

STATE OF MARYLAND

Department of Health and Mental Hygiene

BOARD OF
PHARMACY



FISCAL YEAR 2021
ANNUAL REPORT

July 1, 2020

through

June 30, 2021

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 2021 BOARD COMMISSIONERS

President

Kevin Morgan

Chain Drug Store Representative

Secretary

Kristopher Rusinko

Home Infusion Representative

Treasurer

Jennifer Hardesty

Long Term Care Representative

Daniel Ashby

Acute Care Hospital Representative

Surinder Singal

Independent Pharmacist 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

Neil B. Leikach

Independent Pharmacist Representative

Kristen Fink

At-Large Representative

BOARD COUNSEL

Linda Bethman, AAG

Brett Felter, Staff Attorney

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Maryland Board of Pharmacy

FY 21 Year in Review



DEENA SPEIGHTS-NAPATA

EXECUTIVE DIRECTOR

Board Year In Review Summary

Information/Technology Development

- An electronic Distributor application was developed to ensure an easy distributor application process.
- An electronic inspection form was developed which cut by 50% the time needed to conduct and document an inspection
- Development of Fraud Detection protocol to increase efforts at protecting personal identifier information of licensees

Board of Pharmacy Collaborations

- Maryland Governor's Opioid Operational Command Center member

- UMES and Howard University pharmacy student presentations
- Internship/preceptor agreement with UMES established University of Baltimore Law School internship agreement in progress
- Maryland Society of Health-System Pharmacy member
- Maryland Office of Controlled Substances Administration
- Maryland Medicaid
- MDH Career Day
- MDH Office of Infectious Disease in promotion of syringe sales in pharmacies
- DEA Annual Drug Take Back Day promotion
- Regional Opioid 7 Substance Abuse Summit—Meeting with Washington DC, Virginia, and MD opioid epidemic strategists
- National boards of pharmacy annual regional and national meetings
- Maryland chain pharmacies
- USP 800 Director of Compliance certification
- Maryland Hospital Association—Naloxone Prescribing and Dispensing and Hospital Role in Addressing The Opioid Crises, Overdose Survivors Outreach Project, and Alcohol and Drug Use Screening webinar series
- Pharmacists Prescribing Contraceptives Workgroup
- Maryland Behavioral Health Administration, Prescription Drug Monitoring Program
- East Coast Regional Controlled Substances Coalition
- FDA Annual meeting

Procurements

- Software engineering contract to develop and monitor digital inspection form
- New Rehabilitation Committee contract developed and posted for bid. The new contract expands the scope of work, increases funding, and extends the term of service to up to 5 years.

Staffing

- National certification for staff inspectors and investigators
- National certification in sterile compounding inspections

Legislation and Regulation

- Implementation of Maryland Contraception prescribing legislation
- Investigational Drugs, Biological Products, and Devices - Right to Try Act
- Licensed Pharmacists - Risks of Opioid Addiction - Notifications
- State Board of Pharmacy - Registered Pharmacy Technicians - Exemption for Pharmacy Students

- Oncologists – Dispensing and Insurance Coverage of Orally Administered Cancer Chemotherapy
- Health Care Providers - Opioid Prescriptions - Limitations and Requirements
- Pharmacists - Administration of the Influenza Vaccination - Age Requirement
- Pharmacists - Substitution and Dispensing of Biological Products
- Courts - Criminal and Civil Immunity - Prescribing, Dispensing, and Administering Opioid Antagonists
- Public Health - Expedited Partner Therapy - Trichomoniasis and Pharmacist Dispensing
- Health Insurance - Specialty Drugs - Authority to Dispense
- Health Insurance - Prescription Drugs - Dispensing Synchronization

Events

- Annual Continuing Education Breakfast—Record number of over 300 pharmacists receiving continuing education credits
- Annual reception for departing board commissioners
- Annual staff appreciation luncheon

