

# STATE OF MARYLAND

Department of Health and Mental Hygiene

## BOARD OF PHARMACY



## FISCAL YEAR 2024 ANNUAL REPORT

July 1, 2023

through

June 30, 2024

### 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 2024 BOARD COMMISSIONERS

President

**Kristopher Rusinko**

*Home Infusion Representative*

Secretary

**Javier Vazquez**

*Acute Care Hospital Representative*

Treasurer

**Peggy Geigher**

*Consumer Representative*

**Neil Leikach**

*Independent Pharmacist Representative*

**Kevin Morgan**

*Chain Drug Store Representative*

**Jennifer Hardesty**

*Long Term Care Representative*

**Karla Evans**

*Acute Care Hospital Representative*

**Brenda Oliver**

*Consumer Representative*

**Peggy Geigher**

*Consumer Representative*

**Akash Patel**

*Chain Drug Store 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

# **Maryland Board of Pharmacy**

## **FY 24 Year in Review**



;

**DEENA SPEIGHTS-NAPATA**  
**EXECUTIVE DIRECTOR**

## **OPERATIONS UNIT REPORT**

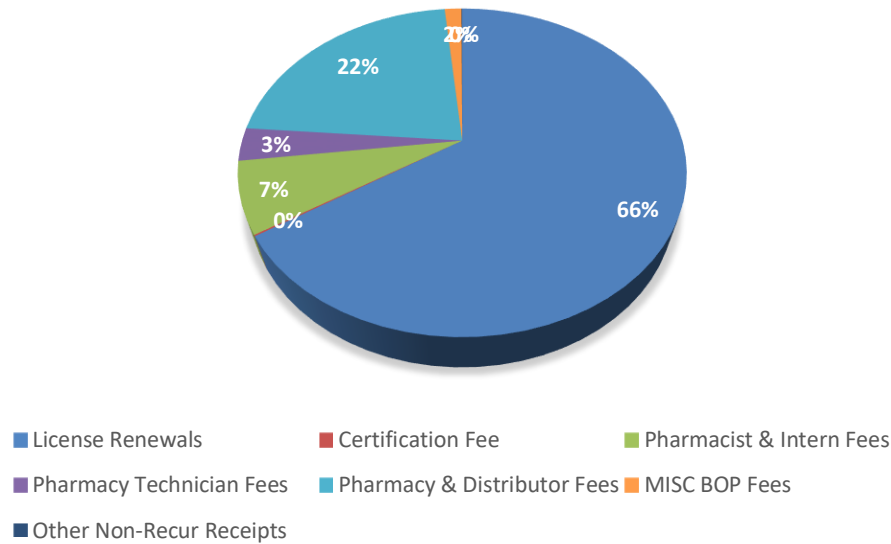
### **Overview**

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**

### **FY 2024 Board of Pharmacy Revenue**



Revenue	Amount	Percent
License Renewals	\$2,441,426.18	66.01%
Certification Fee	\$4,700.00	0.13%
Pharmacist and Intern Fees	\$257,858.88	6.97%
Pharmacy Technician Fees	\$120,546.67	3.26%
Pharmacy & Distributor Fees	\$822,780.50	22.25%
MISC BOP Fees	\$53,815.00	1.46%
Misc – Other Non-Recur Receipts	-\$2,569.00	-0.07%
Revenue FY 2024	\$3,698,558.23	100%

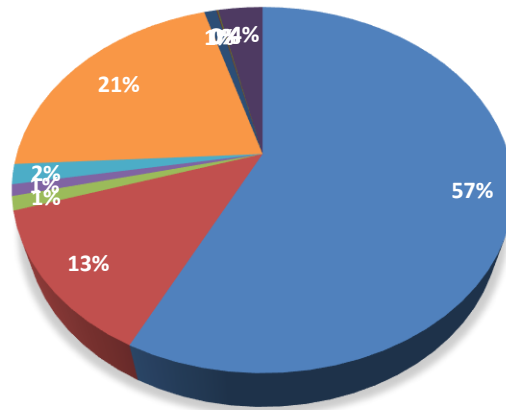
## **Board Revenue**

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 \$312,884.00 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 2024 Board of Pharmacy Expense Activity



Salaries	Technical Services	Communications	Travel
Motor Vehicle	Contractual Services	Supplies	Equipment Replacement
Equipment New	Fixed Charges		

Expense Category	Amount	Percent
Salaries	\$2,896,892.45	57.35%
Technical Services	\$643,872.30	12.75%
Communications	\$62,1134.37	1.23%
Travel	\$50,675.01	1.00%
Motor Vehicle	\$89,549.12	1.77%
Contractual Services	\$1,077,134.48	21.33%
Supplies	\$48,740.26	0.96%
Equipment Replacement	\$3,006.83	0.06%
Equipment New	\$4,202.47	0.08%
Fixed Charges	\$174,621.21	3.46%
Total	\$5,050,828.50	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 employee's 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 FY2024, the Licensing Unit processed 17,687 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 FY2024, the Licensing Unit processed 170 new distributor permits. Additionally, the Unit processed 164 distributor renewals during the renewal period which occurred in FY2022/FY2023.

In FY2024, the Licensing Unit processed 9,194 pharmacist licenses (initial and renewal, including vaccine certifications).

