



Board of Pharmacy

ANNUAL REPORT FY 2023

July 1, 2022 - June 30, 2023

www.pharmacy.ohio.gov

OVERVIEW

MISSION

The Ohio Board of Pharmacy shall act efficiently, consistently, and impartially in the public interest to pursue optimal standards of practice through communication, education, legislation, licensing, and enforcement.

ABOUT THE BOARD

The Ohio Board of Pharmacy was established by the General Assembly in May of 1884 and consists of nine members, eight pharmacists and one member of the public, who are appointed by the Governor for terms of four years. The Board currently has a staff of ninety-nine full-time employees, including 11 pharmacists, who are responsible for carrying out day-to-day operations. The duties of the Board have grown over the years and encompass the enforcement of the following chapters of the Ohio Revised Code:

2925. – Criminal Drug Laws

3715. – Pure Food and Drug Law

3719. – Controlled Substance Act

3796. – Medical Marijuana Control Program

4729. – Pharmacy Practice Act & Dangerous Drug Distribution Act

4752. – Home Medical Equipment Services Providers

In enforcing these chapters, the Board licenses and regulates more than 95,000 professionals, including pharmacists, pharmacy interns and pharmacy technicians, and sites where drugs and home medical equipment are purchased and stored prior to delivery to a patient. The sites licensed by the Board include, but are not limited to, retail pharmacies, medical marijuana dispensaries, home medical equipment services providers, hospitals, drug wholesalers, prescriber offices, drug manufacturers, veterinary clinics, nursing homes, prisons and jails, emergency medical service organizations, medical gas distributors, and pain management clinics.

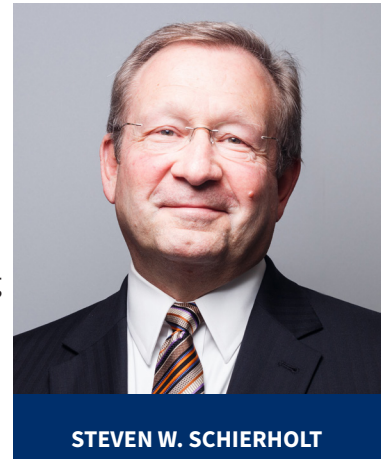
The Ohio Board of Pharmacy is charged with preventing, detecting, and investigating the diversion of dangerous drugs, including controlled substances. The Board investigates and presents evidence of violations of drug laws by any person and refers them for prosecution and/or administrative action. In these efforts, the Board works collaboratively with other state prescriber boards and law enforcement to conduct investigations of healthcare professionals (pharmacists, physicians, dentists, nurses, etc.) who may be in violation of Ohio law.

A LETTER FROM THE EXECUTIVE DIRECTOR

On behalf of the members of the Ohio Board of Pharmacy, I am pleased to present the Fiscal Year 2023 (FY 23) Annual Report. Over the past year, the Board focused on ensuring our licensees can best care for patients during the COVID-19 pandemic.

As a part of these efforts, we engaged in regular communication with licensees, giving them the most up-to-date information about vaccine booster availability, notifications on the newest pharmacy laws and rules, and providing resources and updates from the CDC, DEA, FDA, and other national organizations. We thank our licensees for diligently following the guidance we provided during this challenging time.

Some of our highlights from FY 23 include:



Expanded Access to Medications for Lower Income Patients – The Board, along with representatives from Ohio’s charitable pharmacies, led an effort to expand the types of medications that may be donated to drug repository programs. These programs can now accept medications that have been previously dispensed to a patient. This creates additional pathways for charitable pharmacies and other drug repositories to obtain high-cost drugs that patients would normally go without. To access a list of Ohio’s drug repositories that are accepting donations from the public, visit: www.pharmacy.ohio.gov/donate.

Classified Tianeptine (known as “Gas Station Heroin”) as a Schedule I Controlled Substance – Governor DeWine and the Board issued an emergency rule to classify all products containing an unregulated drug that produces opioid-like effects, tianeptine, as a Schedule I controlled substance. For more information, visit: www.pharmacy.ohio.gov/TIA.

Continued to Provide Law and Responsible Person Review Presentations – The Board continued its presentation series, covering the latest updates on changes to federal laws and rules. More than 1,700 pharmacists, pharmacy interns, pharmacy technicians, and pharmacy compliance staff registered for the virtual events.

