



STATE OF
OHIO
BOARD OF PHARMACY

ANNUAL REPORT FY 2019

July 1, 2018 - June 30, 2019

www.pharmacy.ohio.gov

MISSION

The State of 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 State of Ohio Board of Pharmacy was established by the General Assembly in May of 1884 and consists of nine members, 8 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 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 & Dangerous Drug Distribution Act

4752. – Home Medical Services

In enforcing these chapters, the Board licenses and regulates more than 70,000 pharmacy professionals - including pharmacists, pharmacy interns, and technicians - and sites where dangerous drugs, medical marijuana, 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 service 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 State of Ohio Board of Pharmacy is also charged with preventing, detecting and investigating the diversion of dangerous drugs, including controlled substances. The Board investigates and presents evidence of violations of federal or state drug laws by any person and refers them for prosecution (O.R.C. Chapter 2925.) and/or for administrative action. This includes investigations of physicians, nurses, dentists or other individuals that may not be licensed by the Board.

A LETTER FROM THE EXECUTIVE DIRECTOR

On behalf of the members of the State of Ohio Board of Pharmacy, I am pleased to present our Fiscal Year 2019 Annual Report. This fiscal year included a number of new initiatives intended to promote the safe distribution of drugs and the health and safety of the public, including:

New Rules for Reporting Suspicious Orders by Drug Distributors - In April 2019, new rules went into effect for drug distributors (wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs, and outsourcing facilities) requiring the reporting of suspicious orders and customers to the Board. The rules

also require licensees to exercise due diligence to identify and prevent the sale of controlled substances and other drugs that are likely to be diverted from legitimate channels. These rules have become a national model for other states.



OARRS Academy - To promote the use of OARRS among healthcare students, the Board developed OARRS Academy, a training program designed to simulate the use of OARRS. OARRS Academy comes pre-loaded with data for a variety of sample patients and allows for the creation of additional sample patients. It is available at no cost to all Ohio colleges and universities engaged in the training of pharmacists and prescribers. For more information on OARRS Academy, visit: www.oarrsacademy.ohio.gov.



Electronic Theft and Significant Loss Reporting - In an effort to promote improved reporting and oversight of drug diversion, the Board implemented new rules that require terminal distributors and drug distributors to report theft or significant loss of dangerous drugs and drug documents via an online portal. Ohio became the first state in the country to require the electronic submission of this data.

Naltrexone Dispensing Reported to OARRS - Starting in March 2019, OARRS began collecting naltrexone dispensing information. This data is intended to assist prescribers and pharmacists in identifying who may be receiving treatment for substance use disorder. This information is especially useful for healthcare providers who are considering the use of controlled substances to treat patients.

A LETTER FROM THE EXECUTIVE DIRECTOR

OARRS Integration - Ohio has made significant progress in promoting integration of OARRS into electronic health records and pharmacy dispensing systems. 43,000 pharmacists and prescribers now have direct access to OARRS as part of their workflow.

Launch of the Ohio Medical Marijuana Patient and Caregiver Registry - In December 2018, the Board activated the Patient and Caregiver Registry. At the end of the fiscal year, more than 48,000 patients and 3,400 caregivers were registered with the Board.

Certificates of Operation for Medical Marijuana Dispensaries - In December 2018, the Board issued its first certificate of operation for a provisional dispensary licensee. Since the initial award, dispensaries have opened in every region in the state. Through FY 19, the Board issued 19 certificates of operation in total with more expected to be issued during the remainder of 2019.

First Medical Marijuana Sales - On January 16, 2019, four Ohio dispensaries began selling medical marijuana to patients and caregivers. By the end of first day, the dispensaries sold 8.7 pounds of product, which amounted to total sales of \$75,000. By the end of the fiscal year, more than 25,000 patients had purchased medical marijuana, as reported to OARRS by licensed dispensaries.

In addition to the initiatives outlined above, the State of Ohio Board of Pharmacy was honored to be the recipient of the 2019 Fred T. Mahaffey Award from the National Association of Boards of Pharmacy (NABP). NABP highlighted the Board's efforts to promote the use of Ohio's prescription monitoring program, known as the Ohio Automated Rx Reporting System (OARRS), and the development and implementation of new rules requiring the reporting of suspicious orders by drug distributors.



Executive Director Schierholt and members of the Board of Pharmacy accepting the Fred T. Mahaffey Award at the 2019 NABP Annual Meeting

Thank you for taking the time to review the State of Ohio Board of Pharmacy's Fiscal Year 2019 Annual Report. As this report demonstrates, the Board remains committed to working closely with federal, state and local partners to protect the health and safety of the citizens of Ohio.

