

ANNUAL REPORT FY 2024

July 1, 2023 - June 30, 2024

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-two 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
- 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 93,000 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, 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 2024 (FY 24) Annual Report. Some of our highlights from FY 24 include:

Outpatient Pharmacy Minimum Standards Rules – In May 2024, new outpatient pharmacy minimum standards rules went into effect. These rules are the result of the work of the Ohio Pharmacist Workload Advisory Committee and feedback provided by pharmacy professionals through various surveys and comment periods. To assist licensees in complying with these new regulations, the Board developed a frequently asked questions document that can be accessed here: www.pharmacy.ohio.gov/minstandard



Saving Lives Through Fentanyl Test Strip Distribution – The Ohio Board of Pharmacy, in partnership with the Office of Governor Mike DeWine, RecoveryOhio, the Ohio Department of Mental Health and Addiction Services, and the Ohio Department of Health, began distributing fentanyl test strips and educational handouts to all Ohio licensees. In FY 2024, we distributed over 130,000 test strips and over 119,000 educational handouts. If you are a Board of Pharmacy licensee and would like to order some, visit: www.pharmacy.ohio.gov/ftsorder

Educating Our Licensees – The Board continued its presentation series, covering the latest updates on changes to state and federal laws and rules. 1,946 pharmacists, pharmacy interns, pharmacy technicians, and pharmacy compliance staff registered for the virtual and in-person events.

New Version of OARRS Overdose Risk Score – In November 2023, the Board of Pharmacy in collaboration with Bamboo Health implemented a new version of the Unintentional Overdose Risk Score (ORS). The ORS uses factors available in the patient's dispensing record to understand prescribing patterns associated with unintentional overdose deaths. Along with the ORS, the new version of the tile displays additional risk indicators, including controlled substance-specific exposures. For more information on the ORS risk score, visit: www.pharmacy.ohio.gov/ORS.

On behalf of the Board, thank you for taking the time to review the Ohio Board of Pharmacy's Fiscal Year 2024 Annual Report. We remain steadfast in our commitment to protecting the health and safety of all Ohioans.

Sten M. Schieholt

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 (HME) Services Providers: Sites who are engaged in the sale, delivery, installation, maintenance, replacement, or demonstration of home medical equipment.

FY 2024 ACCOMPLISHMENTS

- Initiated and implemented a change to the pharmacy technician trainee registration period from twelve (12) months to eighteen (18) months to remove administrative burdens of the trainee and pharmacy to request extensions of the registration period.
- Completed an audit of all certified pharmacy technicians' national certification (PTCB or ExCPT) status to ensure compliance with the Board's requirement to maintain the certification in addition to the Board's registration. The audit work will allow the Board to communicate proactively to the certified technicians to educate them on requirements before their certification expires.
- Updated guidance and educated terminal distributors who may now be exempt from licensure requirements related to law changes under H.B. 33. The specific changes included prescriber practices treating opioid use disorder, nursing homes and other facilities providing medical oxygen to patients, and food service and manufacturing/plumbing trades possessing medical grade nitrous oxide.

FY 2024 Licensing Statistics

Type of License	FY 2024 Active*	FY 2024 New [†]
Pharmacist	24,249	1,141
Pharmacy Intern	4,770	757
Pharmacy Technician	38,085	9,472
Terminal Distributors	23,228	1,645
Drug Distributors	2,279	153
HME Service Providers	976	79
Total	93,587	13,247

^{*}Represents all licenses that were active during FY 2024. Issue Date is before July 1, 2024 and expiration date greater than June 30, 2023.

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

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 collaborated extensively with local drug task forces and the United States
 Department of Justice Prescription Strike Force to identify and prosecute egregious
 prescribers of controlled substances within Ohio. Their work led to the conviction of
 an Eastern Ohio pain management physician on 24 counts of unlawful distribution of
 controlled substances, resulting in an 84-month prison sentence.
- In Northern Ohio, Ohio Automated Rx Reporting System (OARRS) agents, in partnership
 with federal authorities, secured the conviction of a physician for prescribing controlled
 substances without a legitimate medical purpose. This prescriber received a 42-month
 prison sentence and was ordered to repay over \$850,000 in restitution.
- Board investigations also led to the indictment and conviction of a physician and pharmacist in Central Ohio for unlawful distribution of controlled substances. The pharmacist was sentenced to 6 months of incarceration followed by three years of supervised release.
- The OARRS Early Intervention program expanded its reach by adding seven new counties, bringing the total number of participating county prosecutor's offices to 22. OARRS Early Intervention agents are actively working to reduce fatal drug overdoses in Ohio by contributing to eleven fatal overdose review committees.
- Compliance continued its focus on education and outreach. Staff developed and delivered ten continuing education webinars—covering topics such as law review, RP 101, RP Roundtable, and Loss Prevention roundtable—drawing over 1,800 registered attendees. Additionally, staff partnered with ten associations to provide training and collaborated with four colleges and universities to offer guidance and instruction to students. Compliance also worked with the U.S. Food and Drug Administration to inform licensees about IV hydration and peptide compounding clinics.
 - *See Events/Organizations listed on page 7.
- Compliance staff conducted 2,944 inspections and issued 1,081 written warnings.
 Five hundred twenty-four cases were referred to the Board's Legal Department for administrative action. Additionally, Compliance presented 35 matters to the Board for summary suspension consideration.

FY 2024 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 2024.