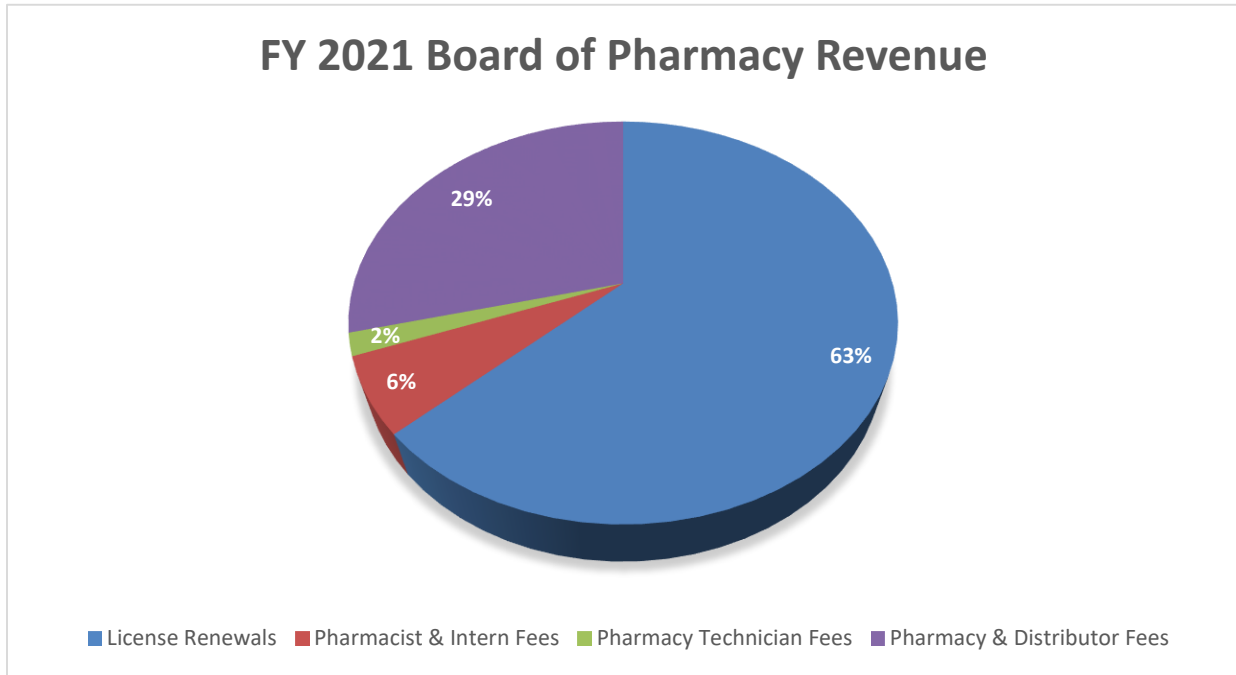
OPERATIONS UNIT REPORT

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	\$2,975,653.30	63.2%
Pharmacist and Intern Fees	\$289,314.78	6.1%
Pharmacy Technician Fees	\$83,190.75	1.8%
Pharmacy & Distributor Fees	\$1,362,290.75	28.9%
Revenue FY 2021	\$4,710,449.78	100%

