

STATE OF MARYLAND

Department of Health and Mental Hygiene

BOARD OF
PHARMACY



FISCAL YEAR 2022
ANNUAL REPORT

July 1, 2021

through

June 30, 2022

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 2022 BOARD COMMISSIONERS

President

Jennifer Hardesty

Long Term Care Representative

Secretary

Kristopher Rusinko

Home Infusion Representative

Treasurer

Neil B. Leikach

Independent Pharmacist Representative

Surinder Singal

Independent Pharmacist Representative

Kevin Morgan

Chain Drug Store Representative

Efstratios (Steve) Bouyoukas

Chain Drug Store Representative

Karla Evans

Acute Care Hospital Representative

Brenda Oliver

Consumer Representative

Peggy Geigher

Consumer Representative

Ellen H. Yankellow

At-Large Representative

Javier Vázquez

Acute Care Hospital Representative

Kristen Fink

At-Large Representative

BOARD COUNSEL

Linda Bethman, AAG

Brett Felter, Staff Attorney

TABLE OF CONTENTS

<u>SECTION</u>	<u>PAGE</u>
Executive Director's Report	1
Operations Report	4
Management and Information Systems Unit Report	8
Licensing Unit Report	9
Compliance Unit Report	12
Customer Service	19
Program Intake Assessment and Evaluation	20

Maryland Board of Pharmacy

FY 22 Year in Review



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DEENA SPEIGHTS-NAPATA
EXECUTIVE DIRECTOR

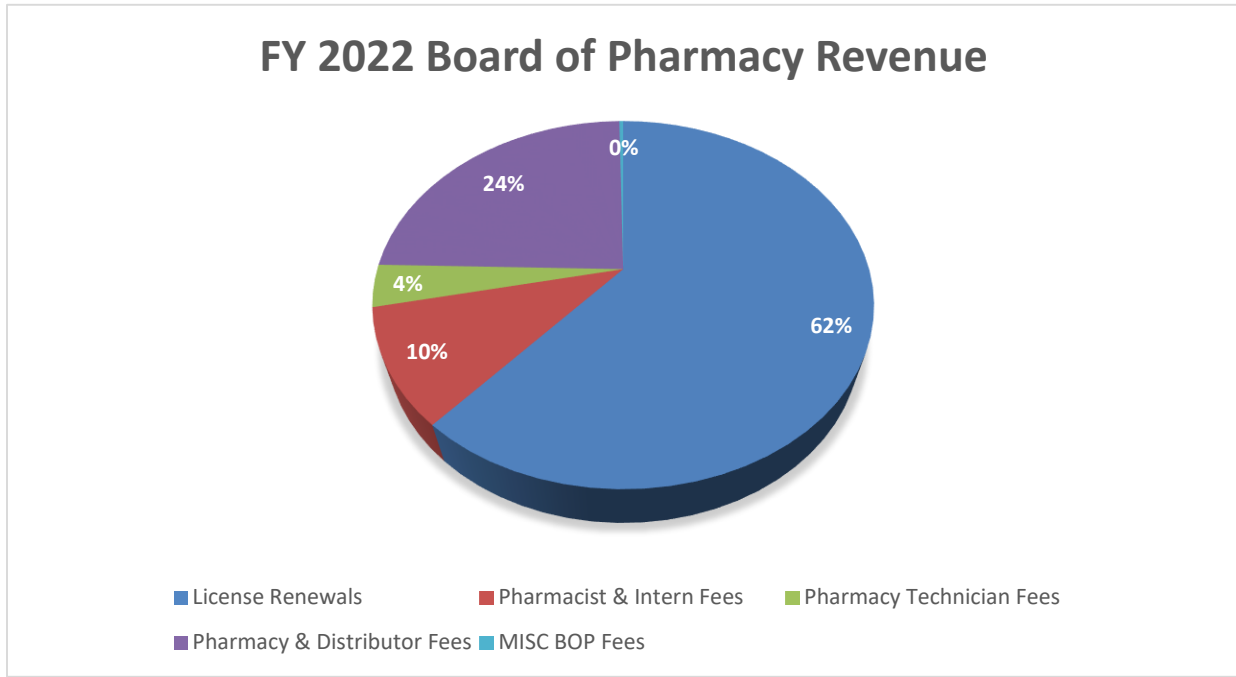
OPERATIONS UNIT REPORT

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	\$2,975,653.50	61.5%
Pharmacist and Intern Fees	\$367,292.50	10.2%
Pharmacy Technician Fees	\$134,257.45	3.7%
Pharmacy & Distributor Fees	\$879,571.75	24.3%
MISC BOP Fees	\$11,070.00	0.3%
Revenue FY 2021	\$3,615,874.70	100%