In FY2024, the Licensing Unit issued 28 Pharmacy Intern Graduate and 205 Pharmacy Intern Student registrations (initial and renewal).

In FY2024, the Licensing Unit processed 334 WSD permits (170 new permits and 154 renewals) compared to 1,396 permits in FY2023 (203 new permits and 1,193 renewals).

In FY2024, as in previous years, the Licensing Unit processed more technician renewal applications than initial applications. The Licensing Unit issued 5,380 technician registrations (initial, renewal, and reinstatement).

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

FY 2024	
Pharmacists	6,535
Pharmacy Intern	233
Pharmacy Technician	5,380
Pharmacies	2,198
Distributors	334
Vaccinations	2,680
VAEIA	0

2024			
New	Renewals	Reinstatements	Totals
604	5,910	21	6,535
179	54	0	233
1,550	3,790	40	5,380
153	2,043	2	2,198
170	164	0	334
255	2,425	0	2,680
0	0	0	0

# COMPLIANCE UNIT REPORT

## Overview

Maryland's Compliance Unit safeguards public health by ensuring that pharmacies adhere to state laws and regulations. Our team includes a Pharmacist Compliance Director, a Pharmacist Investigations Supervisor, four (4) Compliance Investigators, two (2) Laboratory Scientist Surveyors, Compliance Auditor, a Pharmacy Technician Compliance Inspection Director, Inspection Unit Administrative Specialist and six (6) full-time Pharmacy Technician Compliance Inspectors who:

- **Respond to inquiries** from the public.
- **Investigate complaints** and out-of-state disciplinary actions.
- **Monitor** licensees under Board orders.
- **Report** disciplinary actions to national databases.
- **Conduct annual inspections** of sterile and non-sterile facilities.
- **Inspect pharmacies** and wholesale distributors.
- **Follow up on** inspection violations.

## Complaints

The Compliance Unit welcomes complaints from the public about potential pharmacy violations. You can easily obtain a complaint form online at [www.health.maryland.gov/pharmacy](http://www.health.maryland.gov/pharmacy) (link to Maryland Board of Pharmacy website) or by mail upon request. Completed forms can be submitted via fax, mail, email, or in person. We thoroughly investigate all complaints and present the findings to the Board's Disciplinary Committee. The Committee reviews the information and recommends appropriate action. This may involve follow-up by Compliance Unit staff or further review and potential disciplinary action by the full Board. If your complaint falls outside the Board's jurisdiction, we will refer you to the relevant authority.

Figure 1, below, shows a general upward trend in the number of complaints received from FY13 to FY20, with a peak in FY20. However, there's a slight decline from FY20 to FY22 attributed to external factors such as changes in regulations, economic conditions, or the COVID-19 pandemic, followed by a slight increase in FY23 due to improvements made to the complaint process. While there are some years with lower complaint numbers, the overall direction is towards an increase.

### Specific Observations:

- **Highest Year:** FY20 saw the highest number of complaints with a total of 491.
- **Lowest Year:** FY13 had the lowest number of complaints at 314.
- **Periods of Growth:** Significant growth occurred between FY15 and FY17, and again between FY18 and FY20.
- **Period of Decline:** A minor decline was observed between FY20 and FY22.