Ensured Licensee Compliance with Ohio Laws – The Board’s compliance staff conducted 2,548 inspections of Ohio licensed facilities to ensure compliance with Ohio law and rules.

Enforcement of the Drug Laws of Ohio – OARRS agents indicted a Northeast Ohio physician on 32 criminal charges stemming from the unlawful distribution of controlled substances and healthcare fraud. The physician pleaded guilty in the United States District Court - Northern District of Ohio and was sentenced to six years imprisonment.

On behalf of the Ohio Board of Pharmacy, thank you for taking the time to review our 2023 Annual Report. The Board remains committed to working closely with federal, state, and local partners to protect the health and safety of all Ohioans.

Sincerely,



Steven W. Schierholt
Executive Director

LICENSING

The Licensing Department's responsibilities include processing of all licensure and registration applications, all verifications of good standing, organization of all reciprocity reviews and support to all field agents, inspectors, and specialists. The Board licenses/registers all of the following:

- Pharmacists, pharmacy interns, and pharmacy technicians.
- Terminal Distributors of Dangerous Drugs (TDDD): Sites where dangerous drugs are purchased and stored prior to delivery to a patient such as retail pharmacies, hospitals, prescriber offices, veterinary clinics, nursing homes, prisons and jails, emergency medical service organizations and pain management clinics.
- Distributors of Dangerous Drugs: Sites who are engaged in the sale of dangerous drugs at wholesale. A distributor of dangerous drugs includes the following license types: manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, and wholesale distributor of dangerous drugs (includes broker and virtual wholesaler).
- Home Medical Equipment Service Providers (HME): Sites who are engaged in the sale, delivery, installation, maintenance, replacement, or demonstration of home medical equipment.
- Medical marijuana retail dispensaries and dispensary employees.

FY 2023 ACCOMPLISHMENTS

- **The department made it a priority for pharmacy personnel applications (for pharmacists, pharmacy interns, and pharmacy technicians) to be reviewed within 1 to 2 business days after submission to the Board.**
- **Developed a streamlined application for pharmacy technicians who obtained a national certification (PTCB or ExCPT) to easily upgrade their registration type. The new application eliminates the need for technicians to submit documents the Board has on file.**
- **As part of the Board's Pharmacy Workload Advisory Committee recommendations, the Board redesigned the Pharmacy Technician licensing pages to be more user friendly and incorporate more videos, Frequently Asked Questions (FAQ) sections, and step-by-step guides.**

FY 2023 Licensing Statistics

Type of License	FY 2023 Active*	FY 2023 New†
Pharmacist	23,093	1,151
Pharmacy Intern	4,013	727
Pharmacy Technician	36,628	9,584
Terminal Distributors	24,138	1,870
Drug Distributors	2,429	198
HME Service Providers	895	66
Medical Marijuana Dispensary Employees	3,637	1,753
Dispensary - Provisional	11	6
Dispensary - Certificate of Operation	78‡	36‡
Total	95,021	15,391

**Represents all licenses that were active during FY 2023. Issue Date is before July 1, 2023 and expiration date greater than June 30, 2022.*

†Represents all licenses that were issued during FY 2024. Issue Date is on or between July 1, 2022 and June 30, 2023.

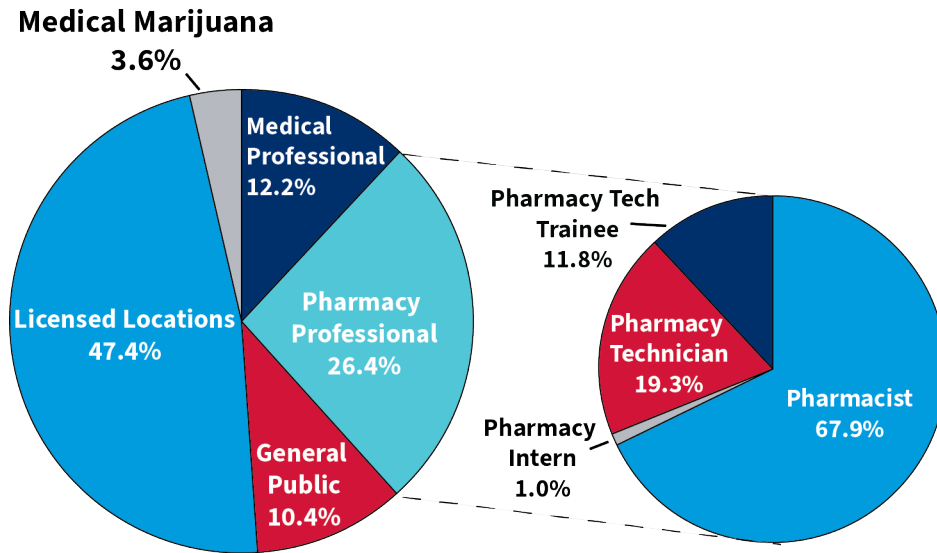
‡Refers to the total dispensary licenses issued, this includes new licenses that have been issued due to Change of Ownership.