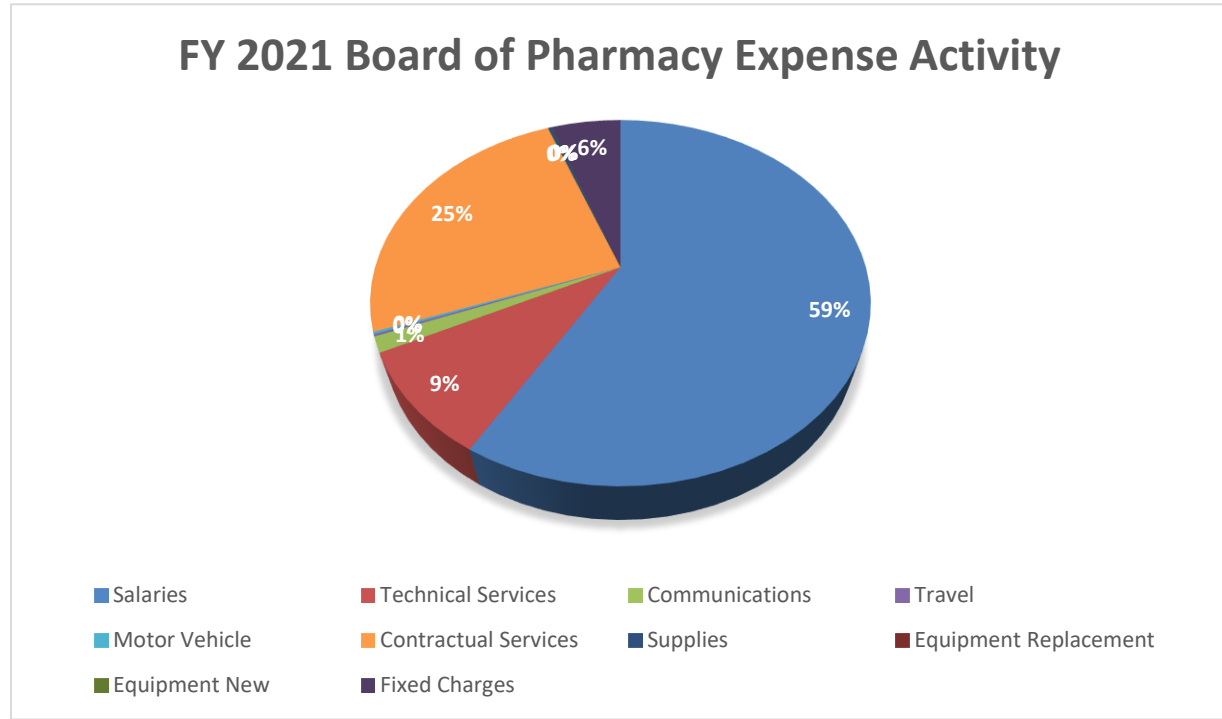
Board Revenue

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

The Board also transferred \$153,452.00 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 2021 Board of Pharmacy Expense Activity



Expense Category	Percent	Amount
Salaries	\$2,320,827.46	58.52%
Technical Services	\$362,714.08	9.15%
Communications	\$54,342.48	1.37%
Travel	\$7,562.34	0.19%
Motor Vehicle	\$8,102.41	0.20%
Contractual Services	\$985,585.15	24.85%
Supplies	\$11,680.88	0.29%
Equipment Replacement	\$399.98	0.01%
Equipment New	\$887.16	0.02%
Fixed Charges	\$213,478.66	5.38%
Total	\$3,965,580.60	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

This year was the cyber-attack and the Board was required to shut down all servers. The Board was able to recover and return back to partially being operational the first month to being fully operational in three months. MIS unit was able to implement a new VPN system to allowed employees to access licensing software and continue licensing operations. The Board began to use clouding services to store documents temporarily as we rebuild our network systems.

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 FY2021, the Licensing Unit processed 10,288 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 FY2021, the Licensing Unit processed 187 new distributor permits, an increase of 36% from FY2020. Additionally, the Unit processed 29 distributor renewals during the renewal period which occurred in FY2019/FY2020.

In FY2021, the Licensing Unit processed 2,977 pharmacist licenses (initial and renewal, including vaccine certifications), a 45% decrease compared to FY2020.

In FY2021, the Licensing Unit issued 36 Pharmacy Intern Graduate and 242 Pharmacy Intern Student registrations (initial and renewal), an increase from the previous fiscal year.

In FY2021, the Licensing Unit processed 216 WSD permits (187 new permits and 29 renewals) compared to 401 permits in FY2020 (203 new permits and 198 renewals). The large disparity in renewals is attributable to the WSD renewal period which occurred in FY2019.

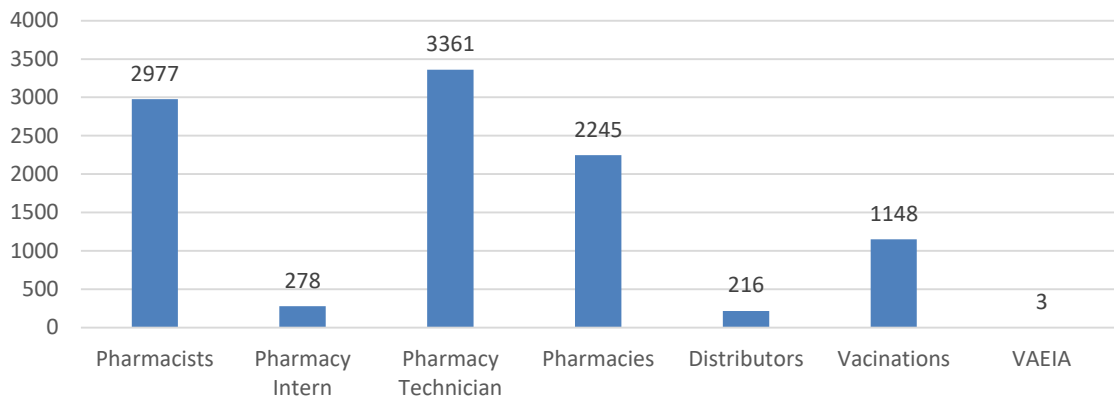
In FY2020, as in previous years, the Licensing Unit processed more technician renewal applications than initial applications. The Licensing Unit issued 3,361 technician registrations (initial, renewal, and reinstatement), a decrease of almost 45% from the previous fiscal year.

