



**STATE OF
OHIO**
BOARD OF PHARMACY

ANNUAL REPORT FY 2017

July 1, 2016 - June 30, 2017

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 eighty-six 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

In enforcing these chapters, the Board licenses and regulates more than 46,000 pharmacy professionals, including pharmacists and pharmacy interns, and sites where dangerous drugs 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*, 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.

**Licensure of medical marijuana dispensaries will not occur until 2018.*

A LETTER FROM THE EXECUTIVE DIRECTOR

On behalf of the members of the State of Ohio Board of Pharmacy, I am pleased to present the Fiscal Year 2017 Annual Report. This fiscal year marked a significant turning point for the Board, as its mission to protect the citizens of Ohio expanded significantly to include the following:

- Ohio Medical Marijuana Control Program – On September 8, 2016, the Board officially began its role as one of the three agencies tasked with the implementation of the Ohio Medical Marijuana Control Program. As part of the program, the Board is responsible for overseeing medical marijuana retail dispensaries, the registration of medical marijuana patients and caregivers, the approval of new forms of medical marijuana and coordinating the Medical Marijuana Advisory Committee. More information about the program and its progress towards full implementation, can be found on the program's website: www.medicalmarijuana.ohio.gov.
- Registration of Pharmacy Technicians – Ohio's Opiate MBR (SB 319 – Eklund), signed by Governor Kasich in January 2017, included a provision requiring the Board to register all pharmacy technicians by April 6, 2018. By joining the 42 states that currently register technicians, Ohio can reduce opportunities for diversion by establishing a registration system that prohibits a technician who engaged in drug theft from easily obtaining employment at another location. In addition, registration will also establish uniform training standards for technicians. Such standards help to ensure that all pharmacy technicians have the same level of competency throughout the state.
- Licensure of all Facilities Possessing Controlled Substances – Ohio's Opiate MBR includes a provision requiring the Board to license all prescriber offices that purchase and distribute controlled substances. Licensure by the Board of Pharmacy provides greater oversight of prescribers who store, administer and dispense dangerous drugs from their offices by allowing proactive inspections and additional safeguards, such as security requirements, to prevent theft or misuse of these highly addictive substances.
- Oversight of Office-Based Opioid Treatment Facilities – The Opiate MBR also included a provision authorizing the Board to license all facilities where prescribers provide medication assisted treatment to more than 30 individuals. Licensure by the Board requires background checks for all owners and individuals working at the facility to restrict those convicted of serious crimes from engaging in office-based opioid treatment. Licensure also allows for implementation of rules on facility operation to ensure prescribers are adhering to the prevailing standards of care set by the Medical Board. More information on this requirement can be accessed here: www.pharmacy.ohio.gov/OBOT.



In addition to the expanded authority provided in FY 2017, the Board continued its efforts to combat Ohio's drug overdose epidemic. A primary focus of these efforts is centered on the Ohio Automated Rx Reporting System (OARRS) and an initiative to integrate OARRS directly into electronic medical records and pharmacy dispensing systems across the state, allowing instant access for prescribers and pharmacists.

A LETTER FROM THE EXECUTIVE DIRECTOR

As a result of this initiative, 17,700 prescribers and pharmacists gained integrated access to OARRS, including:

- A number of major health systems and outpatient clinics, such as: Mount Carmel, Mercy Health, MetroHealth, The Ohio State University Wexner Medical Center, Cleveland Clinic, Avita Health, Southwest General, University Hospital (Cleveland), and Licking Memorial Health System.
- 170 independent Ohio pharmacies.
- Four chain pharmacies: Discount Drug Mart (73 Ohio stores), Kroger (226 Ohio stores), Giant Eagle (5 Ohio Stores), and Meijer (41 Ohio Stores).

Another effort to address drug overdose in Ohio is the Board's commitment to promoting the availability of naloxone, a drug used to reverse an opioid-related overdose. In FY 2017, the Board expanded access to this important medication by:

- Authorizing EMS agencies and other licensed locations to transfer or share naloxone to prevent the expiration of the drug.
- Permitting the transfer or sale of naloxone from law enforcement agencies to other law enforcement agencies, local health departments and emergency medical service organizations.
- Providing an additional \$20,000 to existing state funding to support the purchase of naloxone by Project DAWN sites.

