## STATE OF MARYLAND

Department of Health and Mental Hygiene

# BOARD OF PHARMACY



# FISCAL YEAR 2025 ANNUAL REPORT

July 1, 2024 through

June 30, 2025

#### 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 2025 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

#### **Amir Masood**

Chain Drug Store Representative

#### Karla Evans

Acute Care Hospital Representative

#### Adetoro Oriaifo

At-Large Representative

#### Daphanie Robinson

Pharmacy Technician Representative

#### Akash Patel

Chain Drug Store Representative

#### Karen Slagle

Independent Representative

#### Kristen Fink

At-Large Representative

#### Vacant

Consumer Representative

#### Vacant

Long Term Care Representative

## **BOARD COUNSEL**

Linda Bethman, Assistant Attorney General

Brett Felter, Assistant Attorney General

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# Maryland Board of Pharmacy FY 25 Year in Review



DEENA SPEIGHTS-NAPATA
EXECUTIVE DIRECTOR

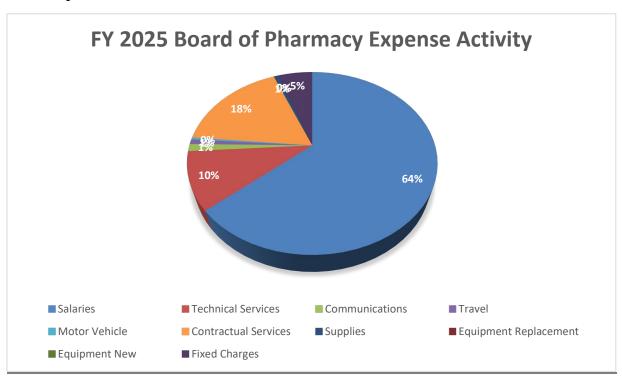
#### **OPERATIONS UNIT REPORT**

#### **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 Expenses**



Expense Category	Amount	Percent
Salaries	\$3,164,162.97	63.74%
Technical Services	\$507,941.39	10.23%
Communications	\$63,732.74	1.28%
Travel	\$42,163.49	0.85%
Motor Vehicle	\$18,814.22	0.38%
Contractual Services	\$867,653.78	17.48%
Supplies	\$36,034.49	0.73%
Equipment Replacement	\$0	0%
Equipment New	\$0	0%
Fixed Charges	\$263,831.00	5.31%
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**

This year MIS has maintained operations and continued to troubleshoot and ensure technology is working. Research was conducted for new licensing software and discussions were had about a new Active Directory and networks for FY 27.

#### 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, five (2) licensing specialists, (1) Administrative Officer II, (1 vacant) 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 FY2025, the Licensing Unit processed 16,301 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 **FY2025**, the Licensing Unit processed **201** new distributor permits. Additionally, the Unit processed 1,199 distributor renewals during the renewal period which occurred in FY2023/FY2024.

In **FY2025**, the Licensing Unit processed **8,840** pharmacist licenses (initial and renewal, including vaccine certifications).

In **FY2025**, the Licensing Unit issued **30** Pharmacy Intern Graduate and **228** Pharmacy Intern Student registrations (initial and renewal).

In **FY2025**, the Licensing Unit processed **1,399** WSD permits (201 new permits and 1,198 renewals) compared to **227** permits in FY2023 (179 new permits and 48 renewals).

In **FY2025**, as in previous years, the Licensing Unit processed more technician renewal applications than initial applications. The Licensing Unit issued 5,583 technician registrations (initial, renewal, and reinstatement).

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

	FY 2025	
Pharmacists	6,290	
Pharmacy Intern	258	
Pharmacy Technician	5,266	
Pharmacies	167	
Distributors	1,399	
Vaccinations	2,898	
VAEIA	1	

2025			
New	Renewals	Reinstatements	Totals
520	5,739	31	6,290
186	72	0	258
1,814	3,636	44	5,494
165	0	2	167
201	1,198	0	1,399
487	2,411	0	2,898
1	0	0	1

#### COMPLIANCE UNIT REPORT Fiscal Year 2025

#### **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, five (5) Compliance Investigators, two (2) Laboratory Scientist Surveyors, Compliance Auditor, a Pharmacy Technician Compliance Inspection Director, Inspection Unit Administrative Specialist and five (5) 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 ww.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.