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

	FY 2021
Pharmacists	2,977
Pharmacy Intern	278
Pharmacy Technician	3,361
Pharmacies	2,245
Distributors	216
Vaccinations	1,148
VAEIA Acceptance Letter	3

2021			
New	Renewals	Reinstatements	Totals
617	2,360	0	2,977
194	84	8	278
1,581	1,765	15	3,361
155	2,090	0	2,245
187	29	0	216
336	812	0	1,148
3	0	0	3

Processed Licenses/Permits/Registration
(New Applications, Renewals and Reinstatements)
FY 21



COMPLIANCE UNIT REPORT

Fiscal Year 2021

Overview

The Compliance Unit protects the public health of Maryland's citizens by enforcing compliance with state laws and regulations regarding the practice of pharmacy. Unit staff consists of a Pharmacist Compliance Director, a Pharmacist Investigations Supervisor, three (3) Compliance Investigators, a Compliance Coordinator/Investigator, two (2) Laboratory Scientist Surveyors, a Pharmacy Technician Compliance Inspection Supervisor, and three (3) full-time Pharmacy Technician Compliance Inspectors.

Compliance Investigators perform the following functions:

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

Compliance Inspectors perform the following functions: ● inspect pharmacies and wholesale distributors

- forward inspection infractions for investigation

Complaints

The Compliance Unit receives complaints from a variety of sources and is charged with addressing each complaint. Individuals may obtain a complaint form by mail or from the Board of Pharmacy's website at www.health.maryland.gov/pharmacy and submit the completed form via fax, mail, email, or in person. All information related to each complaint is investigated and the results presented to the Board's Disciplinary Committee for review and recommended action for follow-up by Compliance Unit staff and/or to the full Board for further review and vote. If the nature of the complaint is outside the Board's purview, it is referred to the appropriate authority

Figure 1, below, provides the number of complaints received in the past nine fiscal years. Complaints received by the Board may include, but are not limited to, an actual complaint made by the public, referrals from other state or federal agencies, or deficiencies found during inspections. There were 491 complaints filed in FY20, compared to 298 complaints in FY21. Fiscal year 2021 complaints are down by approximately 40% compared to the last two years due to COVID. With the numbers improving and people getting vaccinated. Inspections were completed virtually. Due to the state of emergency beginning March 2020 caused the state to shut down and required no in-person inspections.