Suspect Types	Total
Pharmacist	623
Pharmacy Intern	5
Pharmacy Technician Trainee	81
Registered Pharmacy Technician	100
Certified Pharmacy Technician	42
Pharmacy Professional [TOTAL]	851
Pharmacies (licensed locations)	1144
Medical Doctor	67
Doctor of Osteopathic Medicine	11
Medical Assistant	1
Nurse	132
Dentist	21
Veterinarian	11
Registered Vet Tech	1

Top 10 Case Types Investigated	Total
Drug Security	284
Background Investigation	277
Minimum Qualifications of TDDD/ WDDD	191
Suspicious Purchases	172
Theft of Drugs	170
Error in Dispensing	141
Working Conditions/Minimum Standards	121
Deception to Obtain Dangerous Drugs	109
Questionable Dispensing	97
Late Renewal of TDDD/WDDD License	87

Inspection Data		
Total Inspections	2,944	
Written Warnings	1,081	
Administrative Case Data		
Admin. Cases Referred to the Legal Department	524	
Summary Suspensions	35	

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.

*Events/Organizations:

Pharmacy Associations:

OPA

Nicotine Replacement Therapy Course OPA Annual Conference – Law Review OPA Midyear Conference – DSCSA

OSHP

OSHP Annual Conference – Law Review
SSHP – Cedarville University – Law
Review
Ohio College of Clinical Pharmacy

Ohio College of Clinical Pharmacy (OCCP) – Law Review

Other Associations:

- Ohio Dermatological Association Law Review
- NADDI Diversion Awareness
- Southern Ohio Collaborative Group DSCSA
- Ohio Animal Welfare Federation Euthanasia Certification Course
- Henry Schein Wholesale Drug Distributor
- Healthcare Distribution Alliance (HDA) DSCSA Ohio Perspective

- Ohio Midwest Veterinary Conference Law Update
- Partnership for DSCSA Governance (PDG) DSCSA Ohio Perspective
- National Association of Boards of Pharmacies
- National Association of State Controlled Substance Authorities

College of Pharmacies:

- NEOMED New Pharmacy Student Orientation
- Cedarville Neuropsych Module Addiction and Abuse
- Ohio University Intro to Board of Pharmacy
- Cedarville University Alumni Association
 Law Update

FDA:

Intergovernmental Compounding
 Meeting – IV hydration and clinics/peptide
 compounding.

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 2024 ACCOMPLISHMENTS

- The Policy and Communications Department sent over 2.6 million email updates to licensees in FY 24.
- Oversaw the successful development and implementation of new rules for continuous quality improvement and error reporting; outpatient pharmacy minimum standards; and licensing rules for distributors of dangerous drugs, pharmacists, and pharmacy interns.
- Issued new inspection guides for distributors of dangerous drugs, which assists licensees with preparing for inspections by linking to relevant rules, educating licensees on important definitions, and giving reminders of when a licensee is required to submit notification or additional information to the Board.
- Implementation of statewide rebranding of the Board's website, guidance documents, email communications, and training videos.

OHIO AUTOMATED RX REPORTING SYSTEM



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.phamacy.ohio.gov/OARRS

FY 2024 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.
- The Board received a \$1.36 million grant 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 2024, more than 482 million patient reports were requested by OARRS users, averaging 40.1 million patient reports per month.
- As an effort to provide prescribers and pharmacists with information to assist with clinical decisions surrounding safe prescribing, the Board enhanced the NarxCare functionality in OARRS with a new version of the Overdose Risk Score (ORS). The ORS is an indicator that provides the potential of unintentional opioid overdose for a patient based on the patient's prescription drug history.

STATEMENT OF ACTIVITIESFOR STATE FISCAL YEAR 2024 (JULY 1, 2023 - JUNE 30, 2024)

FY 2024 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.	\$10,673,283
Fund 4A50 (Drug Law Enforcement) Fines and bail or property forfeitures that result from the Board's drug law enforcement efforts.	\$13,286
Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grants distributed by the U.S. Department of Justice, Office of Justice Programs.	\$1,510,559
Fund 3HH0 (OARRS Integration) Grant money received from Medicaid to support OARRS integration with medical record systems.	\$623,365
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	\$0
Fund 5SG0 (Drug Database) Donations and grant subawards used to make improvements to OARRS under ORC 4729.83.	\$516,595
Fund 5SY0 (Medical Marijuana Control Program) Revenue comes from fees paid by dispensaries and patients.	\$10,628,729
TOTAL REVENUE FY 2024	\$23,965,818
FY 2024 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).	\$12,359,493
Fund 4A50 (Drug Law Enforcement) Used by the Board for drug law enforcement purposes only.	\$150
Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grants distributed by the U.S. Department of Justice, Office of Justice Programs.	\$1,510,559
Fund 3HH0 (OARRS Integration HITECH) Grant money received from the Ohio Department of Medicaid to support OARRS integration with medical record systems.	\$623,365
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	\$0
Fund 5SG0 (Drug Database) Implement enhancements to OARRS.	\$2,962,713
Fund 5SY0 (Medical Marijuana Control Program) Used by the Board to implement the Medical Marijuana Control Program under ORC Chapter 3796.	\$1,453,040
TOTAL EXPENSES FY 2024 [1, 2]	\$18,909,320

^[1] Expenses reflect actual cash disbursements during FY 2024 and include some expenses budgeted with FY 2023 appropriation. Similarly, some expenses budgeted with FY 2024 appropriation will be disbursed in FY 2025 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 2024.



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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