Figure 1: Complaints Trends Received by Year

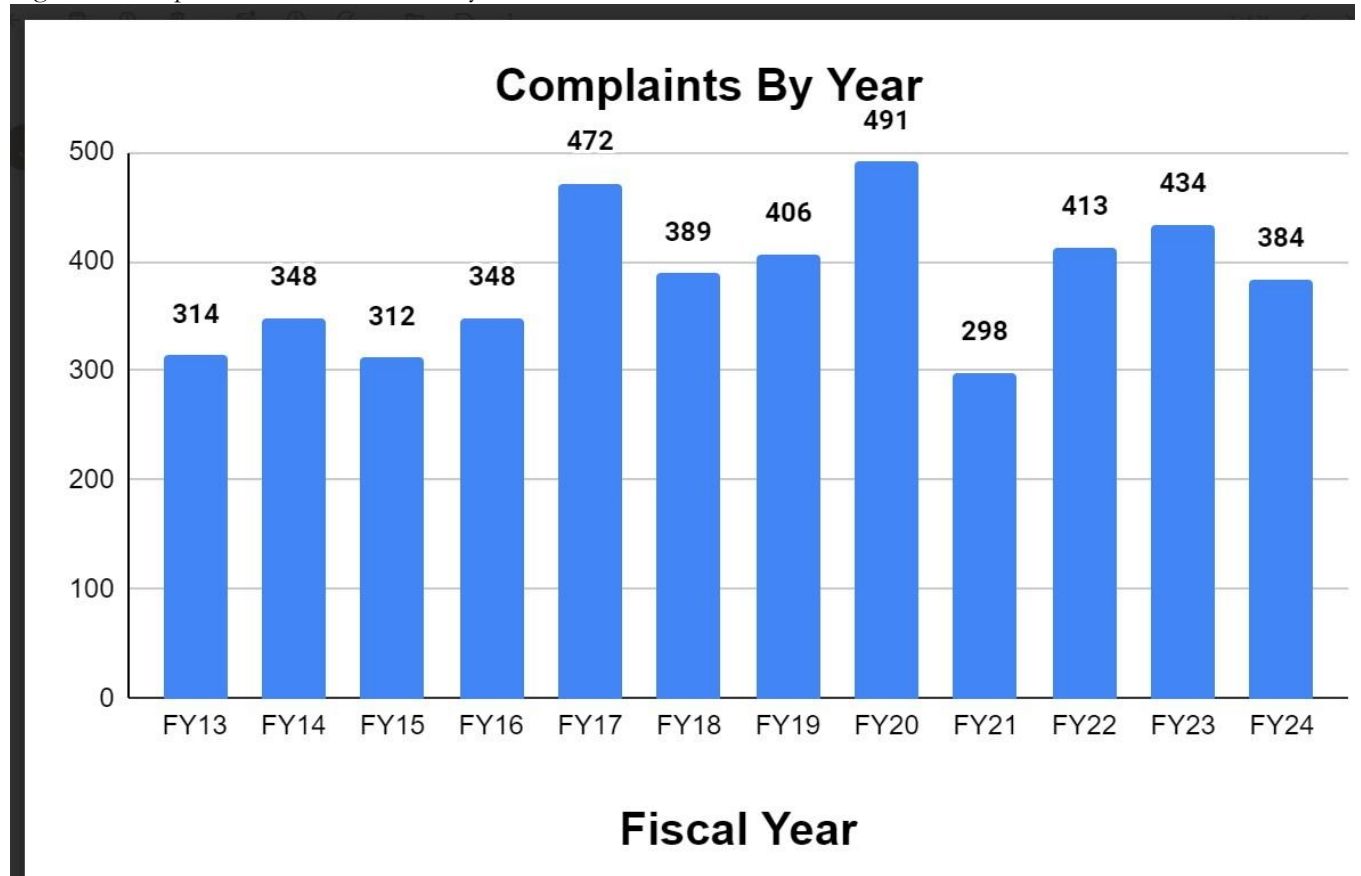


Figure 2, below, depicts the categories of complaints received in FY 24 of a breakdown of the various types of complaints. Inspection Issues make up the largest portion of complaints, accounting for 45.3%. This suggests that issues related to pharmacy inspections, such as non-compliance with regulations or safety standards, are the primary concern.

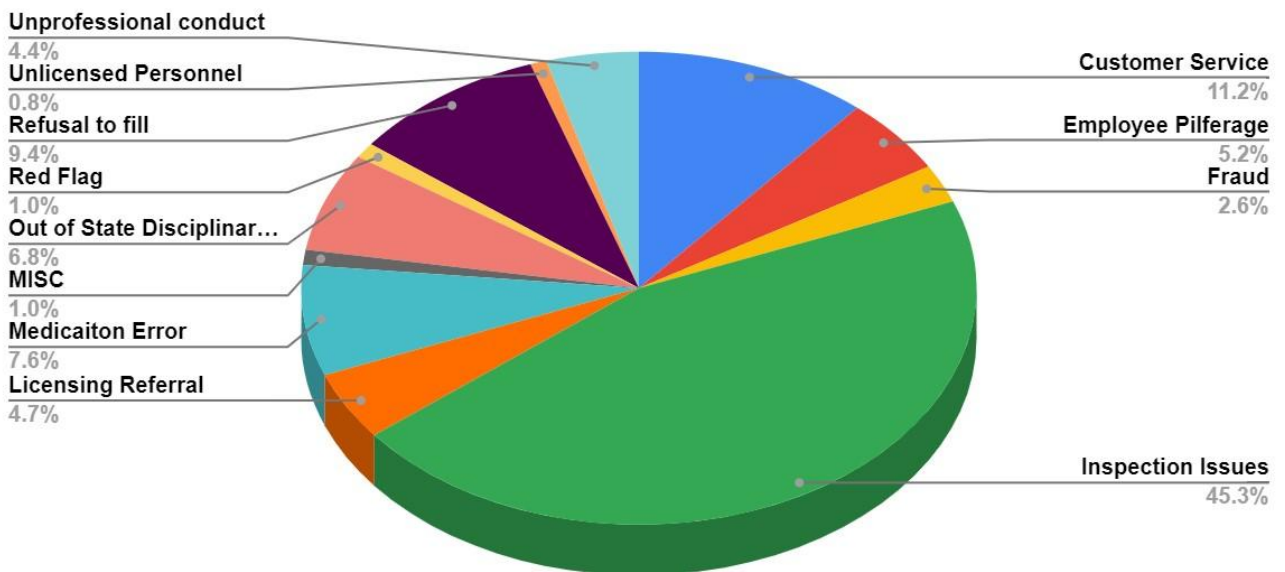
**Customer Service** issues represent the second-largest category of complaints, accounting for **11.2%** of the total. This suggests that there are areas where customer service could be improved.

**Medication Errors** are another significant category, comprising **7.6%** of the total. **Licensing Referral** issues make up **4.7%** of the total, suggesting potential compliance problems.

**Unprofessional Conduct** accounts for **4.4%** of the total, indicating a need for training and disciplinary measures. **Employee Pilferage** is also a concern, representing **5.2%** of the total. This suggests a need for tighter security measures and inventory management. **Fraud** accounts for **2.6%** of the total, indicating a need for stronger fraud prevention and detection measures.