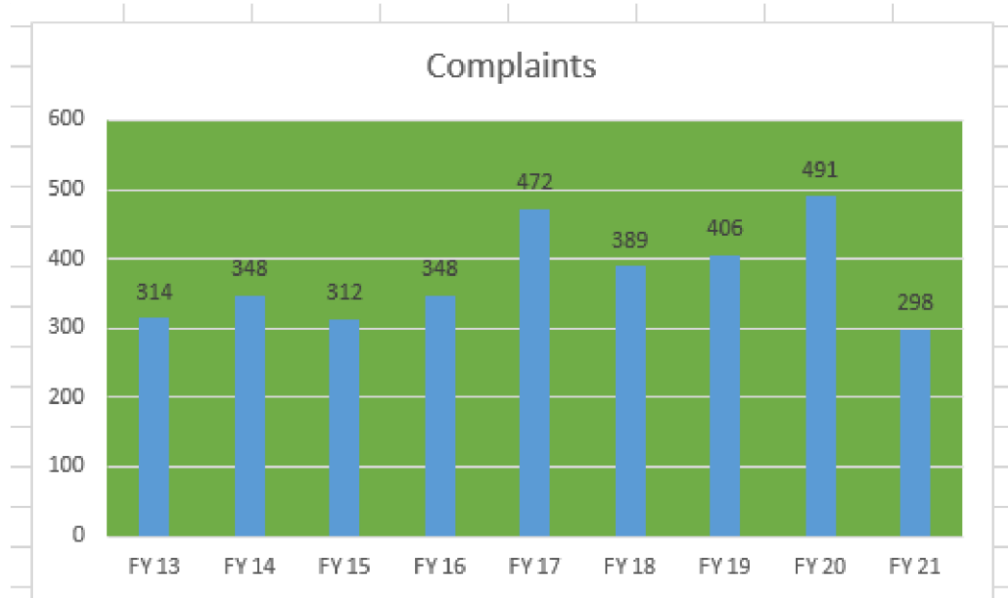
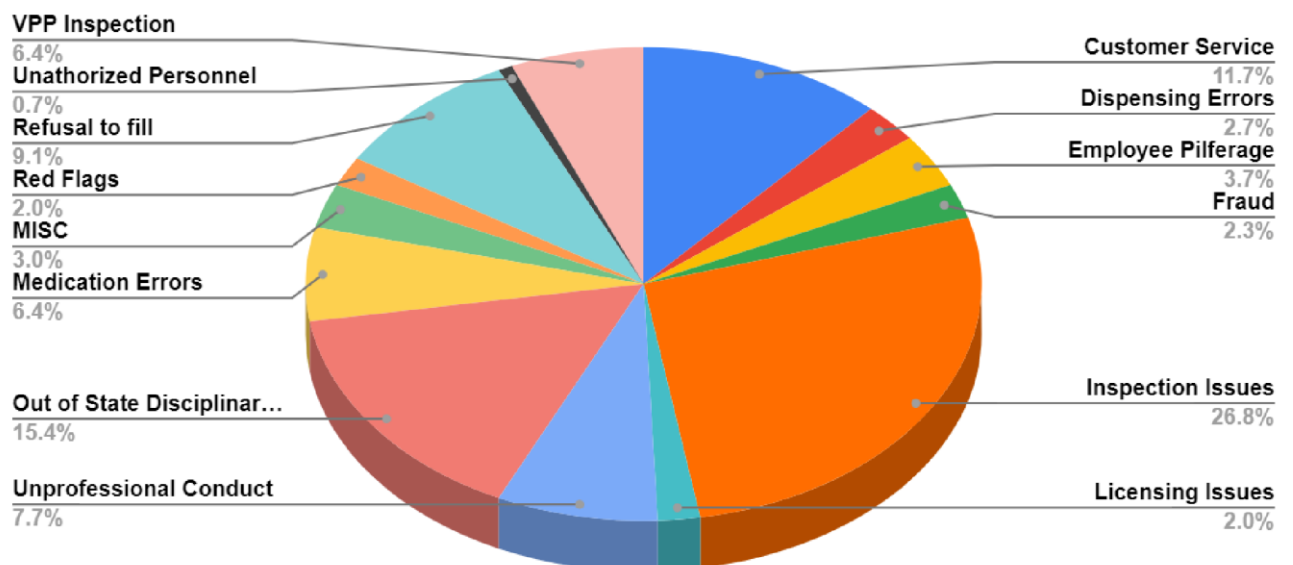


Figure 2, below, depicts the categories of complaints received in FY 21. The primary types of complaints included inspection issues (26%), out-of-state disciplinary actions (15%), and customer service concerns (11%). Majority of the inspection issues were narcotic discrepancies and unlicensed personnel. A few other issues of note during annual inspections involved the repository receptacle not being properly secured, CPR certifications invalid or expired, documents not provided timely, and USP <797> observations during sterile compounding.

Figure 2:

FY 21 Types of Complaints Received



Disciplinary Cases

All complaints are investigated by Board staff members. For the current fiscal year, the Board has taken formal or informal action on complaint cases including the opened complaints that were carried over from the previous fiscal year. Examples of informal actions include letters of education, letters of admonishment, and letters of agreement, informal deficiency letters, and closures. Examples of formal actions include a license or permit being placed on probation, suspension, or revocation, and deficiency fines. Every year there is some carryover of cases from the previous fiscal year. This is due to investigations still pending, those pending action from the attorney general's office, outstanding fines, suspensions pending revocation, probation and formal actions which involve licensee monitoring.