COMPLIANCE AND ENFORCEMENT

The primary responsibility of the Compliance & Enforcement Department, in coordination with the Legal Department, is the investigation and prosecution of administrative violations and criminal acts perpetrated by license holders and applicants, as well as prescription drug-related crimes committed by healthcare professionals and the public. Department staff also perform pharmacy inspections; train pharmacy, medical, and law enforcement personnel; and assist outside agencies with criminal investigations involving prescription drugs.

- **Board agents continued to work closely with the United States Department of Justice Appalachian Region Prescription Opioid (ARPO) Strike Force identifying, investigating, and indicting aberrant controlled substance prescribers. Agents also contributed to overdose fatality review committees in Franklin and Cuyahoga counties where they examined overdose data attempting to identify methods to reduce Ohio's fatal drug overdoses.**
- **OARRS agents indicted a Northeast Ohio physician on 32 criminal charges stemming from the unlawful distribution of controlled substances and healthcare fraud. The physician pleaded guilty in the United States District Court - Northern District of Ohio and were sentenced to six years imprisonment.**
- **A board investigation resulted in the indictment of an eastern Ohio physician. The physician was found guilty in federal court on 24 counts for trafficking in drugs and healthcare fraud. Board agents investigated this matter as part of the ARPO initiative.**
- **A central Ohio physician and pharmacist investigated by Board agents were charged and found guilty on 11 counts of illegal distribution of controlled substance in the United States District Court - Southern District of Ohio.**
- **Board agents contributed to an investigation in which a Southeast Ohio physician was indicted on eight counts of unlawful distribution of controlled substances in United States District Court - Southern District of Ohio.**
- **Compliance staff conducted 2,548 inspections and issued 1,113 written warnings. Five hundred forty-one cases were referred to the Board's Legal Department to be evaluated for administrative action. Compliance presented 32 cases to the Board for summary suspension consideration.**

FY 2023 CASE SUSPECTS BY TYPE



Administrative actions taken against a licensee can range from permanent revocation to imposition of fines or, for pharmacists, interns and technicians, additional continuing education requirements. Suspensions and probations are also utilized, particularly in cases of substance abuse where rehabilitation is deemed possible.

The tables below and on the next page provide a summary of administrative actions taken by the Board in FY 2023.

Case Type	# of New Cases
Consumer Complaint	361
Drug Security	251
Theft of Drugs	199
Error in Dispensing	165
Illegal Processing of Drug Documents	165
Questionable Dispensing	148
Minimum Qualifications of TDDD/WDDD	125

ADMINISTRATIVE ACTIONS IN FY 2023 - PHARMACY

Summary Suspensions* (Total)	32
Summary Suspensions (Pharmacy Technicians)	22
Summary Suspensions (Pharmacists)	9
Summary Suspensions (Interns)	1
Inspections	2,548

*A summary suspension is a method of immediately suspending a license or registration. It is utilized if the alleged offense presents "a danger of immediate and serious harm to others." Licensees and registrants that are summarily suspended are still entitled to a full hearing by the Board in accordance with Chapter 119. of the Revised Code.