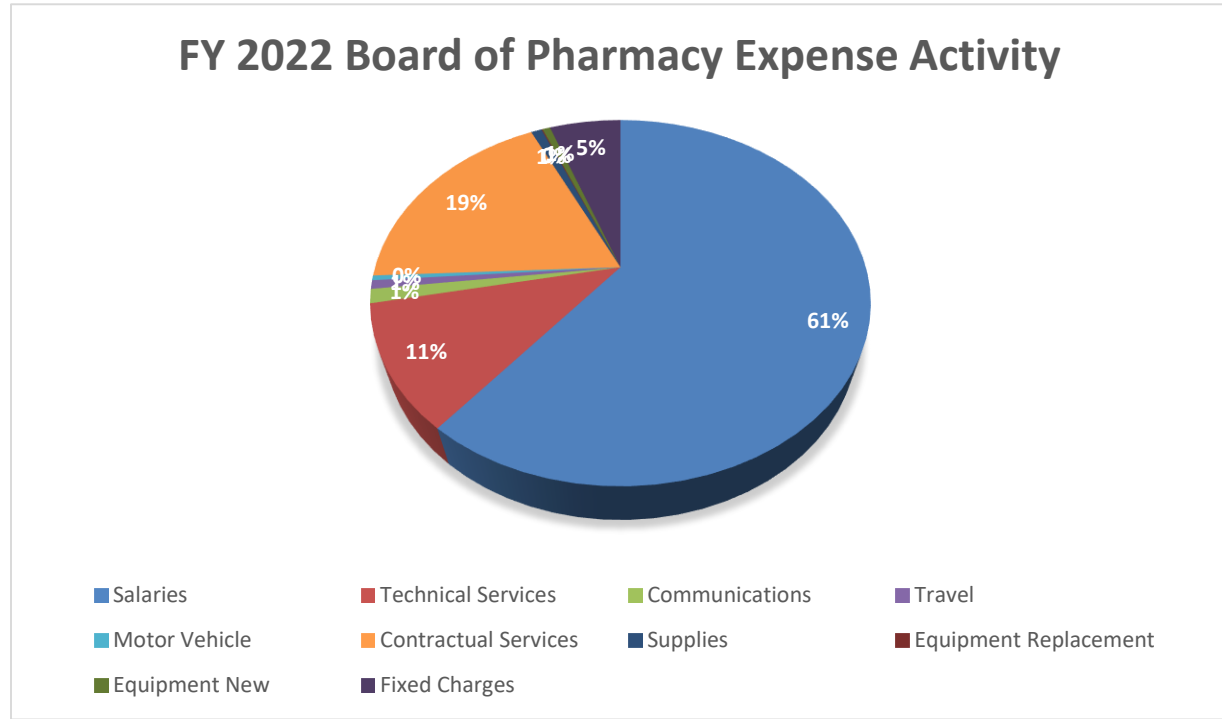
Board Revenue

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 2022, the Distributors renewed their licenses during the March through May renewal period.

The Board also transferred \$328,328.00 related to the Pharmacists license renewal fee to the Maryland Health Care Commission, which represented \$36 of the \$261 license renewal fee.

Board Expenses

FY 2022 Board of Pharmacy Expense Activity



Expense Category	Percent	Amount
Salaries	\$2,306,324.17	60.88%
Technical Services	\$415,376.40	10.96%
Communications	\$47,033.59	1.24%
Travel	\$28,679.48	0.76%
Motor Vehicle	\$15,867.94	0.42%
Contractual Services	\$707,872.87	18.69%
Supplies	\$31,499.80	0.83%
Equipment Replacement	\$3,105.98	0.08%
Equipment New	\$22,645.46	0.60%
Fixed Charges	\$209,812.60	5.54%
Total	\$3,788,218.31	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 FY2022, the Licensing Unit processed 15,348 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 FY2022, the Licensing Unit processed 197 new distributor permits, an increase of 36% from FY2021. Additionally, the Unit processed 1,166 distributor renewals during the renewal period which occurred in FY2020/FY2021.

In FY2022, the Licensing Unit processed 6,219 pharmacist licenses (initial and renewal, including vaccine certifications), a 45% increase compared to FY2021.

In FY2022, the Licensing Unit issued 41 Pharmacy Intern Graduate and 309 Pharmacy Intern Student registrations (initial and renewal), an increase from the previous fiscal year.

In FY2022, the Licensing Unit processed 1,363 WSD permits (197 new permits and 1,166 renewals) compared to 216 permits in FY2021 (187 new permits and 29 renewals). The large disparity in renewals is attributable to the WSD renewal period which occurred in FY2021.

In FY2022, as in previous years, the Licensing Unit processed more technician renewal applications than initial applications. The Licensing Unit issued 5,114 technician registrations (initial, renewal, and reinstatement), a decrease of almost 45% from the previous fiscal year.