Figure 3, below, shows a trend of informal and formal actions taken by the Board over the past six years. The data shows 23 formal and 64 informal disciplinary actions by fiscal year. Disciplinary actions were down over the past year. For FY 21, most of the disciplinary actions were informal actions. The Board was compassionate due to the state's emergency and licensee situations.

Figure 3: Disciplinary action by Fiscal Year

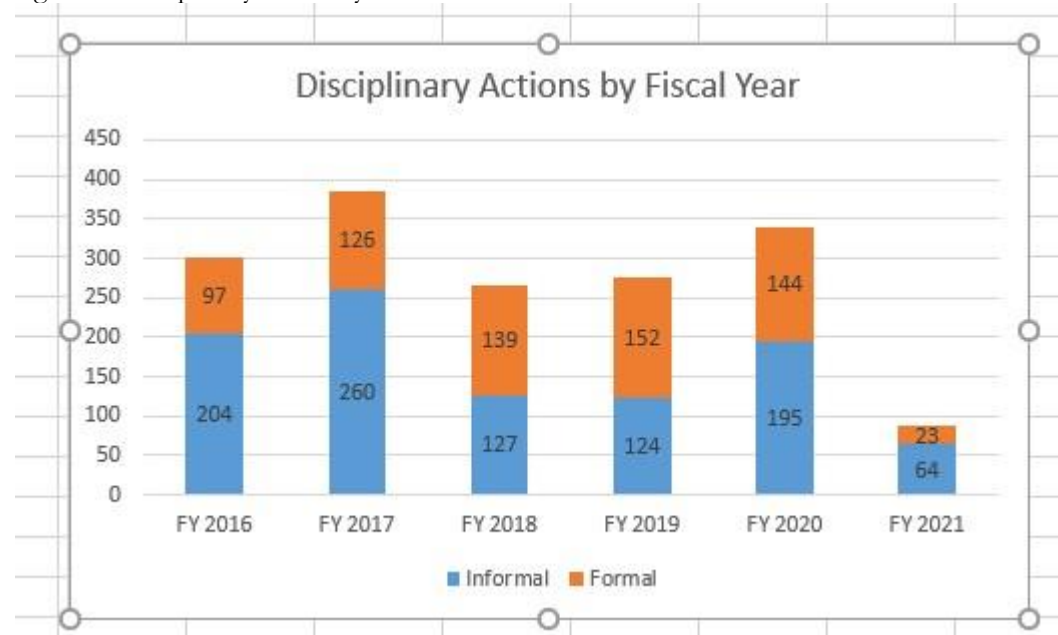


Figure 4, below, represents a categorical description of the various types of Board actions taken against pharmacists, pharmacy technicians, and establishments in the most recent fiscal year. Majority of the cases were closed and the Board determined not to pursue formal disciplinary action.

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



Figure 5, below, reflects the formal actions taken against pharmacists and pharmacy technicians in Fiscal Year 2021. Formal actions, including deficiency fines, issued are published in the Board of Pharmacy newsletter along with name of the licensee, registrant, and permit holder as well as posted on the Board of Pharmacy website. Most of the Board's actions were closed, pending and informal.

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



Majority of the actions were Formal resulting in a fine. Informal actions consisted of Cease and Desist Letters, Letters of Education or Admonishment. Very few cases were not made cases, closed administratively and referred to other agencies. Compared to fiscal year 2020, there were more formal actions.

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. Due to COVID-19 that caused a State of Emergency.

Inspections were conducted Virtually and on site.

The chart in Figure 5 reflects the total number of annual, opening inspections, closing inspections, miscellaneous inspections (relocation, change of ownership, investigative inspections), performed in Fiscal Year 2021. The Board completed 47% of annual inspections for all the facilities permitted in Maryland. Virtual Annual Inspections 1800, Opening Inspection

112, Closing Inspection 38, Change of Ownership/Renovations 27, Board Special Investigations 7. Total inspections of 2007. The inspection team also completed On Site Distributors 122, follow-up inspections for onsite narcotic audits 478 and virtual & on site COVID-19 vaccine storage inspections 331. All inspections were performed virtually. We started COVID vaccine storage inspections to confirm that vaccines were being stored properly at the correct temperature and monitored for security.