Figure 2 FY 24 Types of Complaints Received

## FY 24 Types of Complaints Received



### Complaint Investigation and Resolution

The Board's staff thoroughly investigates all complaints. Depending on the severity and nature of the complaint, we may take formal or informal action.

**Informal actions** can include:

- Educational letters
- Letters of admonishment or agreement
- Informal deficiency letters
- Case closures

**Formal actions** include:

- Placing a license or permit on probation, suspension, or revocation
- Imposing deficiency fines

Some cases carry over from one fiscal year to the next due to ongoing investigations, referrals to the Attorney General's office, outstanding fines, and active probation or suspension periods.

*Figure 3*, below, shows a trend of informal and formal actions taken by the Board over actions taken over twelve fiscal years (FY 13 to FY 24). It offers a visual representation of trends and patterns in disciplinary actions within the Board. There is a general decreasing trend in the number of formal disciplinary actions over the years. While there are some years with lower numbers of formal actions, the overall direction is towards a decrease. FY20 saw the highest number of formal actions with 144. FY21 had the lowest number of formal actions with 23. In FY24, 384 complaints were filed, a slight decrease from FY23.

Figure 3: Disciplinary action by Fiscal Year

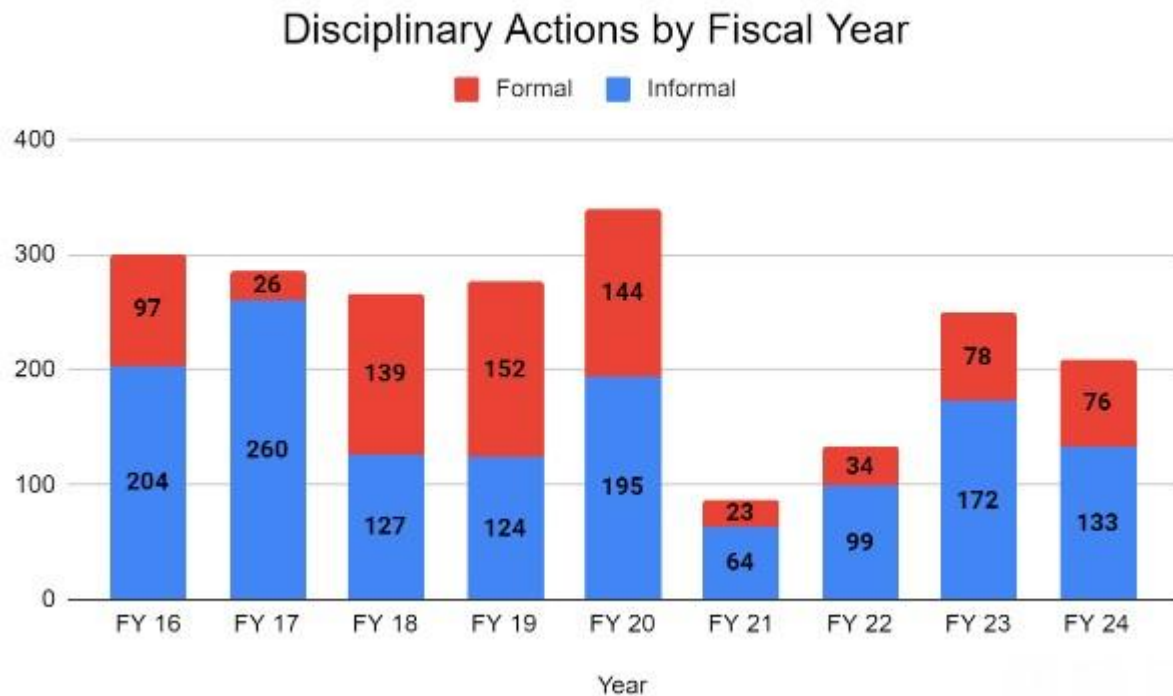


Figure 4, chart below, provides a breakdown of the various actions taken by the Board during this fiscal year. It shows the number of cases that were referred to other agencies, the Attorney General's Office (OAG), classified as non-cases, resulted in formal or informal actions, were still under investigation, were closed without action, or were ultimately closed.

#### Key Findings:

- **Case Closure:** The majority of actions taken were related to closing cases, with 441 cases closed. This suggests that the board is actively resolving complaints and investigations.
- **Closed Without Action:** A significant number of cases, 218, were closed without taking any action. This could indicate that these cases were deemed to be unfounded or not warranting further investigation.
- **Investigation Pending:** 82 cases were still under investigation at the end of the fiscal year. This suggests that some cases require further investigation before a final determination can be made.
- **Informal and Formal Actions:** The board took 133 informal actions and 76 formal actions. This indicates that the board uses a range of actions to address complaints and investigations, depending on the severity of the issue.
- **Referrals:** A small number of cases were referred to other agencies (4) or the Office of the Attorney General (16). This suggests that the board may collaborate with other agencies on certain cases