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

FY 2022	
Pharmacists	6,219
Pharmacy Intern	309
Pharmacy Technician	5,114
Pharmacies	252
Distributors	1363
Vaccinations	2,091
VAEIA	0

2022			
New	Renewals	Reinstatements	Totals
615	5,591	13	6,219
246	63	0	309
1,893	3,192	29	5,114
249	0	3	252
197	1,166	0	1,363
265	1,826	0	2,091
0	0	0	0

COMPLIANCE UNIT REPORT

Fiscal Year 2022

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 Compliance Director, an Investigations Supervisor, a Compliance Officer, three (3) Compliance Investigators, a Compliance Coordinator/Investigator, two (2) Laboratory Scientist Surveyors, an Inspections Supervisor, and four (4) full-time Board Inspectors.

Compliance Investigators perform the following functions:

- receive, investigate, and respond to questions and complaints
- monitor licensees and permit holders who are under Board orders
- report disciplinary actions to national databases

Compliance Inspectors perform the following functions:

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

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 Compliance Committee for review and recommended action. The recommendation is presented 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.

The Board receive a total of 413 new complaints in FY 2022 involving 82 Pharmacists, 11 Pharmacy Technicians, and 299 Establishments.

Figure 1 Complaints Received

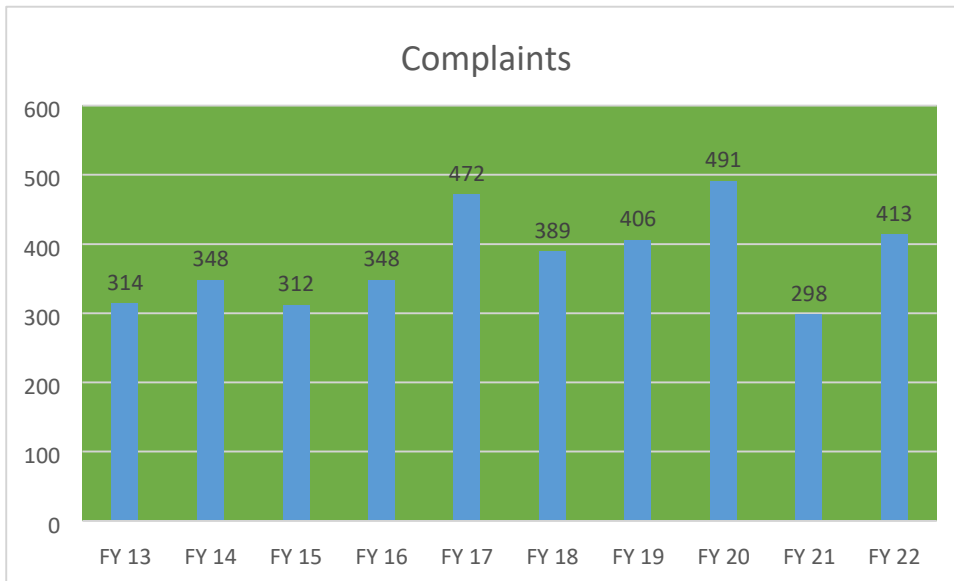


Figure 1, above, provides the number of complaints received in the past ten fiscal years. Complaints received by the Board may include but are not limited to a complaint made by the public, referrals from other state or federal agencies, or deficiencies found during inspections. There were 413 complaints filed in FY22 compared to 298 complaints in FY21; the approximately 72% increase is likely due to COVID-19 numbers decreasing and people getting back to their normal routines. Board inspectors were able to complete inspections in person and thus be more vigilant in the pharmacies.

