

STATE OF MARYLAND

Department of Health and Mental Hygiene

BOARD OF
PHARMACY



FISCAL YEAR 2023
ANNUAL REPORT

July 1, 2022

through

June 30, 2023

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 2023 BOARD COMMISSIONERS

President

Neil B. Leikach

Independent Pharmacist Representative

Secretary

Kristopher Rusinko

Home Infusion Representative

Treasurer

Peggy Geigher

Consumer Representative

Jennifer Hardesty

Long Term Care Representative

Kevin Morgan

Chain Drug Store Representative

Karla Evans

Acute Care Hospital Representative

Brenda Oliver

Consumer Representative

Akash Patel

Chain Drug Store Representative

Karen Slagle

Independent Representative

Javier Vázquez

Acute Care Hospital Representative

Kristen Fink

At-Large Representative

BOARD COUNSEL

Linda Bethman, AAG

Brett Felter, Staff Attorney

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Maryland Board of Pharmacy

FY 23 Year in Review



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DEENA SPEIGHTS-NAPATA
EXECUTIVE DIRECTOR

OPERATIONS UNIT REPORT

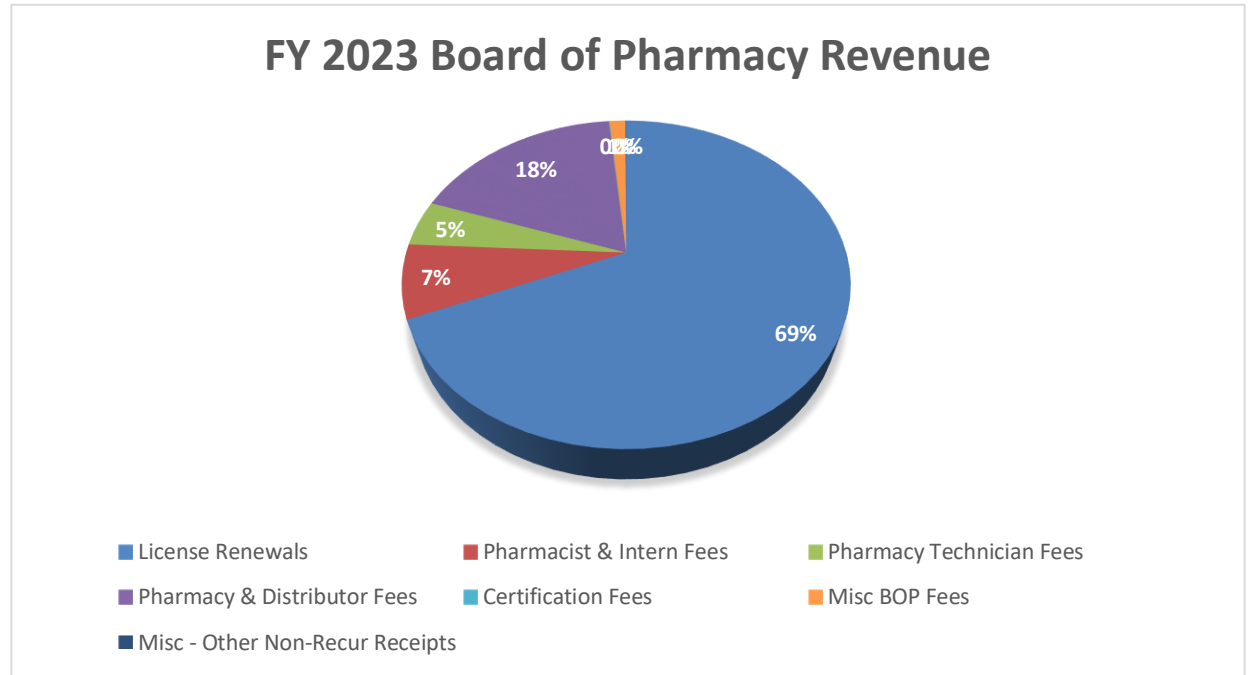
Overview

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

FY 2023 Board of Pharmacy Revenue



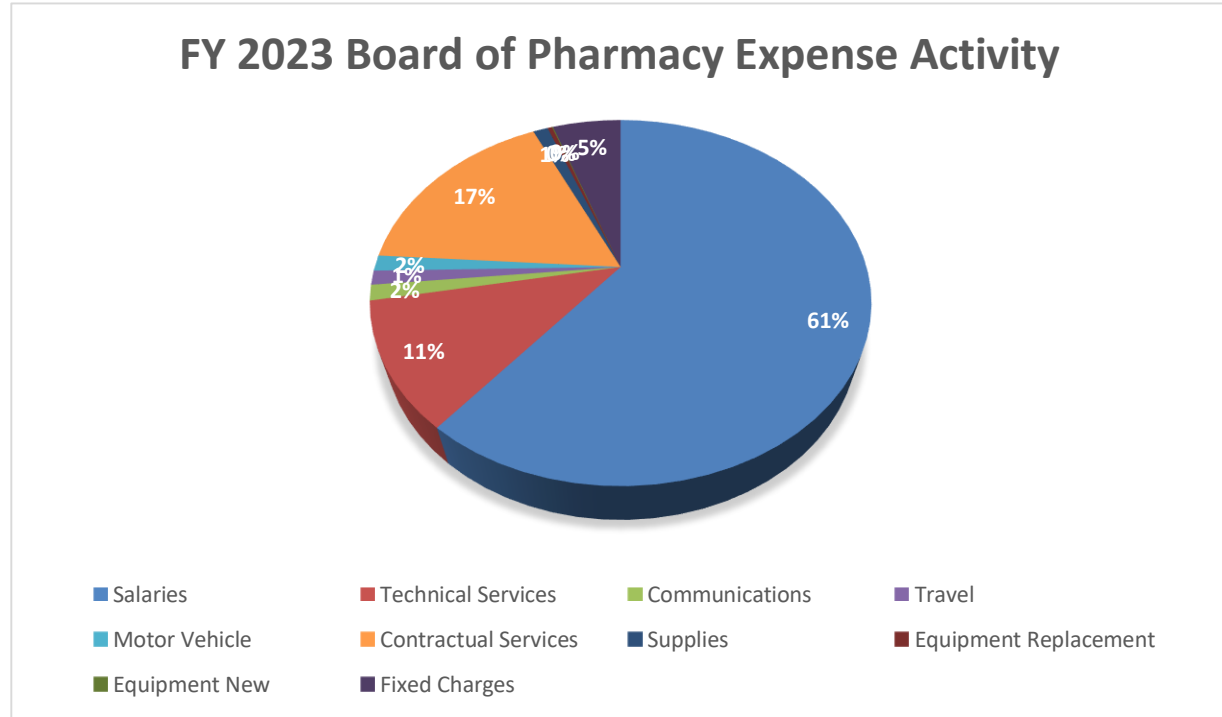
Revenue	Amount	Percent
License Renewals	\$3,319,313.00	68.60%
Certification Fees	\$4,100.00	0.08%
Pharmacist and Intern Fees	\$351,320.97	7.26%
Pharmacy Technician Fees	\$221,578.00	4.58%
Pharmacy & Distributor Fees	\$887,752.25	18.14%
MISC BOP Fees	\$67,795.00	1.40%
MISC-Other Non-Recur Receipts	-\$2,884.00	-0.06%