The Board continued its efforts to investigate the diversion of prescription opioids and other controlled substances. In FY 2017, the Board received a federal grant to hire additional agents specifically assigned to OARRS. These new agents are charged with reviewing data in the system to investigate high-volume controlled substance prescribers for violations of criminal and administrative law.

FY 2017 also saw the Board's continued efforts to promote clear and consistent regulation by educating our licensees on changes impacting the pharmacy profession and the legal distribution of drugs. This included roundtable and pharmacy law presentations for pharmacists, the monthly distribution of the Board's E-News Update to all licensees and the publishing of guidance documents and frequently asked questions on the Board's website.

Thank you for taking the time to review the State of Ohio Board of Pharmacy's Fiscal Year 2017 Annual Report. As this report demonstrates, the Board remains as committed as ever to working collaboratively with federal, state and local partners to protect the health and safety of all Ohioans.

Sincerely,



Steven W. Schierholt, Esq.
Executive Director

LICENSING

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

- Pharmacists & Pharmacy Interns.
- 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.
- Wholesale Distributors of Dangerous Drugs (WDDD): Sites who are engaged in the sale of dangerous drugs at wholesale.

FY 2017 Accomplishments

- The licensing department onboarded more than 5,000 new licenses in FY 2017.
- All license types were moved to an online, paperless renewal system.
- The licensing department implemented an electronic storage process for all initial licensing documentation.

Current and New Active Licenses by Type, FY 2017

Type of License	FY 2017 Active	FY 2017 New
Registered Pharmacist	19,984	1,004
Pharmacy Intern	3,712	1,011
Terminal Distributor of Dangerous Drugs	20,421	2,662
Wholesale Distributor of Dangerous Drugs	2,432	339
Total Licenses Issued	46,549	5,016

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.

FY 2017 Accomplishments

- The conviction of a law enforcement officer, who was indicted on 38 felony and five misdemeanor counts and pled guilty to 13 counts. Sentenced to four years prison, three years of community control and restitution of \$24,000.
- The conviction of a physician, who was indicted on 78 felony counts and pled guilty to eight counts of possession of dangerous drugs, four counts of trafficking dangerous drugs, and one count of attempting to traffic dangerous drugs.
- The conviction of a physician who was charged with nine counts of drug trafficking and pled guilty to one count of obstructing official business.