Figure 4: Board Action taken from July 1, 2020 – June 30, 2021

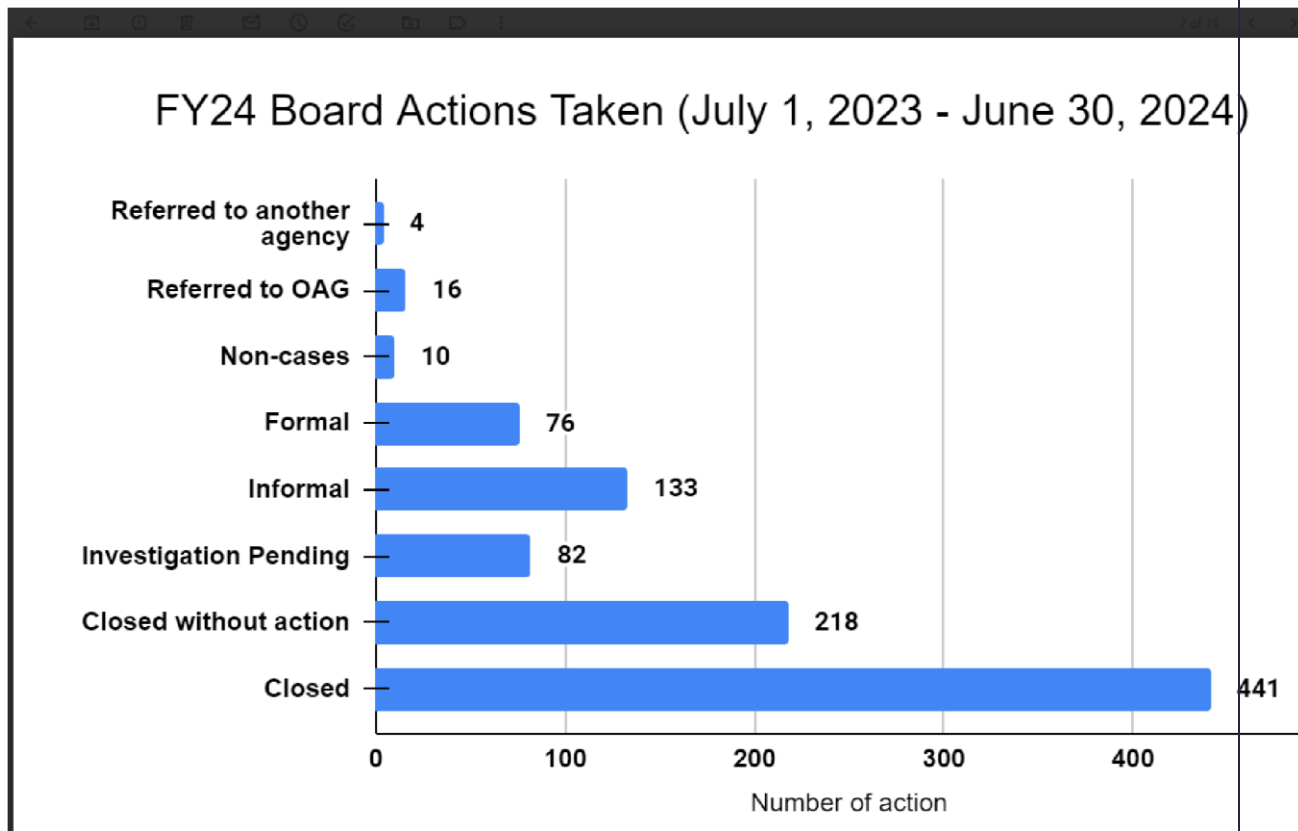


Figure 5, chart below, reflects the formal and informal actions taken against Maryland licensees and permit holders by the Board in FY24. The majority of actions taken were informal, with 133 total informal actions compared to 76 formal actions. This suggests that the board prioritizes less severe disciplinary measures in most cases. The most common informal actions were fines (55) and letters of admonishment (41). This indicates that the board often uses these measures to address minor infractions or to educate licensees. Among the formal actions, fines (55) were also the most common, followed by suspensions (14). This suggests that the board is more likely to impose fines for more serious offenses. Compared to FY23, there was a reduction in the number of fines issued. Only a small number of revocations (2) and reprimands (0) were issued. This indicates that these are reserved for the most serious violations.