Revenue FY 2023	\$4,838,975.22	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 2023, the Distributors renewed their licenses during the March through May renewal period.

The Board also transferred \$306,748.00 related to the Pharmacists license renewal fee to the Maryland Health Care Commission, which represented \$36 of the \$261 license renewal fee.

Board Expenses



Expense Category	Amount	Percent
Salaries	\$2,544,906.82	60.91%
Technical Services	\$466,031.25	11.15%
Communications	\$57,356.81	1.37%
Travel	\$52,129.40	1.25%
Motor Vehicle	\$57,733.18	1.38%
Contractual Services	\$713,060.79	17.07%
Supplies	\$48,081.00	1.15%
Equipment Replacement	\$14,445.00	0.35%
Equipment New	\$3,253.90	0.08%
Fixed Charges	\$221,362.95	5.30%
Total	\$4,178,361.10	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 FY2023, the Licensing Unit processed 12,319 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 FY2023, the Licensing Unit processed 203 new distributor permits, an increase of 36% from FY2022. Additionally, the Unit processed 1,193 distributor renewals during the renewal period which occurred in FY2021/FY2022.

In FY2023, the Licensing Unit processed 6,082 pharmacist licenses (initial and renewal, including vaccine certifications).

In FY2023, the Licensing Unit issued 28 Pharmacy Intern Graduate and 281 Pharmacy Intern Student registrations (initial and renewal).

In FY2023, the Licensing Unit processed 1,396 WSD permits (203 new permits and 1,193 renewals) compared to 1,363 permits in FY2022 (197 new permits and 1,166 renewals).