Figure 2 Complaints by License Type

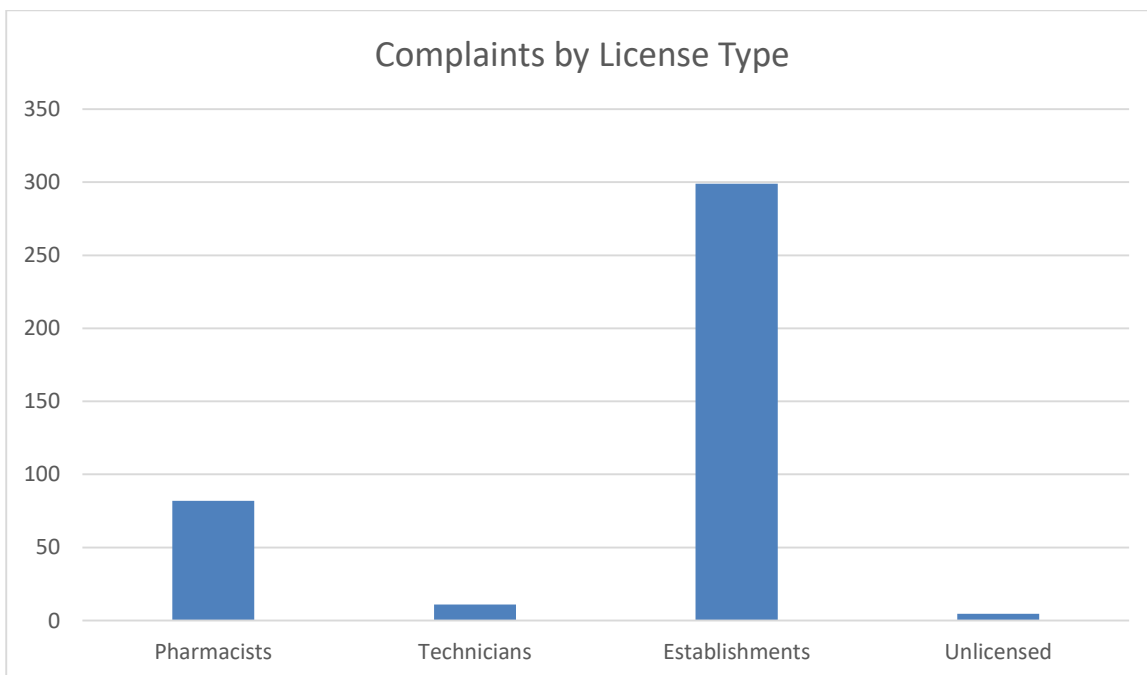


Figure 2, above, reveals that for FY22, the greatest number of complaints was attributed to Establishments followed by complaints against Pharmacists.

Figure 3 Complaint Types Received

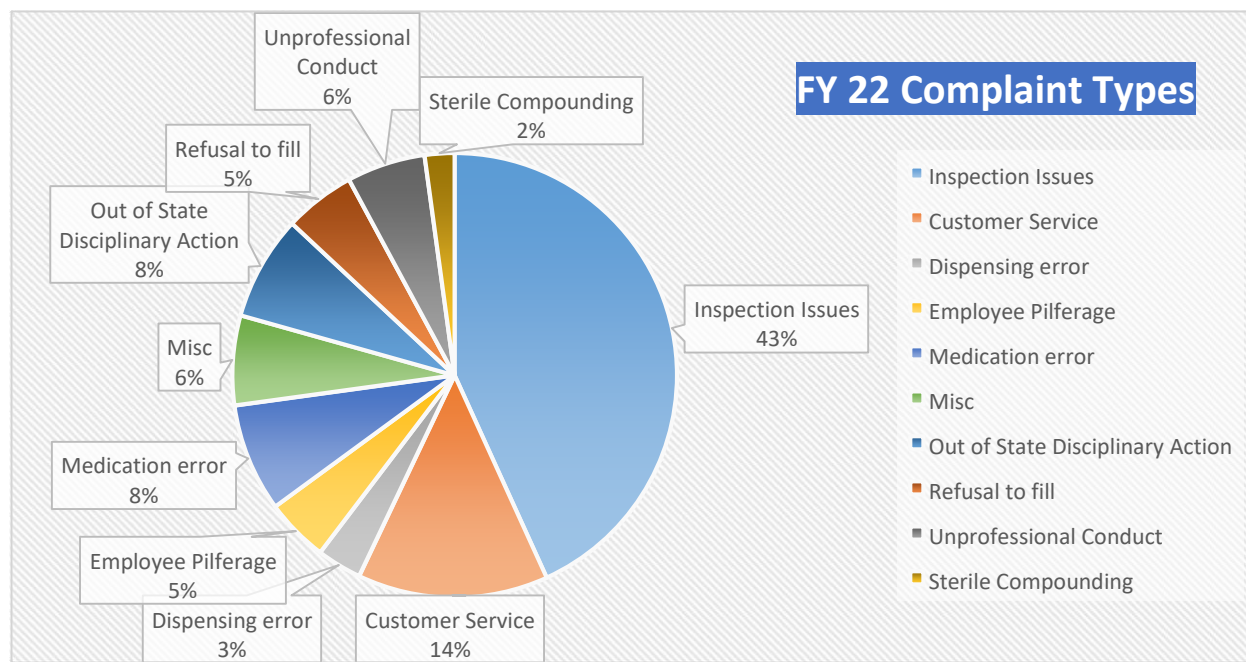


Figure 3, above, shows that for FY22, the most common complaint types were inspection issues (43%) and customer service (14%). The inspection issues included CDS concerns, expired CPR certification, narcotic discrepancies, documents not provided timely, unlicensed personnel, food found in the medication refrigerator, sterile compounding issues, and pharmacy technician training beyond six months. The increase in inspection issue complaints was the result of red flag issues observed by the inspectors. Other types of complaints from consumers commonly seen were medication errors (8%), unprofessional conduct (6%), refusal to fill (5%) and dispensing errors (3%). Additional complaint types included employee pilferage (5%) and out-of-state disciplinary actions (8%).

Disciplinary Cases

All cases are reviewed and investigated by Board staff. For the current fiscal year, the Board has taken actions, both formal and informal, in cases that include complaints carried over from previous fiscal years. Every year, there is some carryover of cases from the previous fiscal year. This carryover is due to investigations still pending, those pending action from the attorney general’s office, outstanding fines, suspensions pending revocation, probation and formal actions that involve licensee monitoring.