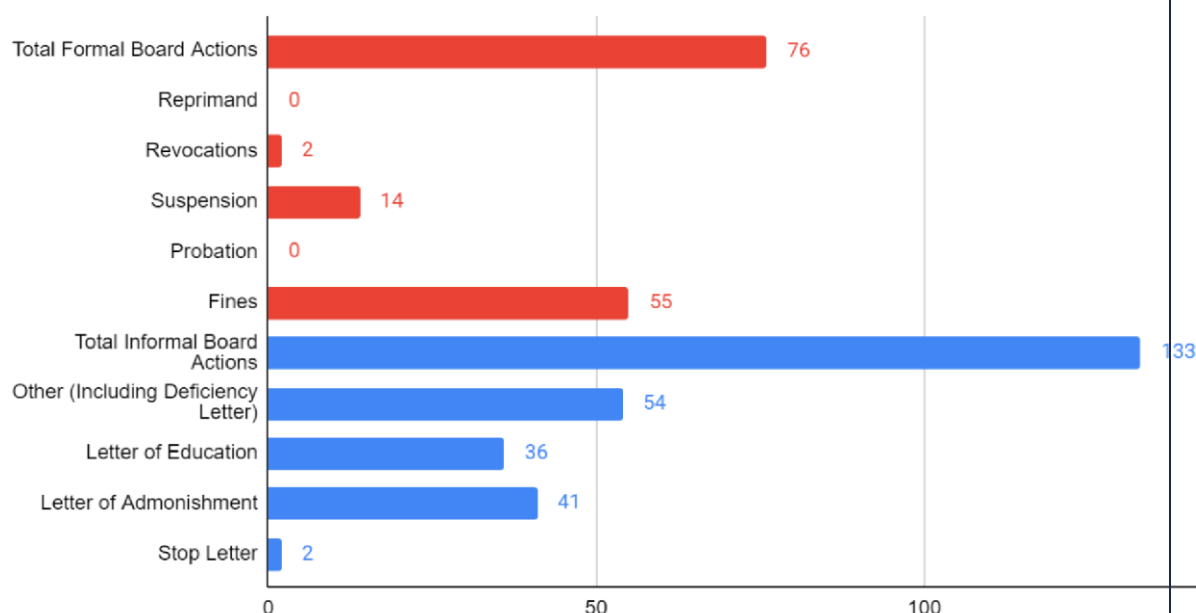
Figure 5: Formal Board Actions Taken from July 1, 2020 - June 30, 2021

## Inspections

The Inspection Unit continues to work closely with the Office of Controlled Substances Administration (OCSA), formerly known as the Division of Drug Control (DDC), in performing referral inspections. The Board of Pharmacy conducts opening, closing, remodels, relocation, change of ownership, and annual inspections of in-state pharmacies. The Board has a goal of inspecting all in-state pharmacies annually.



## FY24 Board actions Taken (Formal and Informal July 1, 2023 to June 30, 2024)



The chart in [Figure 6](#) shows the number of inspections conducted in Fiscal Year 23 and Fiscal Year 24. The total number of inspections increased from 1,239 in FY23 to 1,360 in FY24. This represents an increase of 121 inspections, or approximately 10%. Specific changes noted were:

- **Annual inspections:** The largest category of inspections, Annual Inspections, saw a significant increase from 886 in FY23 to 1,178 in FY24. This represents an increase of 292 inspections, or approximately 33%.
- **Decrease in Opening Inspections:** The number of Opening Inspections decreased from 147 in FY23 to 79 in FY24. This represents a decrease of 68 inspections, or approximately 46%.
- **Slight Increase in Closing Inspections:** The number of Closing Inspections increased slightly from 56 in FY23 to 79 in FY24. This represents an increase of 23 inspections, or approximately 41%.
- **Change of Ownership Inspections:** The number of Change of Ownership Inspections remained relatively stable, with a slight increase from 15 in FY23 to 17 in FY24.
- **Decrease in Miscellaneous Inspections:** The number of Miscellaneous Inspections decreased significantly from 135 in FY23 to 7 in FY24. This represents a decrease of 128 inspections, or approximately 95%.

Figure 6: Different Types of Inspections Completed by Board's Inspectors and Laboratory Scientist Surveyors.

## FY24 Annual Report

	FY23	FY24	
Annual Inspections	886	1,178	
Opening Inspections	147	79	
Closing Inspections	56	79	
Change of Ownership Inspections	15	17	
Miscellaneous Inspections	135	7	
Total Inspections	1,239	1,360	

### Sterile Inspections:

130 annual sterile inspections  
 537 sterile opening/renovation inspections  
 2 Sterile Pharmacy Closings

Figure 7, provides a breakdown of the various sterile compounding observations found during FY2024 sterile inspections. Significant key findings were:

- **Room Issues Dominate:** Room issues, including damage, exposed porous surfaces, stains, dust, residues, and rust, account for the largest proportion of observations, making up **23.7%** of the total. This indicates a significant problem area that needs to be addressed.
- **Cleaning and Hot Water/Sink Issues:** Cleaning and hot water/sink issues represent the secondlargest category of observations, comprising **10.6%** of the total. This suggests that there are areas where cleaning practices and hot water/sink maintenance could be improved.
- **Policies/Documentation/Logs:** Policies, documentation, and log issues are also a significant category, accounting for **20%** of the total. This highlights a potential compliance problem that requires attention.
- **Training and Incubation Temperatures:** Training and incubation temperature issues represent **8.5%** of the total, suggesting a need for improved training and temperature monitoring practices.
- **Pressures/Humidity/Temperatures:** Pressures, humidity, and temperature issues account for