In FY2023, as in previous years, the Licensing Unit processed more technician renewal applications than initial applications. The Licensing Unit issued 4,233 technician registrations (initial, renewal, and reinstatement).

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

FY 2023	
Pharmacists	4,538
Pharmacy Intern	309
Pharmacy Technician	4,268
Pharmacies	174
Distributors	1396
Vaccinations	1,555
VAEIA	0

2023			
New	Renewals	Reinstatements	Totals
615	3,912	11	4,538
246	63	0	309
1,893	2,347	28	4,268
172	0	2	174
203	1,193	0	1,396
265	1,290	0	1,555
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, Pharmacist Compliance Officer, four (4) Compliance Investigators, two (2) Laboratory Scientist Surveyors, a Pharmacy Technician Compliance Inspection Supervisor, and three (3) 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 (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.

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

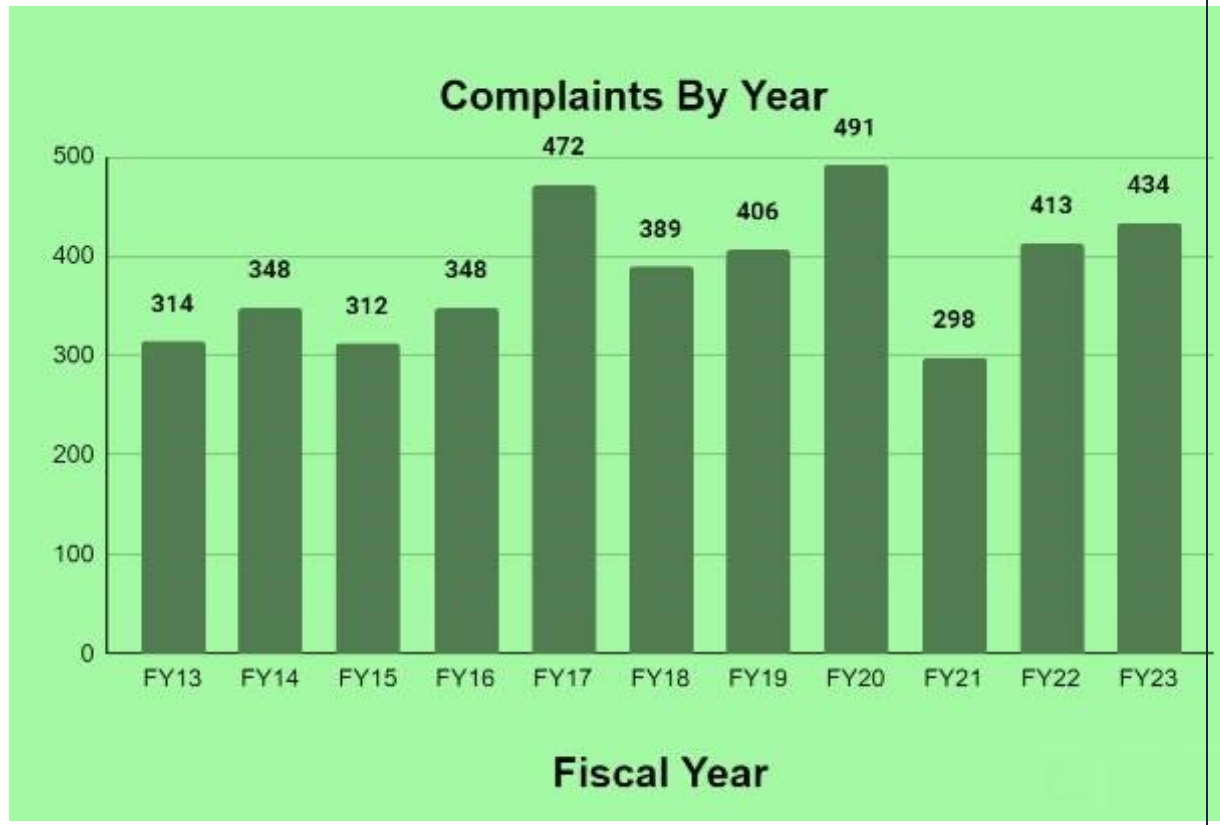
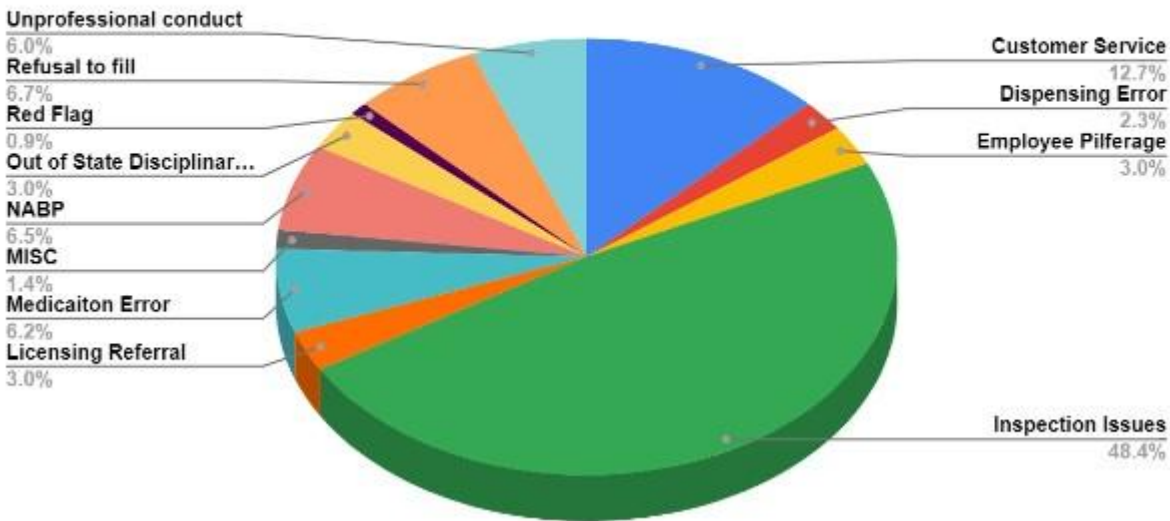