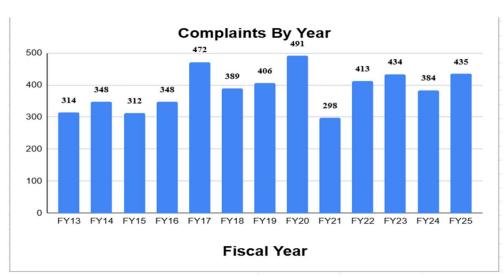


Figure 1: Complaints Trends Received by Year

Figure 1, chart above, illustrates the total number of complaints submitted to the Board over the preceding 13 fiscal years. Sources for these complaints are varied and may include the public, referrals from state and federal agencies, and deficiencies noted during inspections. In FY 2025, a total of 435 complaints were filed, marking a slight increase over the previous fiscal year.

Figure 2 FY 25 Types of Complaints Received

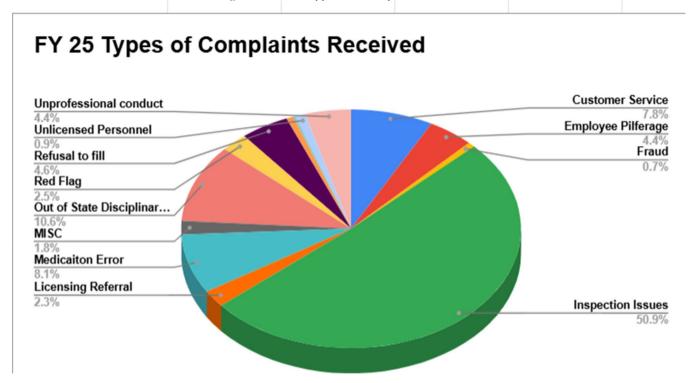
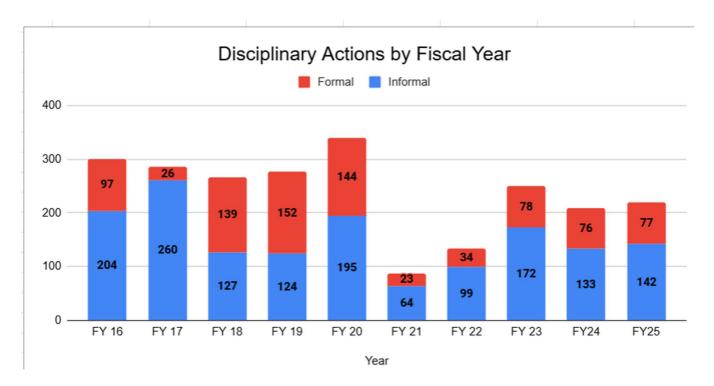


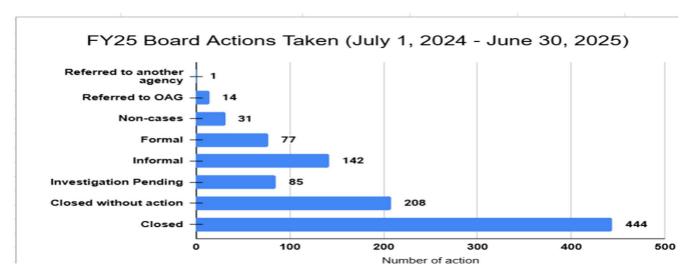
Figure 2, above, depicts the categories of complaints received in FY 2025 and a breakdown of the various types of complaints. Inspection Issues make up the largest portion of complaints, accounting for 50.9%. This suggests that issues related to pharmacy inspections, such as non-compliance with regulations or safety standards, are the primary concern. Out-of-State Disciplinary action represent the second-largest category of complaints, accounting for 10.6% of the total. This is followed by Medication Error (8.1%) and Customer Service (7.8%), which are also significant areas of concern. A cluster of complaints falls into the 4-5% range: Refusal to Fill (4.6%), Unprofessional conduct (4.4%), and Employee Pilferage (4.4%). The remaining complaints each constitute less than 3% of the total. These include Red Flag (2.5%), Licensing Referral (2.3%), MISC (1.8%), Unlicensed Personnel (0.9%), and Fraud (0.7%), which is the least common specific complaint.



*Figure 3*, above, shows disciplinary actions formal and informal taken by the Board over the past ten fiscal years. The data indicates 77 formal and 142 informal disciplinary actions in FY 2025.

All complaints are reviewed and investigated by Board staff. During the current fiscal year, the Board has taken both formal and informal actions on complaint cases, including those carried over from the previous fiscal year. Informal actions may include letters of education, admonishment, agreement, informal deficiency letters, or case closures. Formal actions can involve placing a license or permit on probation, suspension, or revocation, as well as issuing deficiency fines. Some cases carry over each year due to ongoing investigations, pending actions from the Attorney General's office (OAG), unpaid fines, pending suspensions or revocations, probation or licensee monitoring related to formal actions.