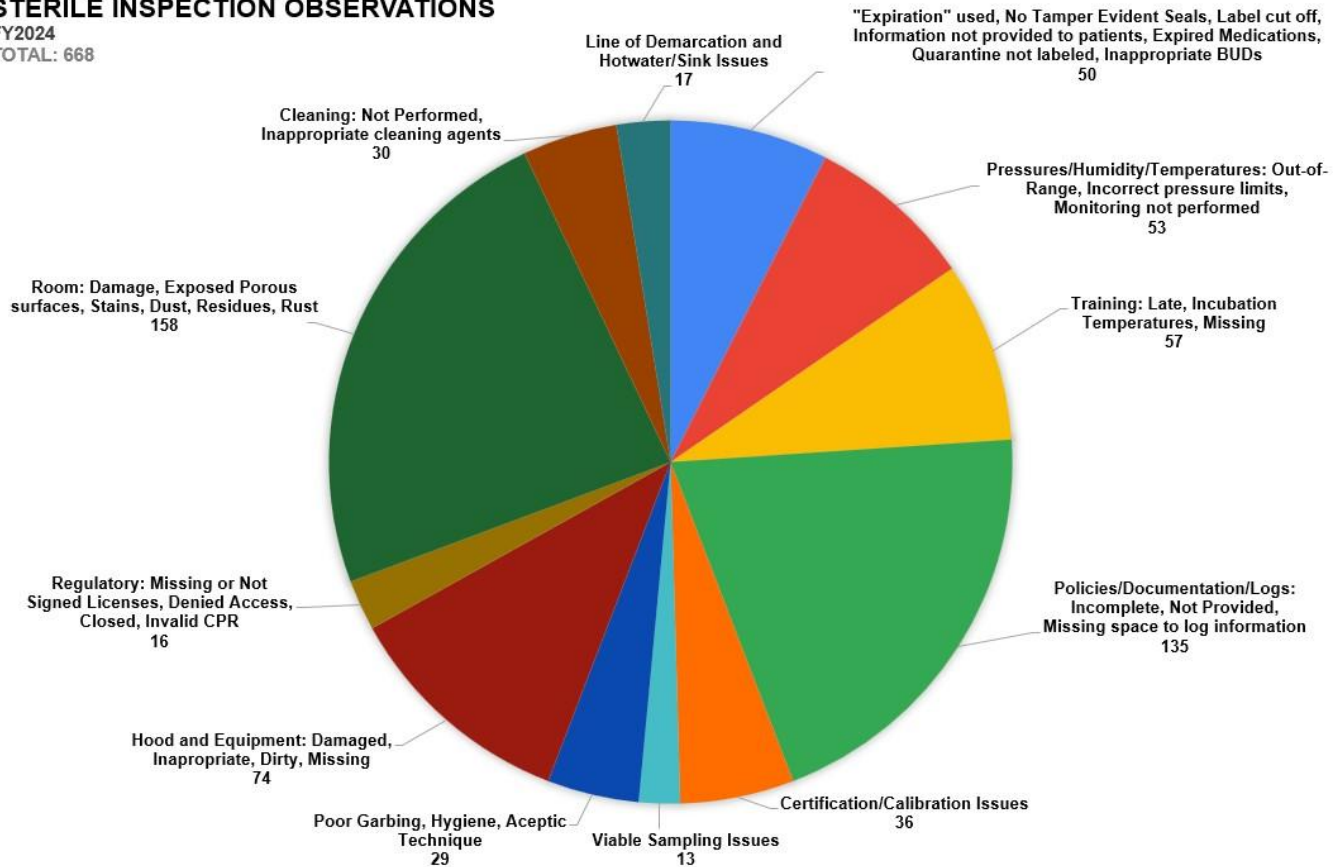
**7.9%** of the total, indicating a potential environmental control problem.

Figure 7:

## STERILE INSPECTION OBSERVATIONS

FY2024

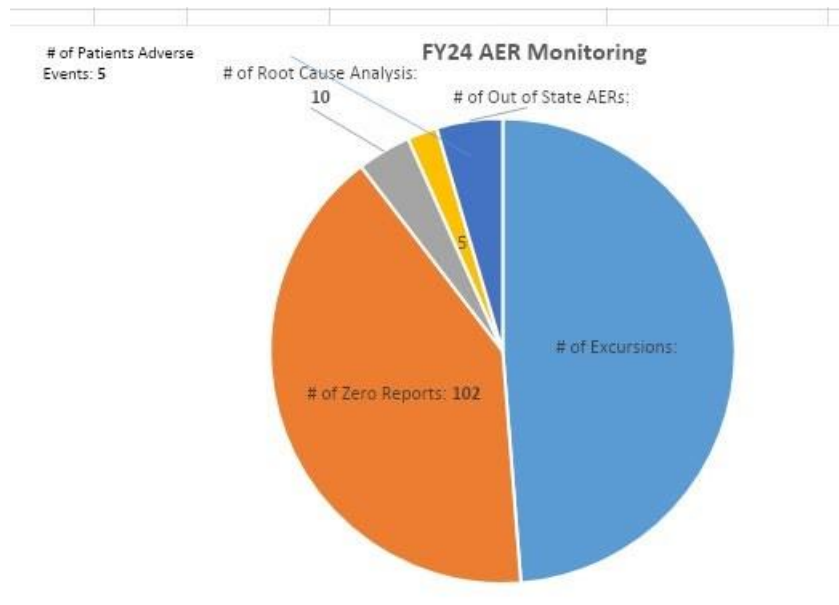
TOTAL: 668



### AER Monitoring

**# 117 of Microbial Excursions Reported (49% of facilities reported at least one microbial excursion)**

- # of Zero Reports: **98 (40.7%)**
- # of Root Cause Analysis (RCA): **6 (3.8%)**
- # of Patient Adverse Events: **5 (2.1%)**
- # of Out-of-State AERs: **11 (4.7%)**