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

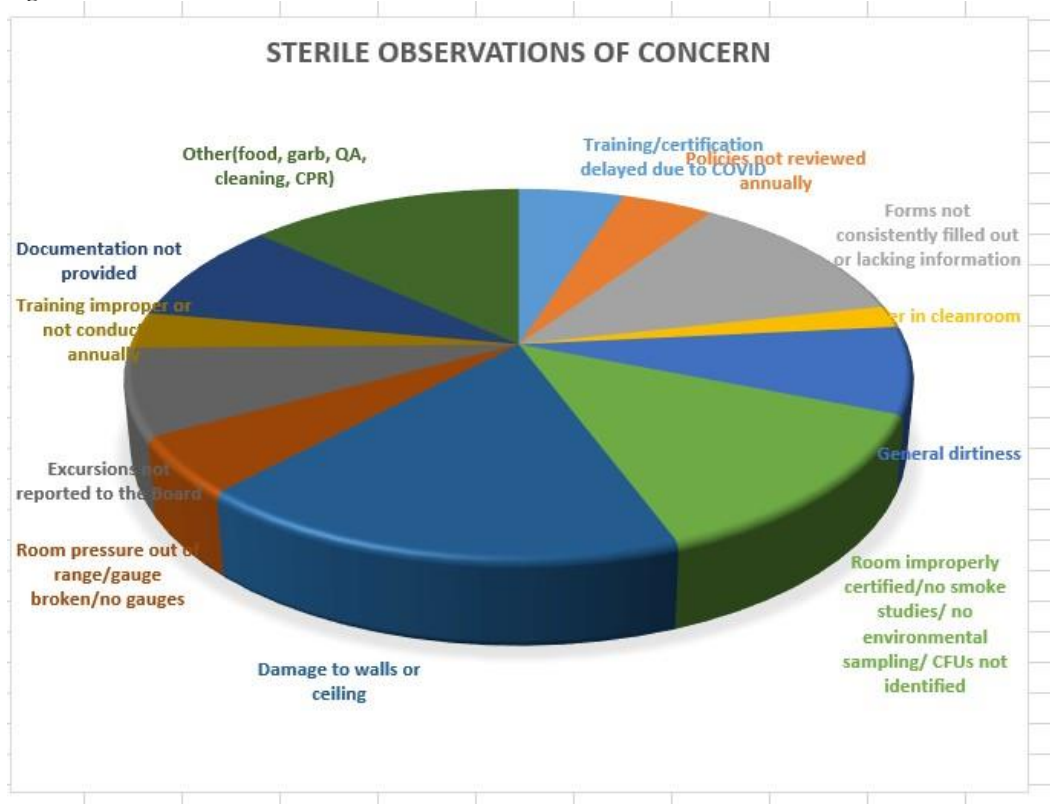
	FY2020	FY 2021
Annual Inspections	1505	1800
Opening Inspections	85	112
Closing Inspections	33	38
Change of Ownership/Renovations	27	19
Board Special Investigations	14	7
Total Inspections	1654	2007

Sterile Inspections:

130 annual sterile inspections
 39 sterile opening/renovation inspections 2 sterile pharmacy closings

There were a total of 171 sterile inspections completed over the year. Majority of the issues found in the below Figure 5 were forms not consistently filled out or lacking information, room improperly certified/no smoke studies/ no environment sampling/CFUs not identified, damage to walls or ceiling and miscellaneous.

Figure 7:



Rehabilitation Monitoring

Chemical dependence among health care professionals has been observed over the years to be at least as prevalent as with the plague in society. In addressing disciplinary actions, the Maryland Board of Pharmacy may opt to mandate substance abuse treatment. If treatment is so ordered, Compliance Unit staff is assigned to monitor the mandated licensees to ensure compliance with the terms of their orders. Public Orders may require routine reports to be submitted from the various programs that provide services to the monitored licensee. Services directly monitored may include, but are not limited to, referrals for the following: · random drug testing · substance abuse treatment or psychotherapy · participation in local NA/AA programs · psychiatric evaluations · employer reports · continued education (CE) requirements · any exams or courses as deemed necessary by the Board.

Over the course of the past year, the Board monitored approximately 14 licensees. Nine of them were pharmacists and five technicians. The number fluctuates as participants no longer need monitoring and new participants enter the program. The Board's designated rehab committee also monitors anonymous participants. The Board strongly believes in assisting licensees with substance use issues.