Figure 4: Board Action taken from July 1, 2024 – June 30, 2025



<u>Figure 4</u>, chart above, provides a breakdown of the various actions taken by the Board during the past fiscal year. The cases are categorized as follows: resolved with action as inform or formal, referred externally to other agencies and OAG, closed without action, pending investigation or non-case inquiries. closed without action or were ultimately closed.

Based on the chart, the most common board action in FY 2025 was "Closed" with 444 cases, followed by "Closed without action" with 208 cases. These two closure categories represent the vast majority of the board's actions, indicating that most matters are resolved by being closed, either with or without a formal action being taken.

#### Key Findings:

- Closures Dominate: The two main closure categories ("Closed" and "Closed without action") together account for 652 actions, or 65% of the total. This is the most significant takeaway from the data.
- Informal vs. Formal Action: "Informal" actions (142) were taken almost twice as often as "Formal" actions (77). This suggests a preference for resolving cases through less severe or complex means.
- Active Workload: There are 85 cases currently in the "Investigation Pending" stage, which represents the board's active, ongoing investigative work.
- Screening and Referrals: A small number of matters were filtered out as "non-cases" (31). Referrals to other entities were rare, with only 14 going to the OAG and just one to another agency.

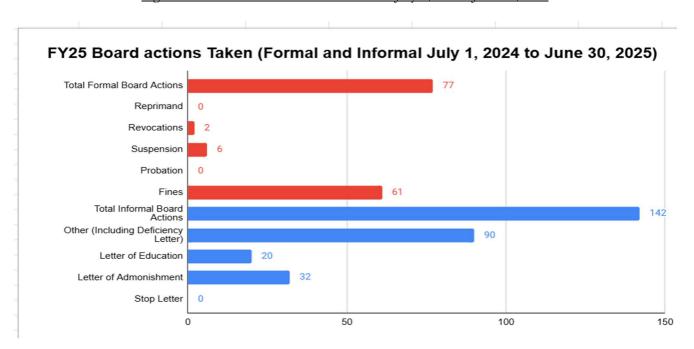


Figure 5: Formal Board Actions Taken from July 1, 2024 - June 30, 2025

<u>Figure 5</u>, chart above, reflects the formal and informal actions taken against Maryland licensees and permit holders by the Board in FY 2025. This chart breaks down the 77 formal and 142 informal actions taken by the board in FY 2025. For formal actions, the vast majority were Fines (61 cases). For informal actions, the most common type was "Other (Including Deficiency Letter)" (90 cases).

#### Formal Actions (Total: 77)

- Fines are the Primary Tool: Fines were used in 61 out of 77 formal cases, making up 79% of all formal actions. This is by far the most common punitive measure.
- Severe Penalties are Rare: Actions that directly affect a professional's license are infrequent. There were only 6 Suspensions and 2 Revocations.
- Unused Actions: No Reprimands or Probations were issued during this period.

#### Informal Actions (Total: 142)

- "Other" Category Dominates: The largest group is the broad category of "Other (Including Deficiency Letter)" with 90 cases, accounting for 63% of informal actions. This suggests that notifying individuals of a deficiency is a primary method of resolution.
- Advisory Letters: Letters of Admonishment (32) and Letters of Education (20) are also common, used to advise or warn individuals without formal discipline.
- Unused Actions: No Stop Letters were issued.

The board's disciplinary approach seems to favor financial penalties over license restrictions. The very low number of suspensions and revocations suggest these are reserved for only the most serious offenses. On the informal side, the board relies heavily on advisory letters—especially deficiency notices—to correct behavior and ensure compliance without escalating to formal disciplinary action.

## **Inspections**

The Inspection Unit continues to work closely with the Office of Controlled Substances Administration (OCSA) in performing referral inspections. The Board of Pharmacy conducts opening, closing, remodels, relocation, change of ownership, and annual inspections of in-state pharmacies and distributors. The Board has a goal of inspecting all in-state pharmacies annually. The Board completes different types of inspections such as Community, Hospital, Comprehensive Care, Openings & Closings, Wholesale Distributor, Repository, Follow-up and Special Packaging.

