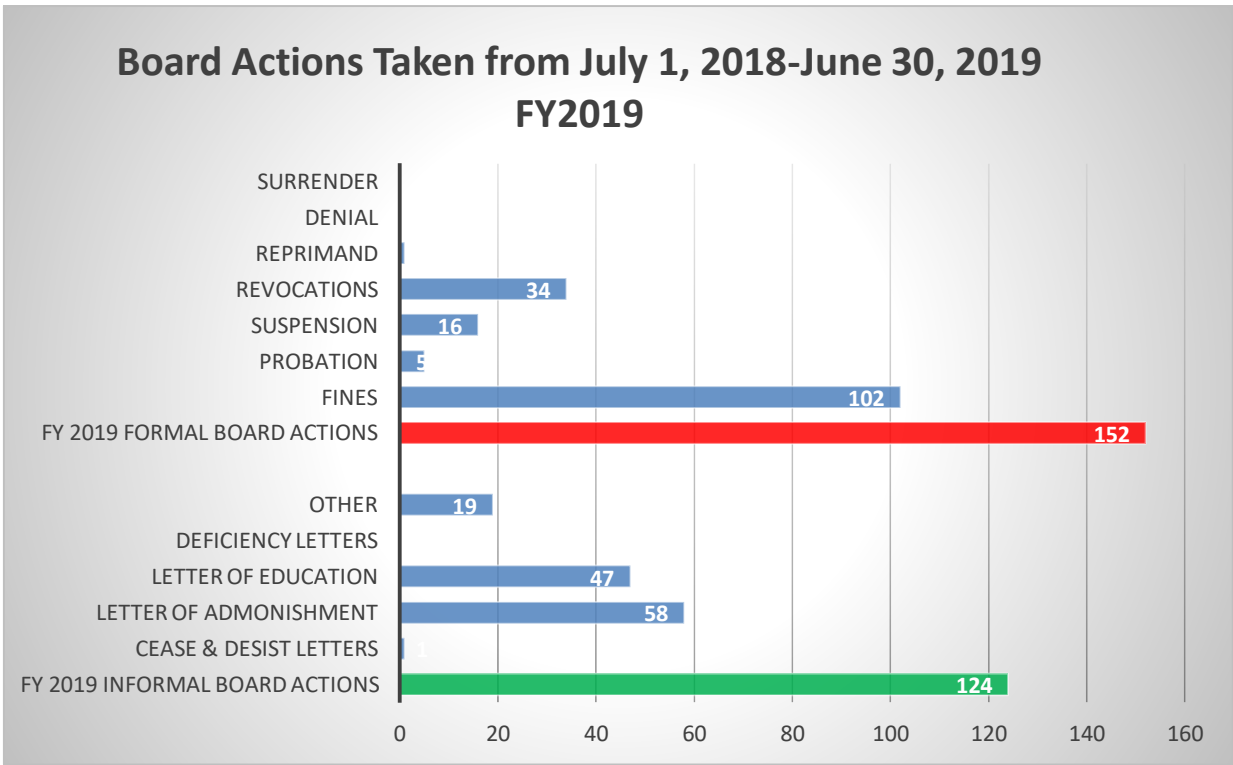
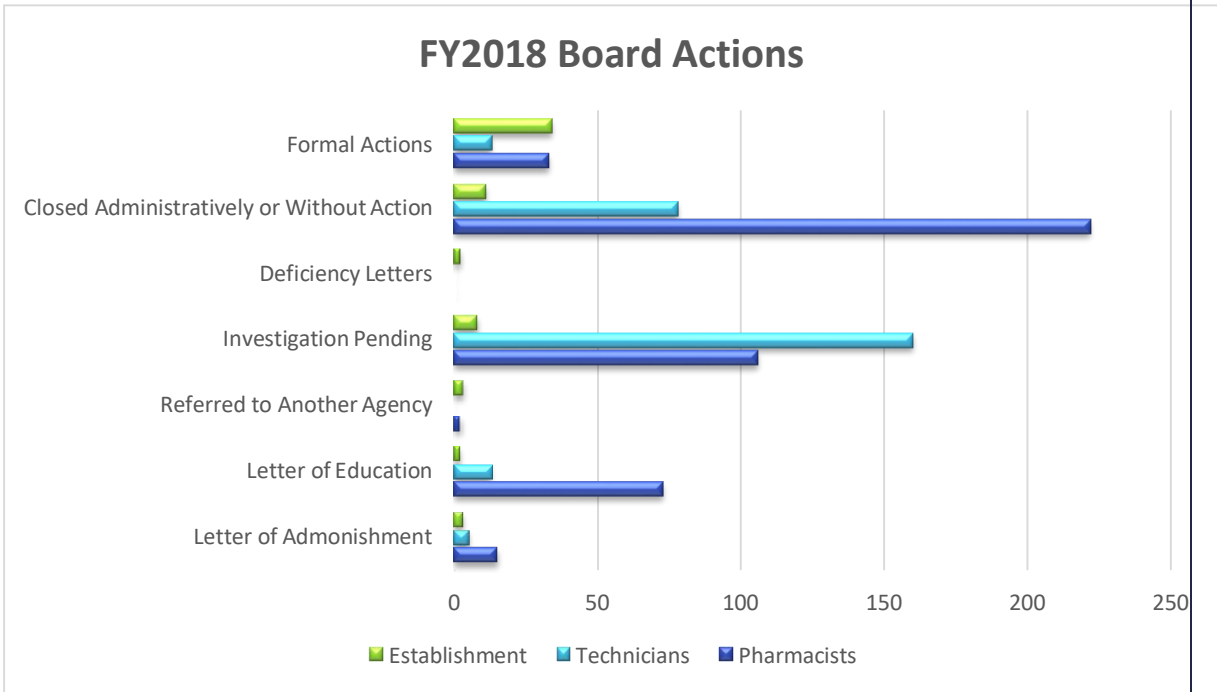
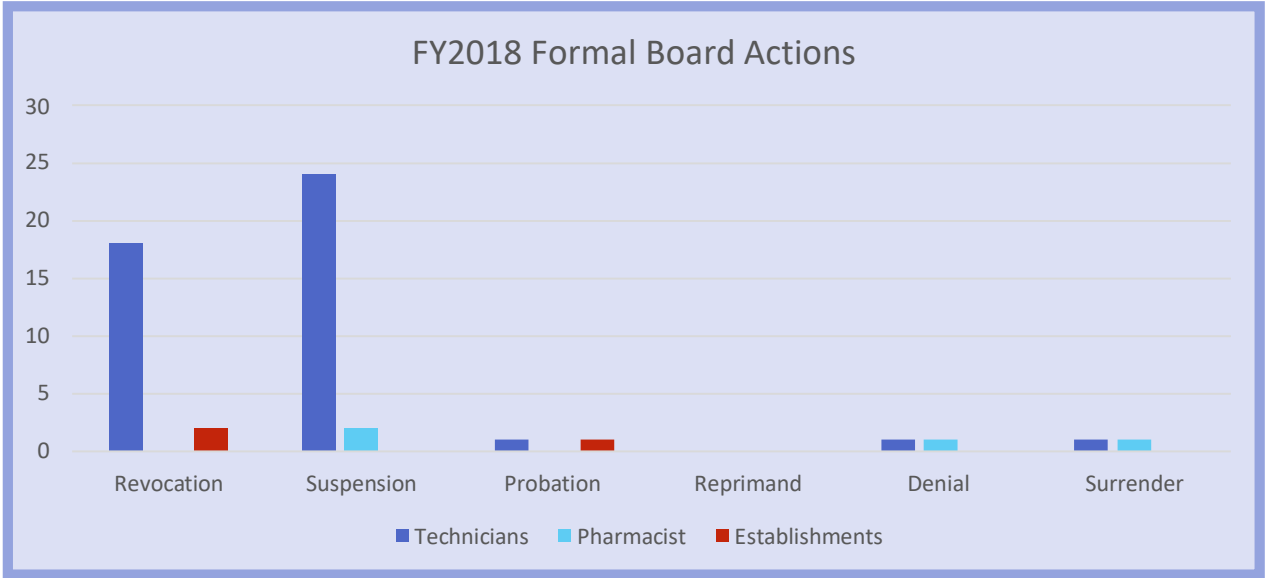