Figure 2, below, depicts the categories of complaints received in FY 23. Inspection Issues make up the largest portion of complaints, accounting for 48.4%. This suggests that issues related to pharmacy inspections, such as non-compliance with regulations or safety standards, are the primary concern. **Customer Service** complaints constitute **12.7%** of the total, indicating that issues related to patient interactions and satisfaction are also a significant concern. **Refusal to Fill** prescriptions account for **6.7%** of complaints, suggesting that pharmacies may be reluctant to fill certain prescriptions as a professional judgment, or other factors. Other categories were **Dispensing Errors** (2.3%), **Employee Pilferage** (3.0%) and **Out of State Disciplinary Actions** (3.0%)

Figure 2 FY 23 Types of Complaints Received

FY 23 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 eight fiscal years (FY 16 to FY 23). It offers a visual representation of trends and patterns in disciplinary actions within the Board. There appears to be a general upward trend in the total number of disciplinary actions over the years, with a significant spike in FY 20. The data shows 78 formal and 172 informal disciplinary actions by the end of fiscal year 2023. While the number of informal actions fluctuates, formal actions seem to be increasing more consistently.

Figure 3: Disciplinary action by Fiscal Year

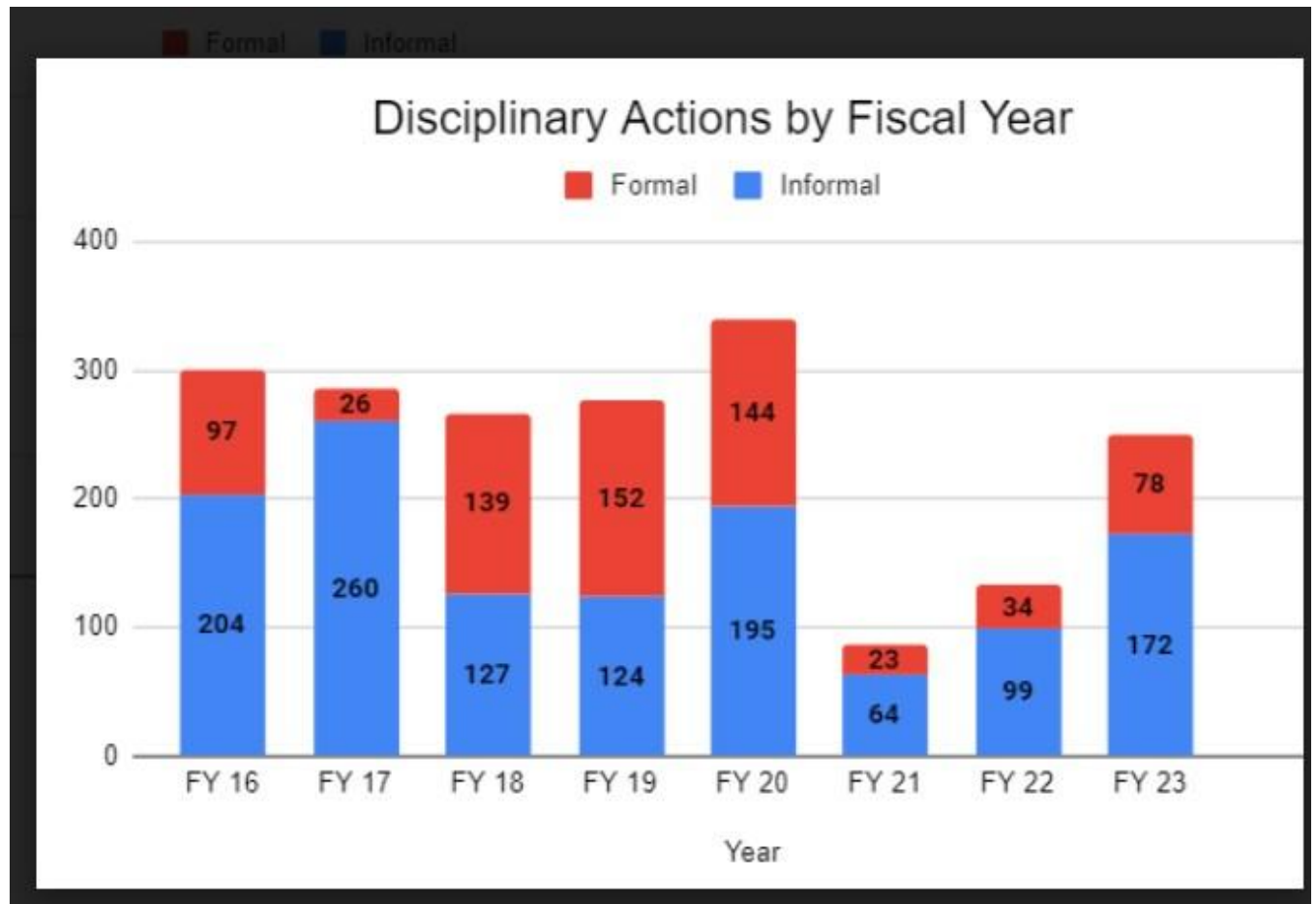


Figure 4, chart below, provides a breakdown of the various actions taken by the Board in FY23. It shows the number of cases that were referred to other agencies, the Attorney General's Office (OAG), classified as non-cases, resulted in formal or informal actions, were still under investigation, were closed without action, or were ultimately closed.

Key Findings:

- **Case Closure:** The majority of cases (518) were closed.
- **Informal Actions:** A significant number of cases (172) resulted in informal actions, suggesting that many complaints were resolved without formal disciplinary measures.
- **Investigations Pending:** 127 cases remained under investigation at the end of the fiscal year.
- **Formal Actions:** 78 cases led to formal actions, indicating that a portion of complaints required more severe disciplinary measures.
- **Referrals:** 2 cases were referred to another agency, and 11 were referred to the OAG.

Interpretations:

- **Effective Complaint Resolution:** The high number of closed cases suggests that the Board is generally effective in addressing complaints.

- **Focus on Informal Actions:** The prevalence of informal actions indicates a focus on resolving complaints through less severe measures, potentially avoiding unnecessary penalties or damage to professional reputations.
- **Ongoing Investigations:** The number of pending investigations highlights the need for continued efforts to address complex or time-consuming cases.

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

FY23 Board Actions Taken (July 1 2022 - June 30, 2023)