Examples of *formal actions* include a license or permit being placed on probation, the issuance of fines, and suspension or revocation. Examples of *informal actions* include

letters of education, letters of admonishment, and inspection deficiency letters. Formal actions are published in the Board of Pharmacy Newsletter along with name of the licensee, registrant, or permit holder, as well as posted on the Board of Pharmacy website.

Figure 4 Disciplinary Actions

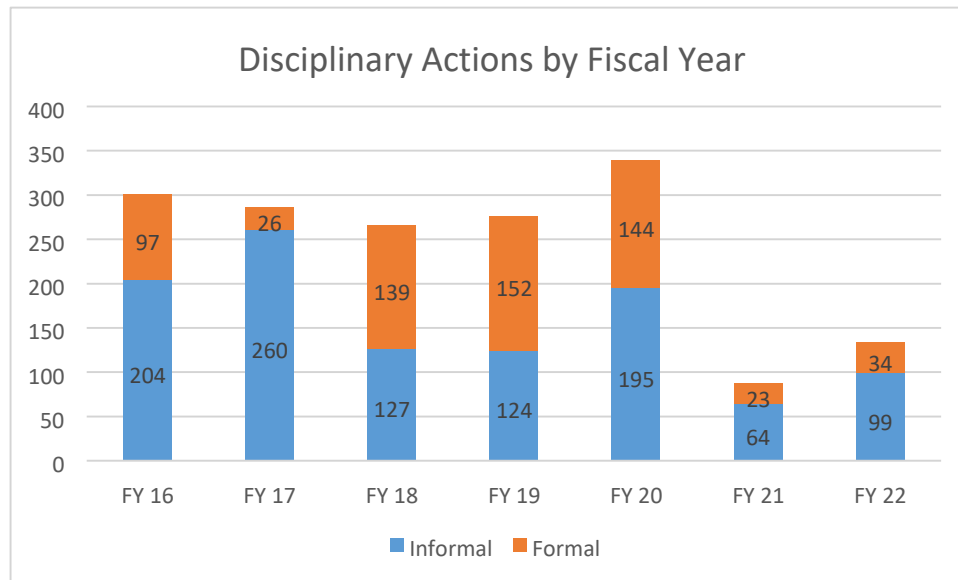


Figure 4, above, compares the number of formal and informal disciplinary actions taken each year from FY16 through FY22. The numbers had been much higher in fiscal years 2016 through 2020 but there was a sharp decrease in FY 21, likely due to the COVID-19 pandemic. The numbers, however, appear to be trending back up; the data shows 99 formal and 34 informal disciplinary actions taken in FY22.

Figure 5 Board Action Taken

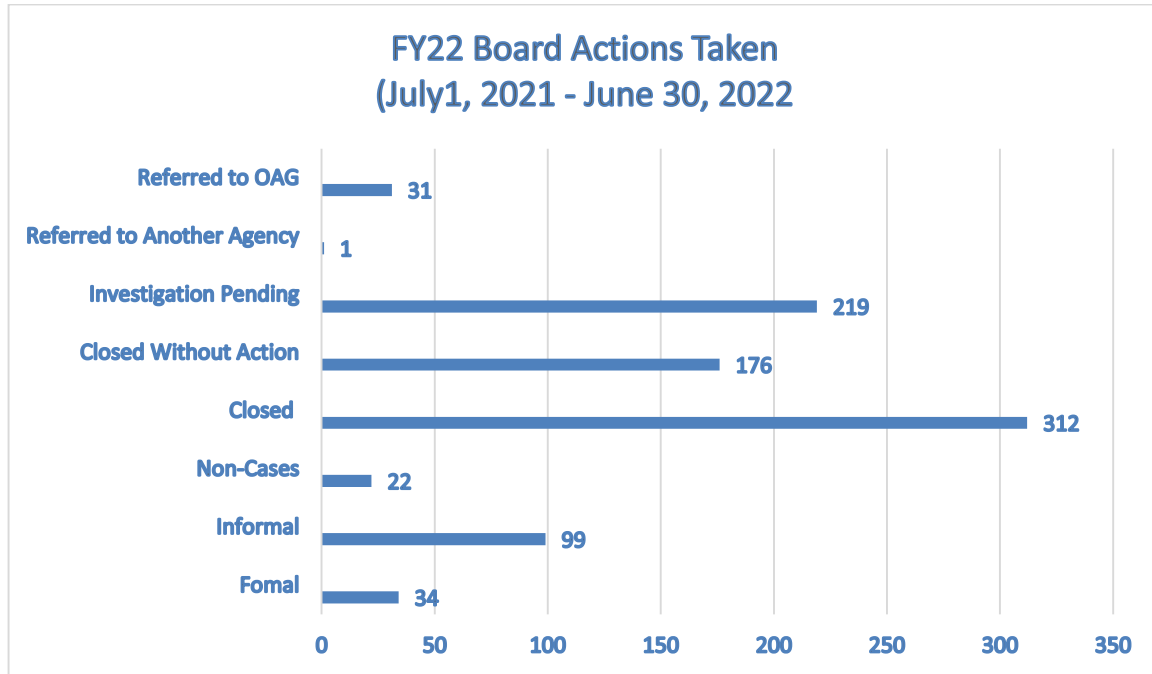


Figure 5, above, reflects the Board actions taken against pharmacists, pharmacy technicians and establishments in Fiscal Year 2022. Most cases were either closed, still pending or voted as informal actions.