Conclusion

We hired two investigators to complete the investigation team. Unfortunately, due to unforeseen circumstances, one of them was not a good fit for the unit. We were able to "Go Live" with a complaint base electronic database called Compliance Enforcement Module. A position as Compliance Auditor was newly created to assist with DEA analyzation and data entry of cases.

Next Year at a Glance

For Fiscal Year 2022, the Compliance Unit plans to:

- Increase investigation team
- Attend more training in communication and investigation to improve skills
- Continue to resolve cases within goal
- Create and revise policies and procedures for the investigative team

CUSTOMER SERVICE

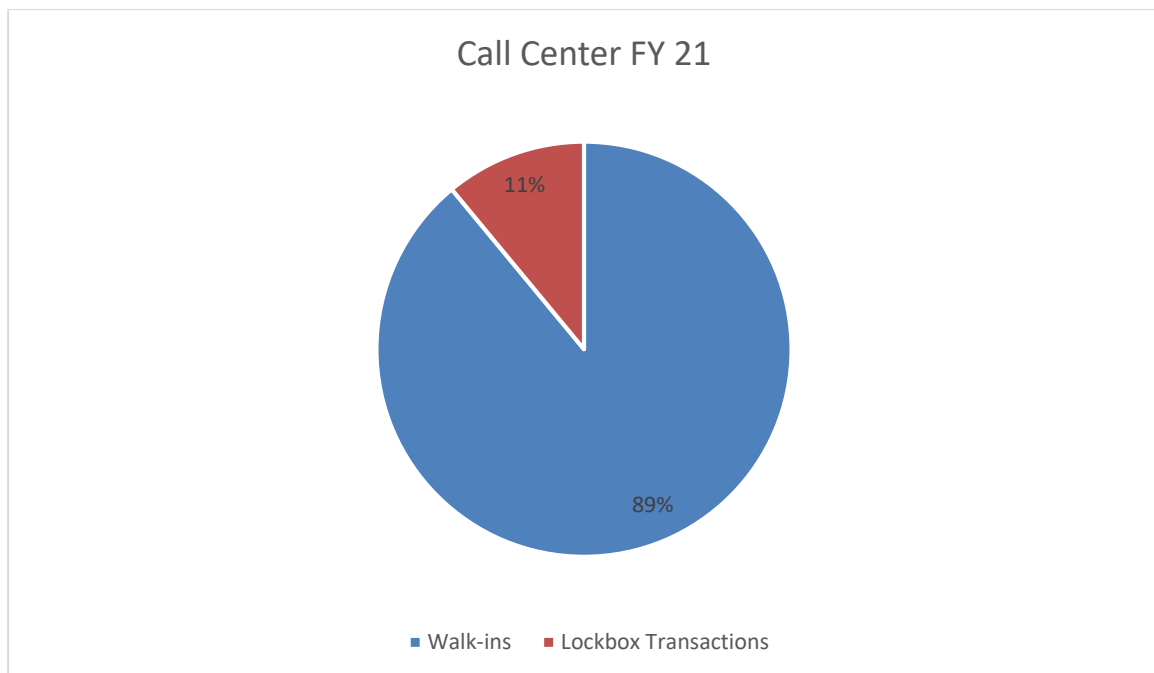
Overview

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 resumed (due to COVID) with accepting 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 FY21, we assisted 405 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; specific to call center operations · Learning more about the operation of other units.
- ✓ Responding accurately to clients; and communicating with applicants when necessary.



PROGRAM INTAKE ASSESSMENT AND EVALUATION

Overview

The data entry section of the Program Intake Assessment and Evaluation unit of the Maryland Board of Pharmacy (Board) was created to provide a smoother transition for licenses needing to be processed. Rather than licenses coming directly into the Board, a new system has been created whereby the licenses are processed through a lock-box system and then sent to the Board. This alleviates the Board handling large sums of money.

The Board now only accepts credit card transactions in the Walk-in center; all other transactions (checks and money orders) have to be sent to the lock-box address. This makes for a smoother operation here at the Board office.

In FY 2021 data processing processed a total of 3,280 lockbox transactions.

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** is combined into one unit. This helps staff to be able to respond to the areas needing increased resources.
- ✓ **Monthly staff** customer service unit meetings and bi-weekly meetings with staff has produced a well-trained staff focused on providing quality customer service.

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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