Sincerely,

A handwritten signature in black ink that reads "Steven W. Schierholt".

Steven W. Schierholt, Esq.
Executive Director

LICENSING

The Licensing Department's responsibilities include processing of licensure and registration applications, verifications of good standing, organization of reciprocity reviews and support to field agents, inspectors and specialists. The Board licenses or 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.
- Drug Distributors: Sites engaged in the sale of dangerous drugs at wholesale. Drug distributors include the following license types: manufacturers, outsourcing facilities, third-party logistics providers, repackagers, and wholesale distributors of dangerous drugs (including brokers and virtual wholesalers).
- Medical marijuana dispensary provisional licenses, dispensary certificates of operation, and medical marijuana dispensary employees.
- Home Medical Equipment (HME) Service Providers: Sites engaged in the sale, delivery, installation, maintenance, replacement, or demonstration of home medical equipment.

FY 2019 Accomplishments

- Transitioned terminal distributor and drug distributor license types to a biennial renewal cycle.
- Implemented new pharmacy technician training program rules.
- Decreased processing time of pharmacy school graduates applying for examination.

Current and New Active Licenses/Registrations by Type, FY 2019

| Type of License | FY 2019 Active | FY 2019 New |
|---------------------------------------|----------------|---------------|
| Pharmacist | 20,704 | 1,084 |
| Pharmacy Intern | 2,951 | 946 |
| Pharmacy Technician | 24,269 | 8,936 |
| Terminal Distributors | 19,555 | 1,954 |
| Drug Distributors | 1,802 | 211 |
| HME Service Providers | 874 | 170 |
| Medical Marijuana Dispensary Employee | 614 | 757 |
| Dispensary - Provisional | 37 | 56 |
| Dispensary - Certificate of Operation | 19 | 19 |
| Total | 70,825 | 14,114 |

COMPLIANCE AND ENFORCEMENT

The primary responsibility of the Compliance and 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.