Figure 6 Formal and Informal Board Actions Taken

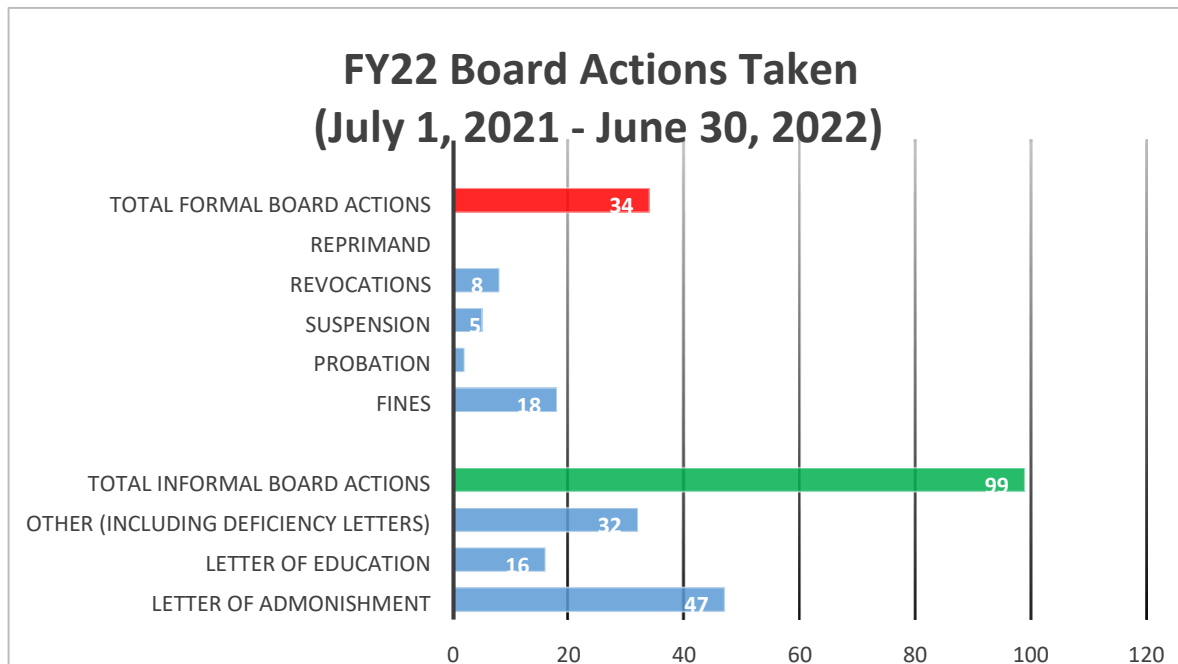


Figure 6, above, shows that in FY22, the majority of the Board actions taken were informal rather than formal; however, compared to FY21, the Board saw an increase in the number of formal disciplinary actions. The most prevalent formal actions were monetary fines; the most prevalent informal actions were

Letters of Admonishment. In addition, numerous Inspection Deficiency Letters were issued based on violations observed by Board inspectors.

Inspections

The Board of Pharmacy conducts opening, closing, remodel, relocation, change of ownership, and annual inspections of in-state pharmacies. The Board has a goal of inspecting all in-state pharmacies annually. The Board inspectors perform all inspections relating to community and hospital pharmacies, long-term care facilities and wholesale distributors. The laboratory scientist surveyors perform all inspections involving sterile compounding, including nuclear pharmacies, and infusion and oncology centers.

Figure 7 Types of Inspections
Completed by Board Inspectors and Laboratory Scientist Surveyors

<i>Types of Inspections</i>		
	<i><u>FY 2021</u></i>	<i><u>FY 2022</u></i>
<i>Annual Inspections</i>	<i>1800</i>	<i>1104</i>
<i>Opening Inspections</i>	<i>112</i>	<i>72</i>
<i>Closing Inspections</i>	<i>38</i>	<i>14</i>
<i>Change of Ownership/Renovations</i>	<i>19</i>	<i>4</i>
<i>Board Special Investigations</i>	<i>7</i>	<i>0</i>
<i>Misc. (i.e. COVID Storage, Follow-up Narcotic Audits)</i>	<i>Not Reported</i>	<i>379</i>
<i>Total Inspections</i>	<i>2007</i>	<i>1573</i>

Figure 7, above, reflects the total number of annual, opening, closing, and miscellaneous inspections (relocation, change of ownership, investigative), performed in Fiscal Year 2022. The Board completed 70% of its annual inspections for all facilities permitted in Maryland for a total of 1573 inspections.