<u>Figure 6: Different Types of Inspections Completed by Board's Inspectors and Laboratory Scientist Surveyors</u>

	FY24	FY25
Annual Inspections	1,178	1080
Opening Inspections (New, Remodel,	79	76
Relocation, Reinstatement, Repository		
Opening)		
Closing Inspections	79	54
Change of Ownership Inspections	17	18
Miscellaneous Inspections	7	26
Total Inspections	1,360	1,254

<u>Figure 6</u>, chart above provided, the total number of inspections completed by the Board Inspectors which shows a decrease by nearly 8% between Fiscal Year 2024 and 2025, dropping from 1,360 to 1,254.

This overall decline was primarily driven by a reduction in Annual Inspections and a significant drop in Closing Inspections. Conversely, Miscellaneous Inspections saw a dramatic increase.

#### Key Observations:

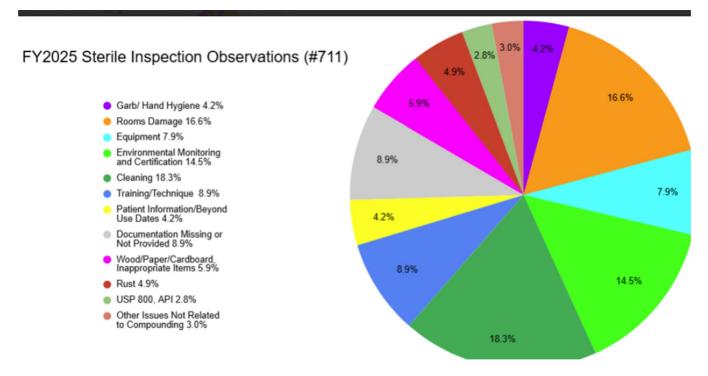
- Overall Decrease: The total number of inspections fell by 106 year-over-year.
- Annual Inspections Decline: The largest category, Annual Inspections, decreased by 98 (from 1,178 to 1,080).
- Fewer Closures: Closing Inspections dropped by over 31% (from 79 to 54), which is a significant change.
- Spike in Miscellaneous: The most striking change is in Miscellaneous Inspections, which more than tripled from 7 in FY 2024 to 26 in FY 2025. Miscellaneous inspections included primarily attempted inspections by the inspectors.
- Stable Activity: Opening Inspections and Change of Ownership Inspections remained relatively stable.

Total Number of Sterile Inspections completed by Laboratory Scientists: The most notable finding is the complete drop in closing inspections to zero. This suggests that these highly specialized and regulated businesses remain operational.

124 annual sterile inspections

18 Openings inspections 2 Change of Ownership No Closing inspections

Figure 7: FY 2025 Sterile Inspection Observations

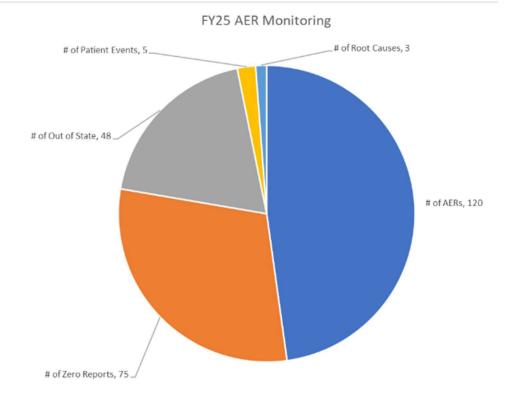


<u>Figure 7</u> provides a breakdown of the various sterile compounding observations found during FY 2025 sterile inspections. This chart breaks down 711 specific deficiencies, or "observations," noted during sterile inspections in Fiscal Year 2025. The most prominent issues are related to the cleanliness and physical condition of the sterile environment.

The three most common problems found were Cleaning (18.3%), Rooms Damage (16.6%), and Environmental Monitoring (14.5%). Combined, these three fundamental categories account for nearly half (49.4%) of all deficiencies. This data provides a clear road map for quality improvement efforts for sterile compounding facilities in Maryland Significant key findings were:

- A "Back-to-Basics" Approach is Needed: The most frequent observations are not complex or esoteric; they are failures in foundational pillars of sterile compounding (a clean, well-maintained
  space and proper monitoring). This suggests a need to reinforce core principles.
- Clear Priorities for Action for next fiscal year: The Board will prioritize resources to address these specific areas. The data strongly supports focusing on:
  - o Improving cleaning protocols and verification.
  - o Implementing robust facility maintenance schedules.
  - Ensuring environmental monitoring procedures are correctly performed and documented.