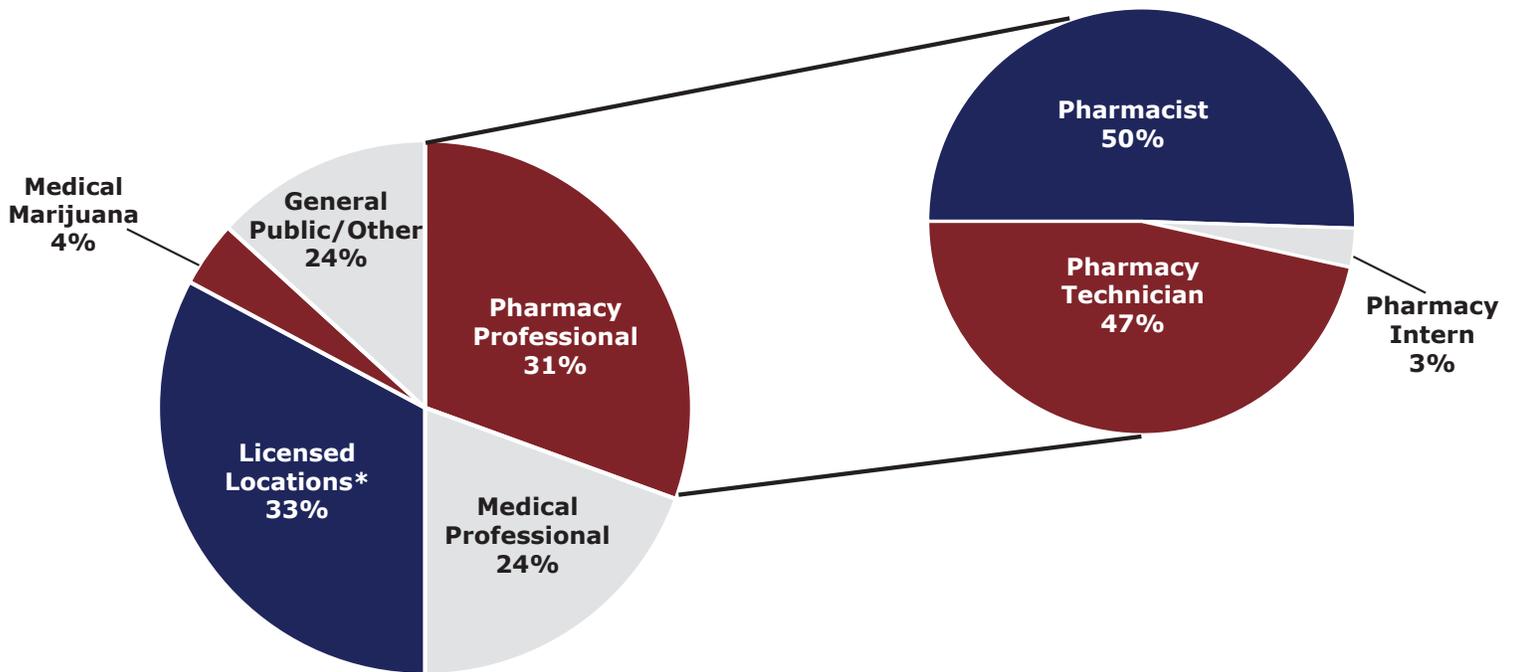
FY 2019 Accomplishments

- After a joint investigation with local law enforcement, the Board helped to secure the indictment of an Ohio physician on 272 felony charges. The charges included manslaughter, engaging in a pattern of corrupt activity, aggravated trafficking in drugs, and healthcare fraud. After a five-week trial, the physician was found guilty on 187 charges and sentenced to a 113 year prison term.
- The Board began an investigation of a wholesale distributor supplying multiple Ohio physicians with high quantities of controlled substance diet drugs. The top Ohio recipients of the wholesaler's drug sales were found to be illegally distributing controlled substances. In April 2019, the wholesaler signed a settlement agreement with the Board that permanently surrendered its Ohio license. In September 2019, three executives of the wholesaler were indicted in Cuyahoga County on multiple counts of drug trafficking.
- An investigation by the Board resulted in federal convictions of four licensed healthcare providers, two pharmacists and two physicians, for drug trafficking and Medicaid fraud.

New Cases by Type (Top 10), FY 2019

| | |
|---|------------|
| Theft of Drugs | 249 |
| Background Investigation | 238 |
| Deception to Obtain Dangerous Drugs | 206 |
| Consumer Complaint | 151 |
| Minimum Qualifications of Licensees | 145 |
| Questionable Prescribing | 133 |
| Error in Dispensing | 112 |
| Medical Marijuana Consumer Complaint | 75 |
| Late Renewal of License | 65 |
| Questionable Dispensing | 58 |

Case Suspects by Type, FY 2019



*Includes the following license types: terminal distributors, drug distributors, and HME service providers.

Administrative actions taken against a licensee can range from permanent revocation to imposition of fines or additional continuing education requirements. Suspensions and probations are also utilized, particularly in cases of substance abuse where rehabilitation is deemed possible. The tables below represent administrative actions taken by the Board in FY 2019.

| ADMINISTRATIVE ACTIONS FY 2019 - TRADITIONAL PHARMACY | |
|--|------------|
| Summary Suspensions (Total) | 54 |
| Summary Suspensions (Pharmacy Technicians) | 33 |
| Summary Suspensions (Pharmacists) | 12 |
| Summary Suspensions (Interns) | 1 |
| Summary Suspensions (TDDD) | 6 |
| Summary Suspensions (WDDD) | 1 |
| Summary Suspensions (OARRS) | 1 |
| Citations Issued (Includes Summary Suspensions) | 124 |
| Proposals to Deny | 24 |
| Settlement Agreements | 44 |
| License Revocations | 5 |
| Pharmacist Probation | 64 |

| ADMINISTRATIVE ACTIONS FY 2019 - MEDICAL MARIJUANA | |
|---|----------|
| Summary Suspensions (Patients/Caregivers) | 5 |
| Citations (Includes Summary Suspensions) | 8 |

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.
- Coordinating the Home Medical Equipment Services Advisory Council.

FY 2019 Accomplishments

- Facilitated the inclusion of several policy proposals as part of HB 166, Ohio's Biennial Budget, including the creation of separate funds for federal forfeitures.
- Successful development and implementation of new rules governing suspicious order monitoring, reporting of theft or significant losses, terminal distributors, and OARRS.
- Convened the first meeting of the Home Medical Equipment Services Advisory Council.
- Secured \$647,500 in federal grant funding from the U.S. Department of Justice to support Board agents charged with investigating controlled substance diversion using OARRS data.
- Continued reorganization of the Board's rules to divisions based on license type. This included the implementation of new rules for:
 - Drug distributors
 - Charitable pharmacies
 - Non-resident terminal distributors
 - Medical oxygen, nitrous oxide, medical gases and dialysis solutions
 - Prescription drug collection
 - Ephedrine products