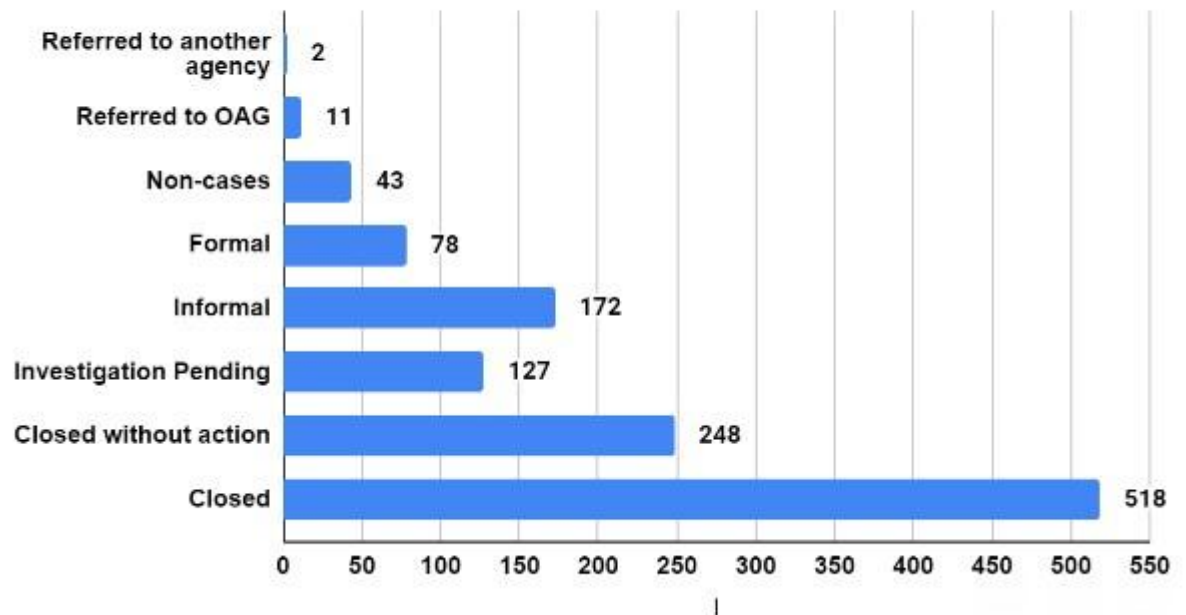
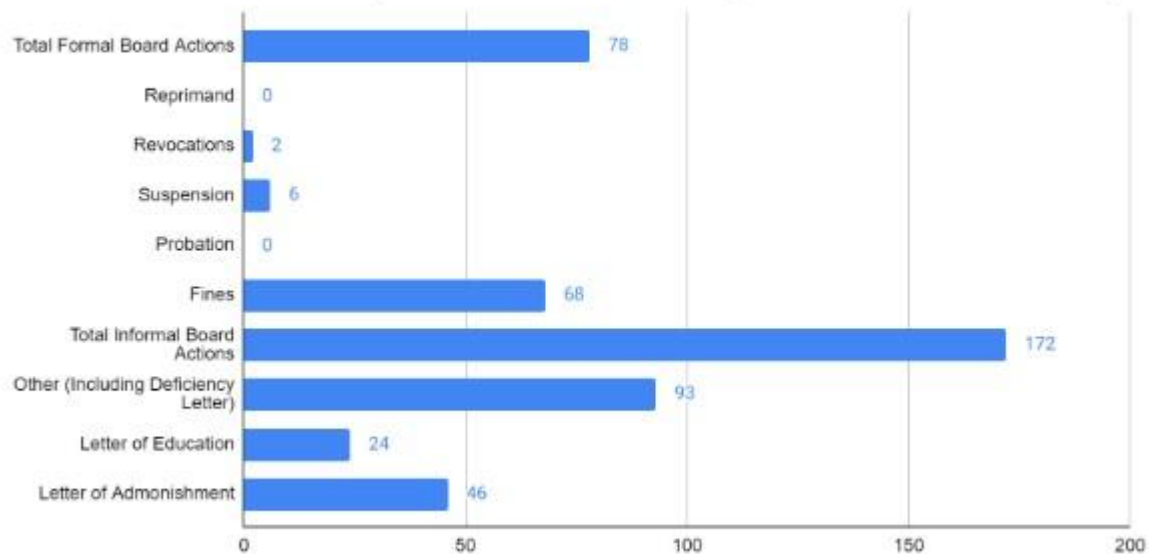


Figure 5, chart below, reflects the formal and informal actions taken against Maryland licensees and permit holders by the Board in FY23. The total number of informal actions (172) significantly outnumbers formal actions (78), indicating that the Board primarily relies on less severe measures to address complaints. Among formal actions, fines are the most common, accounting for 68 cases. While less frequent, suspensions and revocations are the most severe formal actions taken. The most common informal actions are "other" (including deficiency letters), followed by letters of admonishment and education.

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

FY23 Board actions Taken (Formal and Informal July 1, 2022 to June 30, 2023)



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.

The chart in [Figure 6](#) shows a **decrease** in the total number of inspections conducted from FY22 to FY23, from 1,573 to 1,239. This represents a decrease of approximately **21%**. Specific changes noted were:

- **Annual Inspections:** There was a significant drop in annual inspections, from 1,104 to 886, representing a **19.7%** decrease.
- **Opening Inspections:** The number of opening inspections increased from 72 to 147, a **104.2%** increase.
- **Closing Inspections:** While there was a slight increase from 14 to 56, closing inspections still account for a relatively small portion of the total.
- **Change of Ownership Inspections:** The number of change of ownership inspections increased from 4 to 15, a **275%** increase.
- **Miscellaneous Inspections:** Miscellaneous inspections saw a significant decrease from 379 to 135, a **64.4%** decline.