Figure 8: Adverse Events Reported to the Board



#### **AER Monitoring**

# 120 of Microbial Excursions Reported (48% of facilities reported at least one microbial excursion)

# of Zero Reports: 75 (30%)

• # of Root Cause Analysis (RCA): 3 (1.2%)

# of Patient Adverse Events: 5 (2.0%)

• # of Out-of-State AERs: 48 **(19%)** 

### Rehabilitation Monitoring

Substance use disorder within the healthcare profession is a serious issue that can have devastating consequences for both the individual and the public. To address this, the Maryland Board of Pharmacy partners with a dedicated rehabilitation program, Pharmacy Rehabilitation Services (PRS).

The PRS program provides support to pharmacists, pharmacy technicians, pharmacy students, and their families who are facing personal or health-related challenges. It is designed to help individuals manage conditions that could lead to impairment, such as stress, depression, substance use disorders, and other medical illnesses, including infectious diseases and neurological disorders.

When treatment is mandated by the Board, the Compliance Unit actively monitors licensees to ensure they adhere to their rehabilitation agreement. This monitoring process incorporates several key components, including:

• Regular progress reviews with counselors

- Participation in designated group treatments and therapies
- Random drug screenings
- Employer reports
- Medical or psychiatric

Program Statistics (Past Year)

The number of active cases fluctuates as individuals complete their programs and new participants enter. Over the past year, our records show a total of 15 active participants, categorized as follows:

Board-Mandated Cases: 10

- Profession: 8 Pharmacists and 2 Pharmacy Technicians
- Gender: 6 Males and 4 Females
- Outcome: 2 participants in this group successfully completed the PRS

program. Non-Board / Self-Reported Cases: 5

- Profession: 4 Pharmacists and 1 Pharmacy Technician
- Gender: 3 Males and 2 Females

The Board remains committed to helping licensees who are struggling with substance use disorders, ensuring a path to recovery while upholding its primary duty to protect public health and safety.

#### **Conclusion**

The Compliance Unit concluded a highly productive fiscal year. The data presented provides valuable insights into key operational areas, including inspections, disciplinary actions, and adverse event monitoring. Notably, the unit successfully eliminated existing backlogs while effectively managing its ongoing workload, ensuring timely regulatory oversight.

#### 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

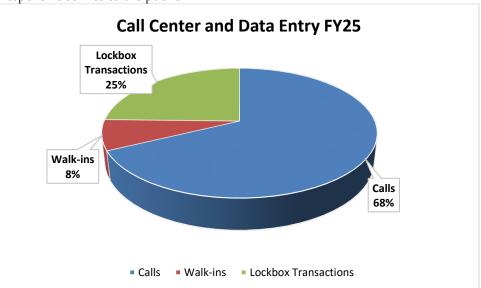
#### Overview

The Customer Service and Data Entry Unit serves as a vital point of contact for both licensees and the general public. This unit handles incoming phone calls and directs email inquiries to the appropriate staff members for resolution. It also provides in-person support at the walk-in center, helping customers navigate services such as application submission and online renewals.

In Fiscal Year 2025, the unit demonstrated its ongoing value in supporting the Board's mission. Staff answered **12,387 phone calls** and assisted **1,388 walk-in customers**, offering guidance and responding to a wide range of concerns.

Additionally, the unit plays a key role in processing documentation to ensure the timely handling of licensure applications. In FY25, the team processed **4,498 transactions** received through the agency's lockbox system, contributing to the efficient operation of licensing services.

The performance of the Customer Service and Data Entry Unit underscores its importance in delivering accessible and responsive service to the public.



#### Next Year at a Glance - FY26 Goals and Initiatives

Looking ahead to Fiscal Year 2026, the Customer Service and Data Entry Unit will focus on continued improvement and innovation in service delivery. Key priorities include:

- Enhanced Technology Integration: Implement new tools and systems to streamline application processing and improve call tracking and response management.
- **Expanded Staff Training:** Continue investing in staff development to ensure consistent, high-quality service across all channels, including phone, email, and in-person interactions.
- Data-Driven Improvements: Leverage customer service metrics and feedback to identify service gaps and guide process enhancements.
- Walk-In Center Optimization: Explore strategies to enhance the in-person experience for visitors.

These initiatives are aligned with the Board's mission to ensure responsive, efficient, and user-friendly services for the public and our stakeholders.

#### Conclusion

The unit continues to serve as a critical point of contact for individuals who are unable to find answers through the website or online FAQs. Over the past year, the Board has invested considerable time and effort into enhancing staff training and overall productivity. Recognizing that fulfilling our mission to serve the public also means strengthening support for our stakeholder community, we have prioritized improvements in service delivery. These efforts have led to faster response times, a better-informed stakeholder base, stronger relationships, and more effective, customer-focused service.

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