OHIO AUTOMATED RX REPORTING SYSTEM

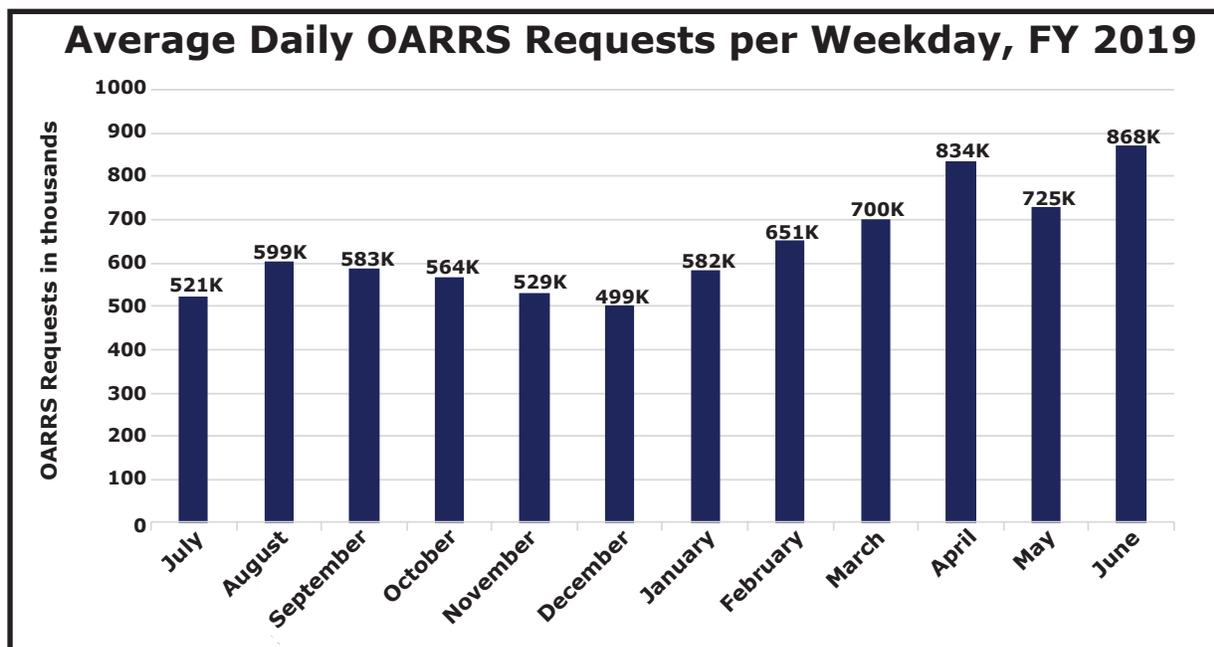


OHIO AUTOMATED RX REPORTING SYSTEM

To address the growing misuse and diversion of prescription drugs, the State of 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 pharmacies and personally furnished by prescribers in Ohio. Drug wholesalers are also required to submit information on all controlled substances (and gabapentin) sold to an Ohio pharmacy or prescriber. The data is reported every 24 hours (except wholesalers who report monthly) and is maintained in a secure database.

FY 2019 Accomplishments

- Ohio has made significant progress in promoting integration of OARRS into electronic health records and pharmacy dispensing systems. 43,000 pharmacists and prescribers now have direct access to OARRS as part of their workflow.
- As a result of integration, OARRS averaged 868,000 requests per weekday at the end of FY 19 (see chart below). It is expected that OARRS will average one million patient queries per weekday by 2020.
- OARRS began collecting naltrexone dispensing data in March 2019. This data is intended to assist prescribers and pharmacists in identifying who may be receiving treatment for substance use disorder. This information is useful for healthcare providers who are considering the use of controlled substances to treat patients.



MEDICAL MARIJUANA

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

- Operating the patient and caregiver registry;
- Licensing of retail dispensaries;
- Licensing of dispensary employees;
- Managing the toll-free helpline;
- Approving new forms of medical marijuana; and
- Coordinating the Medical Marijuana Advisory Committee.