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

FY23 Annual Report

	FY22	FY23
Annual Inspections	1,104	886
Opening Inspections	72	147
Closing Inspections	14	56
Change of Ownership Inspections	4	15
Miscellaneous Inspections	379	135
Total Inspections	1,573	1,239

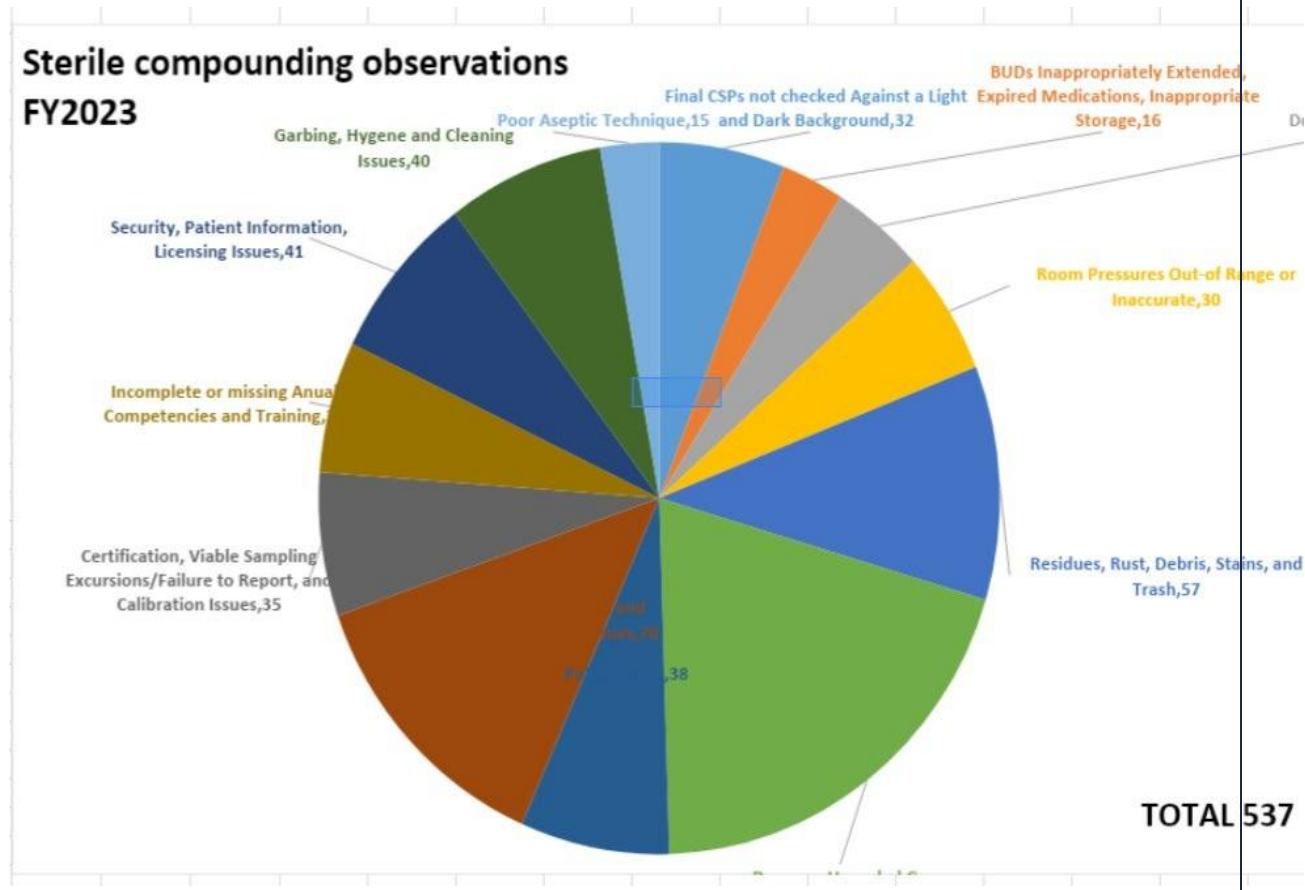
Sterile Inspections:

- 130 annual sterile inspections
- 537 sterile opening/renovation inspections
- 2 Sterile Pharmacy Closings
- 181 AERs Reported
- 106 Microbial Excursions (**59%** of facilities reported at least one microbial excursion)
- 75 Zero Reports (**41%** of facilities reported zero microbial excursions).