Figure 6, below, reflects the formal actions taken against pharmacists and pharmacy technicians in Fiscal Year 2018. Formal actions, including deficiency fines, issued are published in the Board of Pharmacy newsletter along with name of the licensee, registrant, and permit holder as well as posted on the Board of Pharmacy website. Starting in FY 2019, the Board no longer separated complaints by pharmacist, technicians and establishments.

Figure 6 Formal Board Actions Taken from July 1, 2017-June 30, 2018



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, closing inspections, miscellaneous inspections (relocation, change of ownership, investigative inspections), performed in Fiscal Year 2018 and 2019. The Board completed 100% of annual inspections for all the facilities permitted in Maryland.

Figure 7

	FY 2018	FY 2019
Annual Inspections	1511	1599
Opening Inspection	74	73
Closing Inspection	33	71
Change of Ownership	121	22
Miscellaneous Inspection	23	0

Total Inspections	1753	1805
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FY 2018

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.

FY 2019

The increased number of inspections from 2018 to 2019 was due Distributors renewals.

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 2018, the Board monitored 26 pharmacists and 9 technicians, which includes 6 pharmacists and 1 pharmacy technician who were under Orders that involved substance abuse.

The Maryland Board was temporarily using a few services to provide assessments, treatment referrals, and monitoring of pharmacists and pharmacy technicians that anonymously and voluntarily request substance abuse Permit Rescinded CE Fines Technicians Pharmacists Establishments FY 2018 Board Monitoring Permit Rescinded CE Fines assistance. On April 1, 2018, the Board contracted with the University of Maryland, Department of Psychiatry for rehabilitation and monitoring services. The University of Maryland program will provide treatment and monitoring for pharmacists, technicians, interns and pharmacy students in need of treatment for drug abuse, alcoholism, chemical dependency or other mental health issues.

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.

In FY 2019, the Board monitored 11 cases (9 known licensees+ 2 anonymous). The breakdown for the Board referrals were 6 pharmacists and 3 three technicians. The nine (9) were Board referred licensees. The two anonymous were self-referred technicians. The Board continued to utilize the services of Pharmacy Rehabilitation Services (PRS).

Next Year at a Glance

For Fiscal Year 2019, 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
- Upgrade the software system that is conducive to the business operations of inspections and investigations

For Fiscal Year 2020, the Compliance Unit plans to:

- Keep investigation cases under 180 days
- Hire new staff members to join our team i.e. Investigator, Administrator and Laboratory Scientist.
- Create additional Standard Operation Procedures for the investigation department
- Analyze the DEA 106 Data submitted to the Board
- Go Live with the Compliance Enforcement Module
- Update all the templates used
- Have no cases greater than 90 days with Office of Attorney General Office
- Continue to Rehabilitate Pharmacist and Technicians

STATE OF MARYLAND
BOARD OF PHARMACY



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