The Board is responsible for reviewing and assigning product identifiers for medical marijuana products. The chart below includes the number products assigned an identifier by the end of FY 2019.

| MMCP Products Available FY 19 | |
|---------------------------------------|---------------------|
| Forms | IDs Assigned |
| Tier I plant material | 1,445 |
| Tier II plant material | 320 |
| Edible for oral administration | 88 |
| Metered oil or solid for vaporization | 76 |
| Transdermal patches | 27 |
| Tinctures | 16 |
| Capsule | 2 |
| Oil for oral administration | 1 |

FY 2019 Accomplishments

- Activated the Ohio Medical Marijuana Patient and Caregiver Registry in December 2018. At the end of the fiscal year, more than 48,000 patients and 3,400 caregivers were registered with the Board.
- In December 2018, the Board issued its first certificate of operation for a provisional dispensary licensee. Since the initial award, dispensaries have opened in every region in the state. Through FY 19, the Board issued 19 certificates of operation in total with more expected to be issued during the remainder of 2019.
- On January 16, 2019, four Ohio dispensaries began selling medical marijuana to patients and caregivers. By the end of first day, the dispensaries sold 8.7 pounds of product, which amounted to total sales of \$75,000. By the end of the fiscal year, more than 25,000 patients had purchased medical marijuana, as reported to OARRS by licensed dispensaries.

STATEMENT OF ACTIVITIES

FOR STATE FISCAL YEAR 2019 (JULY 1, 2018 - JUNE 30, 2019)

| FY 2019 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. | \$15,178,074 |
| Fund 4A50 (Drug Law Enforcement) Fines and bail or property forfeitures collected as a result of the Board's drug law enforcement efforts. | \$40,175 |
| Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grants distributed by the U.S. Department of Justice, Office of Justice Programs. | \$275,305 |
| Fund 3HH0 (OARRS Integration HITECH) Grant money received from the Ohio Department of Medicaid to support OARRS integration. | \$2,007,225 |
| Fund 5SG0 (Drug Database) Donations and grant subawards from other state agencies to make improvements to OARRS as authorized in ORC 4729.83. | \$278,699 |
| Fund 5SY0 (Medical Marijuana Control Program) Revenue from fees paid by dispensaries, patients, and caregivers. | \$3,564,162 |
| TOTAL REVENUE FY 2019 | \$19,521,554 |

*Revenue for Fund 4K90 includes biennial license fees for terminal distributors and drug distributors.

| FY 2019 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). | \$9,376,444 |
| Fund 4A50 (Drug Law Enforcement) Used by the Board to provide its compliance and enforcement staff with current technology and training for the purpose of increasing their productivity and ability to obtain evidence of pharmacy and drug law violations. The fund's use is restricted to drug law enforcement purposes only. | \$147,422 |
| Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grants distributed by the U.S. Department of Justice, Office of Justice Programs. | \$280,666 |
| Fund 3HH0 (OARRS Integration HITECH) Grant money received from the Ohio Department of Medicaid to support OARRS integration. | \$2,007,225 |
| Fund 5SG0 (Drug Database) Implement memorandums of understanding with the Ohio Department of Health and the Ohio Department of Mental Health and Addiction Services to enhance OARRS. | \$283,710 |
| Fund 5SY0 (Medical Marijuana Control Program) Used by the Board to implement the Medical Marijuana Control Program under ORC Chapter 3796. | \$3,324,680 |
| TOTAL EXPENSES FY 2019 [1,2,3] | \$15,420,146 |

[1] Expenses reflect actual cash disbursements during FY 2019 and include some expenses budgeted with FY 2018 appropriation. Similarly, some expenses budgeted with FY 2019 appropriation will be disbursed in FY 2020 and reflected on that year's annual report.

[2] Because of the state's biweekly pay schedule, each fiscal year has an extra day (two in a leap year) beyond the 26 pay periods of 14 days each. The accumulation of these days year after year results in one extra pay period (the 27th pay period) in a fiscal year every ten years or so. The fiscal year 2020-2021 transportation budget (Am. Sub. H.B. 62, Sect. 509.30) authorized the Director of Budget and Management flexibility to process the 27th pay period in fiscal year 2019. Therefore, funds for the 27th pay period are encumbered against fiscal year 2019 but were disbursed in fiscal year 2020. Thus, the 27th pay period is NOT reflected in the above disbursement totals.

[3] Pursuant to section 119.092(E), the State of Ohio Board of Pharmacy did not pay any fees to a prevailing eligible party in Fiscal Year 2019.



The State of 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

Shawn C. Wilt, R.Ph., President
Jennifer M. Rudell, R.Ph., Vice-President
Joshua M. Cox, Pharm.D, BCPS, R.Ph.
Megan E. Marchal, Pharm.D., R.Ph.
D. Rich Miller, III, B.S., R.Ph.
Richard J. Newlon, Public Member
Fred M. Weaver, B.S., R.Ph.
Kilee S. Yarosh, B.S., R.Ph.

State of Ohio Board of Pharmacy
77 South High Street
17th Floor
Columbus, OH 43215
Phone: 614-466-4143
www.pharmacy.ohio.gov/contact