Figure 7, provides a breakdown of the various sterile compounding observations found during FY2023 sterile inspections. Significant key findings were:

- **Residues, Rust, Debris, Stains, and Trash** are the most common observation, accounting for **57** instances.
- **Garbing, Hygiene, and Cleaning Issues** are also a significant concern, with **40** observations.
- **Security, Patient Information, and Licensing Issues** account for **41** observations.
- **Room Pressures Out-of-Range or Inaccurate** were observed in **30** cases, indicating potential issues with the integrity of the sterile environment.
- **Certification, Viable Sampling Excursions/Failure to Report, and Calibration Issues** were observed in **35** cases, suggesting deficiencies in quality assurance and control procedures.
- **Incomplete or Missing Annual Competencies and Training** were noted in **38** cases, indicating potential gaps in staff training and qualifications.
- **Aseptic Technique Issues** were observed in **15** cases, suggesting that staff may not be following proper aseptic techniques during compounding.
- **BUDs Inappropriately Extended, Final CSPs not Checked Against a Light, Expired Medications, and Inappropriate Storage** were observed in **32** cases, indicating issues with the preparation, storage, and handling of compounded sterile products.

Figure 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 18 active cases. Of these, 9 were related to licensed pharmacists or technicians (Board cases), while the remaining 9 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

The Compliance Department underwent significant staffing changes, losing several investigators and inspectors. Despite these losses, the team persevered, closing cases by implementing and adapting new strategies. The number of cases handled in 2023 was substantially higher than in previous years, indicating a significant increase in workload. However, the number of cases carried over into FY24 (135) remained relatively low, suggesting effective backlog management and timely case completion. The high percentage of cases completed within 180 days (51.83%) demonstrates the team's efficiency and productivity in handling complaints. While overall performance is positive, there is still room to improve in terms of reducing the overall time to resolution, especially for cases that take longer than 180 days

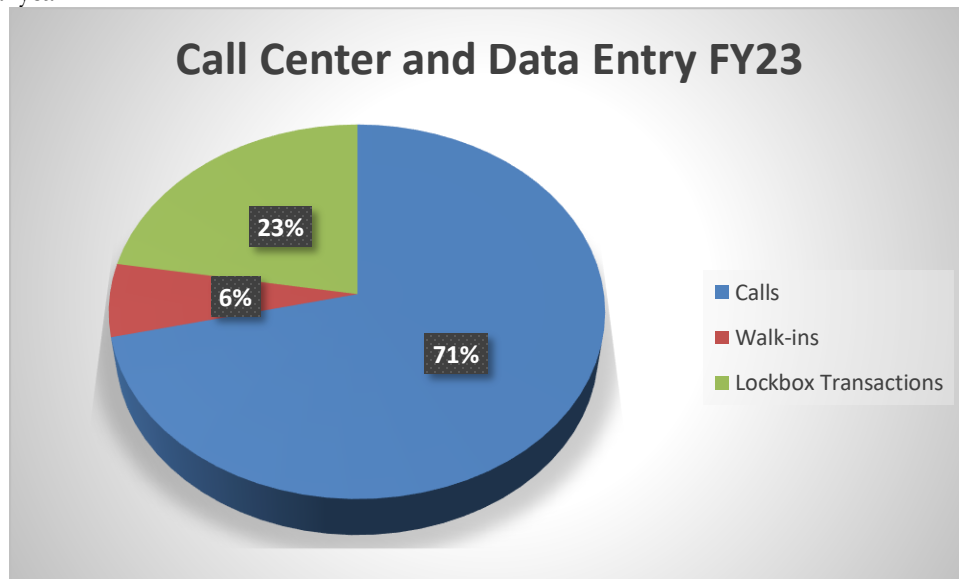
Next Year at a Glance

- Target to meet the Board's benchmark of 180 days by continuing to resolve cases within goal
- Continuous monitoring and evaluation of performance metrics will be essential to ensure that the team remains able to meet the increasing demands and maintain high levels of service quality
- Create and revise policies and procedures for the investigative team that will shift the organization's approach to addressing disciplinary issues.

CUSTOMER SERVICE

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 FY23, the unit answered 13,103 calls and assisted 1,022 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 5,407 transactions sent through our lockbox. This is over 1,000 more transactions than the previous fiscal year.



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.

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 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.

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