In our continuing effort to educate stakeholders, Compliance presented to the following groups:

- **Ohio Board of Pharmacy**
 - Law Review (4)
 - Responsible Person Roundtable (2)
 - Responsible Person 101 (2)
 - Loss and Prevention Roundtable (1)
- **Pharmacy Associations (OPA, OSHP, SSHP-local chapters)**
 - Law review
 - DSCSA
- **Law Enforcements**
 - NADDI
 - Southern Ohio Collaborative
- **Regulatory Agency**
 - FDA - Compounding Drugs, DSCSA
 - NABP - DSCSA
- **Other Associations**
 - Ohio Dermatological Association (ODA)
 - Cedarville University
 - Healthcare Distribution Alliance (HDA)

POLICY AND COMMUNICATIONS

The Policy and Communications Department is responsible for the development and implementation of strategies to advance the Board's policy initiatives and outreach to external stakeholders, including all of the following:

- Articulating the Board's position on legislation proposed by the General Assembly.
- Facilitating the administrative rules process by coordinating the Board's Rules Review Committee, submission of proposed rules to the Common Sense Initiative, and rule filings with the Joint Committee on Agency Rule Review.
- Coordinating the Board's responses to legislative committee requests and other inquiries from individual members and General Assembly staff.
- Assisting with the implementation of legislative and regulatory changes.
- Developing educational materials and guidance for licensees on Board initiatives and policy changes.
- Serving as a liaison to the public and the media on the role of the Board in protecting the health and safety of Ohioans.

FY 2023 ACCOMPLISHMENTS

- **The Policy and Communications Department sent over 300,000 individual email updates to licensees as a part of the Board of Pharmacy's COVID-19 response efforts, including updated guidance for the end of the Federal Public Health Emergency (PHE) effective May 12, 2023.**
- **Published guidance on the electronic prescribing of Schedule II controlled substances in response to the passing of House Bill 193. The guidance can be found here: www.pharmacy.ohio.gov/C2.**
- **Secured passage of HB 558 (134th General Assembly), which expanded the Board's Drug Repository Program by allowing charitable pharmacies, hospitals, and nonprofit clinics to accept or distribute donated drugs that are not in their original sealed and tamper-evident unit dose packaging.**
- **Oversaw the successful development and implementation of new rules governing drug repositories. For more information visit: www.pharmacy.ohio.gov/repository.**

OHIO AUTOMATED RX REPORTING SYSTEM



Board of Pharmacy

Ohio Automated Rx Reporting System

To address the growing misuse and diversion of prescription drugs, the Ohio Board of Pharmacy created Ohio's prescription drug monitoring program, known as the Ohio Automated Rx Reporting System (OARRS). Established in 2006, OARRS collects information on all

outpatient prescriptions for controlled substances (and two non-controlled drugs, gabapentin and naltrexone) dispensed by Ohio-licensed pharmacies and personally furnished by licensed prescribers in Ohio. Drug wholesalers are also required to submit information on all controlled substances sold to an Ohio licensed pharmacy or prescriber. The data is reported every 24 hours (except wholesalers who report monthly) and is maintained in a secure database.

For more information on OARRS, including resources, reports, and data, please visit the OARRS website at <https://www.pharmacy.ohio.gov/OARRS>

FY 2023 ACCOMPLISHMENTS

- **OARRS was the first PDMP in the country to receive certification from the Centers for Medicare and Medicaid Services. As a certified system, OARRS now receives CMS funding to support the system and share data with the Ohio Department of Medicaid.**
- **In FY 2023, the Board received a \$1.4 million dollar grant from the U.S. Department of Justice to promote collaboration among the Board, law enforcement, and prosecutors by funding four Board of Pharmacy Enforcement Agents (OARRS Agents) to conduct criminal investigations of drug diversion utilizing data from OARRS.**
- **The Board was awarded \$1.36 million from the U.S. Department of Justice to assess and implement strategies to maintain and improve the information collected in OARRS to ensure accurate information is available to support safe prescribing and clinical decision making by healthcare providers. The grant will continue to support the capability of the Board to analyze and use PDMP data to implement data driven strategies to identify and reduce drug diversion, aberrant prescribing, and substance use disorder in Ohio.**
- **OARRS is a highly utilized system. In FY 2023, more than 425 million patient reports were requested by OARRS users, averaging 35.4 million patient reports per month.**

MEDICAL MARIJUANA CONTROL PROGRAM

As one of the three state agencies charged with the implementation of the Ohio Medical Marijuana Control Program (MMCP), the Board is responsible for:

- The patient and caregiver registry;
- Licensing of retail dispensaries;
- Licensing of dispensary employees;
- Managing the toll-free helpline;
- Approving new forms of medical marijuana.