Figure 8 Sterile Observations of Concern by Laboratory Scientists

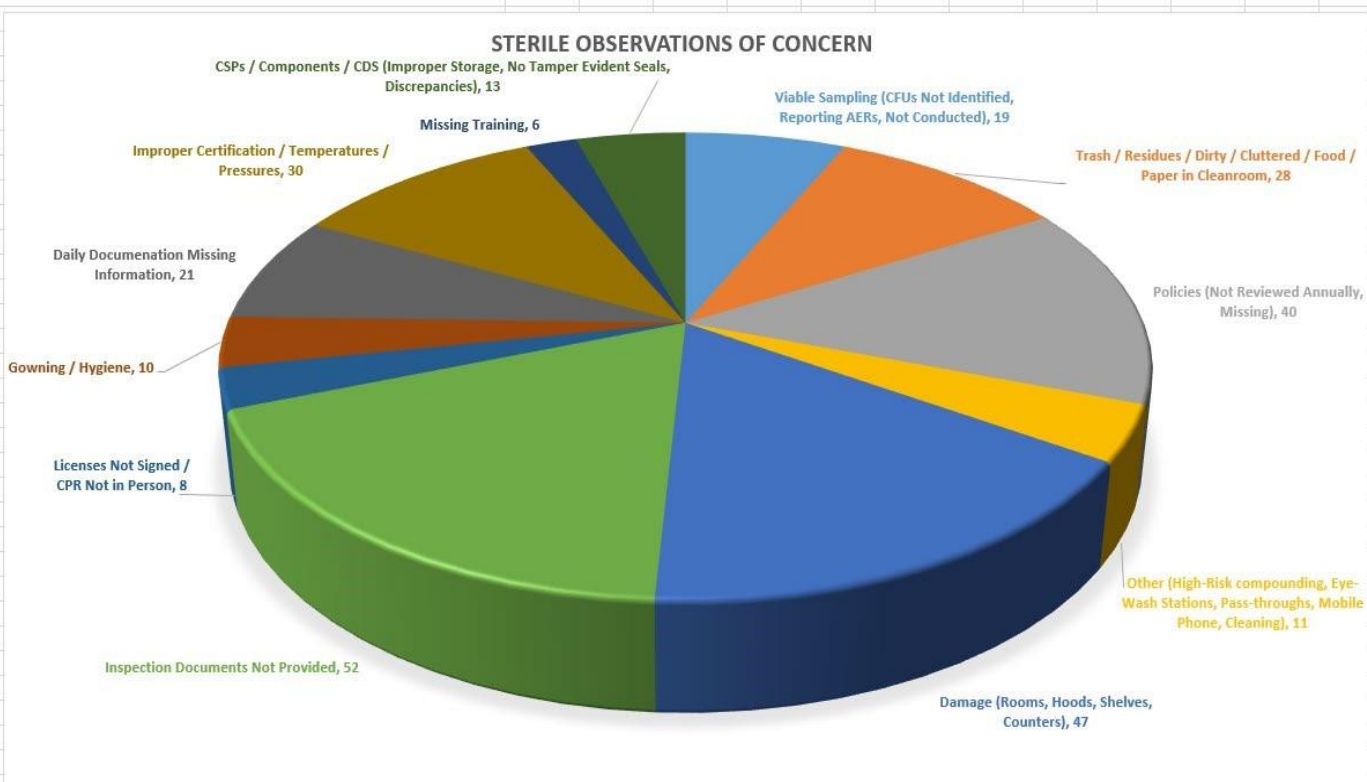


Figure 8, above, shows the observations made during the 150 sterile inspections completed over the course of the year. The most prevalent observations noted were physical damage and policy issues. In FY22, there were fewer renovations than the year before.

Sterile Inspection Statistical Data:

- 124 annual sterile inspections
- 15 follow up Narcotic Audits
- 10 sterile opening/renovation inspections
- 1 sterile pharmacy closings
- 268 Adverse Event Reports received

Rehabilitation Monitoring

The Board’s designated rehabilitation committee includes Board staff and Pharmacy Rehabilitation Services (PRS), which is staffed by counselors from the University of Maryland Baltimore. This committee evaluates and assists any pharmacist, registered pharmacy intern, or registered technician and their families in need of treatment and rehabilitation for alcoholism, drug abuse, chemical dependency, or other physical, emotional, or mental condition. The Board encourages people who need assistance to contact this program.

Over the past year, the program has monitored approximately 15 participants including 5 pharmacists, 3 pharmacy technicians and 7 anonymous participants. The number fluctuates as participants no longer need monitoring and new participants enter the program. Each client monitored is required to sign a treatment contract indicating that he or she understands that the Board of Pharmacy will be notified if the terms of their contract is violated.