## Rehabilitation Monitoring

Substance abuse within the healthcare profession is a serious issue that can have devastating consequences for both the individual and patients. The Board partners with a rehabilitation program called Pharmacy Rehabilitation Services (PRS) to address this problem. The Maryland Board of Pharmacy may require licensed individuals who struggle with addiction to undergo treatment. If mandated, the Compliance Unit monitors licensees to ensure they adhere to the terms of their treatment plans. This may involve reviewing regular reports from treatment programs and requiring participation in specific activities, such as:

- Random drug testing
- Substance abuse treatment or psychotherapy
- Participation in support groups like NA or AA
- Psychiatric evaluations
- Employer reports
- Continuing education requirements
- Additional exams or courses as deemed necessary by the Board

Over the past year, our records show a total of 20 active cases. Of these, 12 were related to licensed pharmacists (9) or technicians (3) [Board cases], while the remaining 8 involved other individuals, such as pharmacy students or family members. The number of active cases can change as individuals complete their programs and others enter. We also monitor anonymous participants through our designated rehabilitation committee. The Board remains committed to helping licensees who are struggling with substance abuse issues.

## **Conclusion**

Overall, the Compliance Unit had a productive year. The provided charts and graphs offer valuable insights into various aspects of healthcare operations, including inspections, disciplinary actions, and adverse event monitoring. In the office, we met with the audit team to look at our case load considering the increase in backlog from last fiscal year. As a result of the meeting, the benchmark for completing investigative cases were increased to 270 days from 180 days. Despite losing two key positions, Investigator and one Compliance Pharmacist, we successfully managed 434 cases, a slight decrease from the previous year.

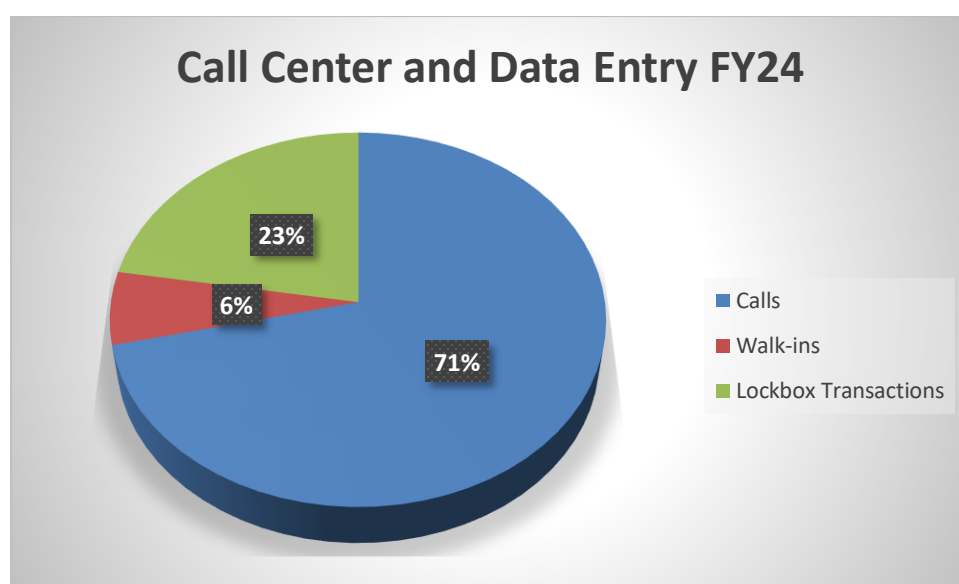
## **Next Year at a Glance**

1. Utilize data analysis to identify trends, prioritize areas for improvement, and allocate resources effectively.
2. Implement a culture of continuous improvement by regularly reviewing processes, policies, and procedures.
3. Provide comprehensive training to staff on relevant topics, such as cleaning practices, documentation, and adverse event reporting.
4. Foster open communication between staff, management, and regulatory agencies to address concerns and share information.
5. Collaborate with other healthcare organizations to share best practices and learn from each other's experiences.

## **CUSTOMER SERVICE AND DATA ENTRY UNIT**

### **Overview**

The Customer Service and data entry unit of the Maryland Board of Pharmacy responds to concerns from the licensees and the public. The unit answers call and send email inquiries to the appropriate staff for assistance. The unit 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 servicing the public. In FY24, the unit answered 14,499 calls and assisted 1,275 walk-in customers. The customer service and data entry unit of the Maryland also receives and enters applications and documents to provide a smoother transition for licenses needing to be processed. In FY23 the call center and data processing team has processed 4,548 transactions sent through our lockbox.



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

This unit is only going to continue to get more efficient by participating in the following:

- Obtaining more training.
- Hiring and training new staff
- Using newer technology to streamline calls to make a smoother customer experience.

### **Conclusion**

The unit continues to serve as a one-stop shop for the public when they cannot get questions answered by viewing the website or online FAQ. The Board has devoted a significant amount of time and energy this year to 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.

# STATE OF MARYLAND BOARD OF PHARMACY



4201 Patterson Avenue

Baltimore, MD 21215

410-764-4755

410-358-9512 FAX

<http://health.maryland.gov/pharmacy>

[mdh.mdbop@maryland.gov](mailto:mdh.mdbop@maryland.gov)