The Board is responsible for reviewing and assigning product identifications for medical marijuana products.

MEDICAL MARIJUANA CONTROL PROGRAM HAS MOVED

As of January 1, 2024, the Medical Marijuana Control Program has been transferred from the Board of Pharmacy to the Ohio Department of Commerce. All responsibilities previously held by the Board of Pharmacy will now be completed by the Department of Commerce Division of Cannabis Control (DCC). Additionally, the State Medical Board of Ohio is responsible for certifying physicians to recommend medical marijuana and approving qualifying conditions.

For more information about the Medical Marijuana Control Program, please visit the Board of Commerce's website: www.com.ohio.gov/divisions-and-programs/cannabis-control/



STATEMENT OF ACTIVITIES

FOR STATE FISCAL YEAR 2023 (JULY 1, 2022 - JUNE 30, 2023)

FY 2021 Revenue	
Fund 4K90 (Operating Expenses) License fees and other assessments as well as various fines, forfeited bonds and bail collected by the State Board of Pharmacy that are not credited to Fund 4A50.	\$14,878,862
Fund 4A50 (Drug Law Enforcement) Fines and bail or property forfeitures that result from the Board's drug law enforcement efforts.	\$96,090
Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grants distributed by the U.S. Department of Justice, Office of Justice Programs.	\$1,245,560
Fund 3HH0 (OARRS Integration) Grant money received from Medicaid to support OARRS integration with medical record systems.	\$2,054,107
Fund 3HM0 (Equitable Sharing Treasury) Money derived from the proceeds of investigations worked with federal agencies under the administrative umbrella of the Department of the Treasury	\$0
Fund 3HN0 (Equitable Sharing Justice) Money derived from the proceeds of investigations worked with federal agencies under the administrative umbrella of the Department of Justice	\$6,930
Fund 5SG0 (Drug Database) Donations and grant subawards used to make improvements to OARRS under ORC 4729.83.	\$0
Fund 5SY0 (Medical Marijuana Control Program) Revenue comes from fees paid by dispensaries and patients.	\$18,832,634
TOTAL REVENUE FY 2023	\$35,060,076
FY 2023 Expenses	
Fund 4K90 (Operating Expenses) Used by the Board to administer and enforce laws governing the legal distribution of dangerous drugs and the practice of pharmacy. A portion of this funding also goes to support the operation of Ohio's prescription drug monitoring program known as the Ohio Automated Rx Reporting System (OARRS).	\$12,597,898
Fund 4A50 (Drug Law Enforcement) Used by the Board for drug law enforcement purposes only.	\$292
Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grants distributed by the U.S. Department of Justice, Office of Justice Programs.	\$1,245,560
Fund 3HH0 (OARRS Integration HITECH) Grant money received from the Ohio Department of Medicaid to support OARRS integration with medical record systems.	\$1,169,233
Fund 3HN0 (Equitable Sharing Justice) Money derived from the proceeds of investigations worked with federal agencies under the administrative umbrella of the Department of Justice	\$0
Fund 5SG0 (Drug Database) Implement enhancements to OARRS.	\$0
Fund 5SY0 (Medical Marijuana Control Program) Used by the Board to implement the Medical Marijuana Control Program under ORC Chapter 3796.	\$3,426,427
TOTAL EXPENSES FY 2023	\$18,439,410

[1] Expenses reflect actual cash disbursements during FY 2023 and include some expenses budgeted with FY 2022 appropriation. Similarly, some expenses budgeted with FY 2023 appropriation will be disbursed in FY 2024 and reflected on that year's annual report.

[2] Pursuant to section 119.092(E), the Ohio Board of Pharmacy did not pay any fees to a prevailing eligible party in Fiscal Year 2023.



Board of Pharmacy

The Ohio Board of Pharmacy is committed to protecting the health and safety of all Ohioans through the administration and enforcement of laws governing the legal distribution of dangerous drugs and the practice of pharmacy. Should you need any assistance or additional information, please do not hesitate to contact the Board.

Board Members

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Jason M. George, PharmD
N. Victor Goodman, Public Member
Tod J. Grimm, R.Ph., MBA
Jeff Huston, BPharm, PharmD, R.Ph.
D. Rich Miller III, B.S., R.Ph.
Christine Pfaff, R.Ph.

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