Conclusion

Fiscal year 2022 has been a fulfilling year for the Compliance Unit. Our work inspecting Maryland facilities and investigating complaints should assure the public that safety is the Board's top priority. The team has worked diligently to ensure that our licensees follow all rules and regulations, as well as meet the goals set forth by the State.

Next Year at a Glance

For Fiscal Year 2023, the Compliance Unit plans to:

- Expand the compliance team
- Attend additional training to enhance our investigative knowledge
- Collaborate with other state agencies
- Continue to resolve cases within the Department's goal

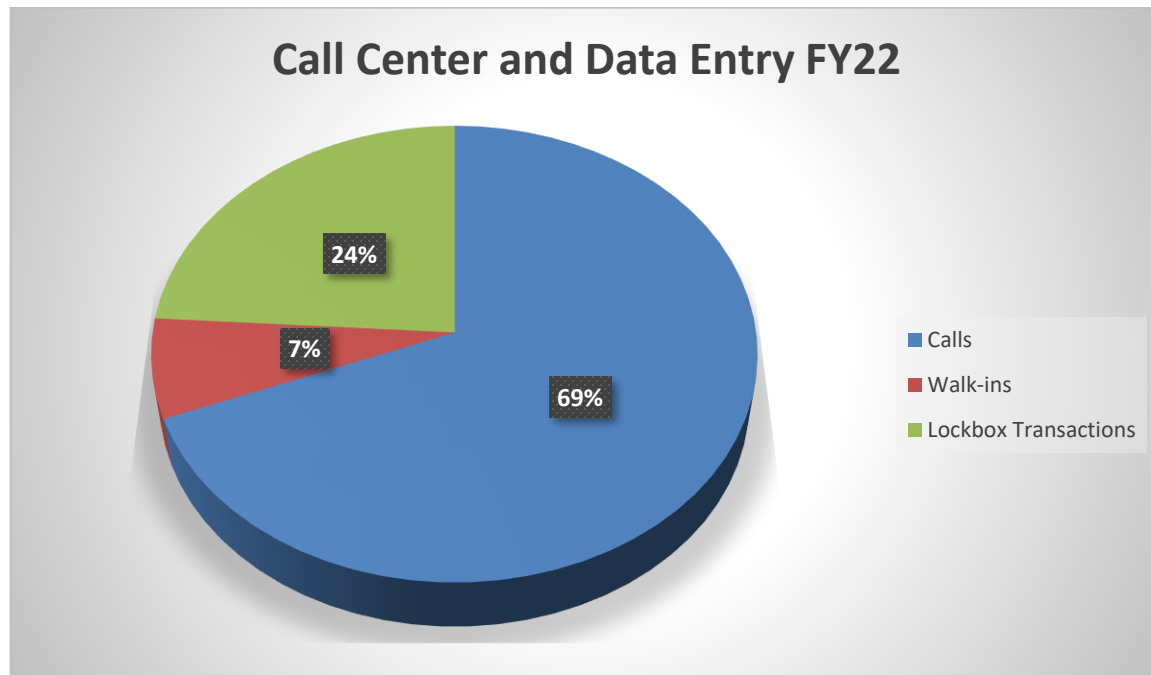
CUSTOMER SERVICE

Overview

The Customer Service Unit of the Maryland Board of Pharmacy responds to concerns from the licensees and the public. The call center answers call and send email inquiries to the appropriate staff for assistance. The call center also assists with customers that come into the walk-in center. The unit assist with accepting applications and walking customers through self-serve options like online renewals. It has become evident, that the call center is an asset. In FY22, the call center answered 12,748 calls and assisted 1,377 walk-in customers. It continues to serves as a one-stop shop for the public when they cannot get questions answered by viewing the website or online FAQ.

Next Year at a Glance

This unit is only going to continue to get more efficient by participating in the following: · Obtaining more training. Using newer technology to streamline calls to make a smoother customer experience.



PROGRAM INTAKE ASSESSMENT AND EVALUATION

Overview

The data entry section of the Program Intake Assessment and Evaluation unit of the Maryland Board of Pharmacy was created to provide a smoother transition for licenses needing to be processed. In FY22 the call center and data processing team has processed 4,484 transactions sent through our lockbox. The Board has devoted a significant amount of time and energy this year to systems improvement, 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, and improved relationships with stakeholders, and more effective customer service.

Systems Improvements

- ✓ Call Center and Data Entry staff have collaborated with licensing staff to ensure information is consistent when assisting customers.
- ✓ Call Center has made updates in processes to assist with quality control and minimal errors in data entry.

Public Relations/Communications

- ✓ **Improved quarterly newsletter** that includes NABP articles, new Frequently Asked Questions column, and increased pharmacy articles of interest
- ✓ 3rd Continuing Education event offered in person and by web access
- ✓ **Increased use of surveys**
- ✓ **Increased involvement in pharmacy conferences and events**

STATE OF MARYLAND
BOARD OF PHARMACY



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