Administrative Actions

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

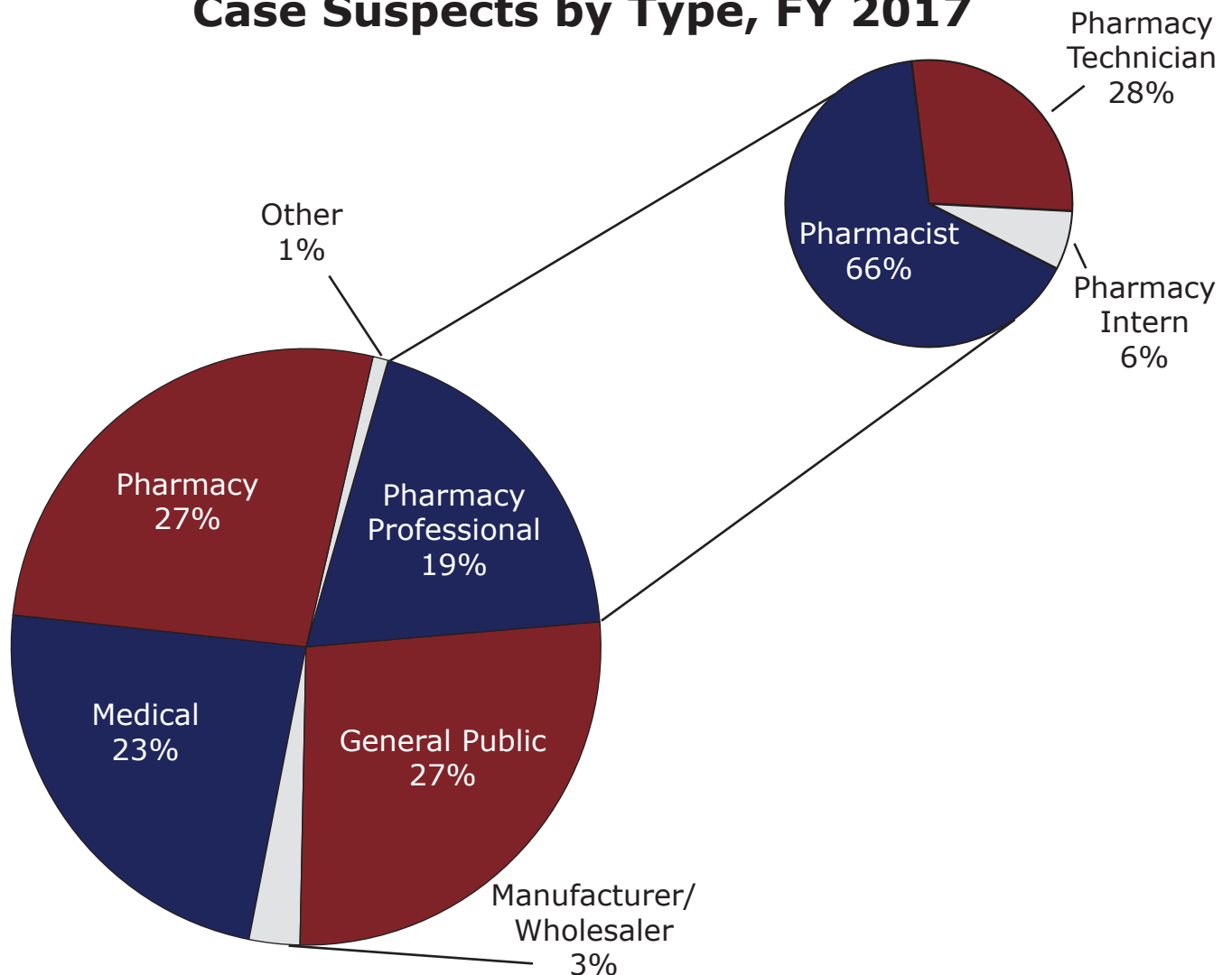
The following numbers represent administrative actions taken by the Board in FY 2017.

ADMINISTRATIVE ACTIONS IN FY 2017	
Citations Issued	67
Proposals to Deny License (New, Reciprocal or Renewal)	17
Settlement Agreements	77
Summary License Suspensions	7
Suspensions	8
License Revocations	4
Pharmacists Currently Serving Terms of Probation	27

New Cases by Type (Top 10), FY 2017

Deception to obtain dangerous drugs	251
Consumer complaints	210
Theft of drugs	200
Background investigation	140
Errors in dispensing	117
Questionable prescribing	100
Questionable dispensing	72
Falsification	42
Unprofessional conduct/gross immorality	39
Illegal drug sales	28

Case Suspects by Type, FY 2017



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 2017 Accomplishments

- Successful passage of Ohio SB 319 (Ohio's Opiate MBR). This legislation, signed by Governor Kasich in January 2017, authorizes the Board to:
 - Register pharmacy technicians;
 - License all facilities that possess controlled substances;
 - Expand access to naloxone; and
 - License all entities providing office-based opioid treatment to more than 30 patients.
- Development and implementation of the Ohio Medical Marijuana Control Program's website (www.medicalmarijuana.ohio.gov).
- Facilitated the inclusion of several policy proposals as part of HB 49, Ohio's Biennial Budget, including:
 - Moving all licenses to a two-year renewal cycle;
 - Updating wholesaler laws to reflect changes in federal law; and
 - Expanding OARRS access to drug courts, coroners and hospital peer review committees.

OHIO AUTOMATED RX REPORTING SYSTEM



OHIO AUTOMATED RX REPORTING SYSTEM

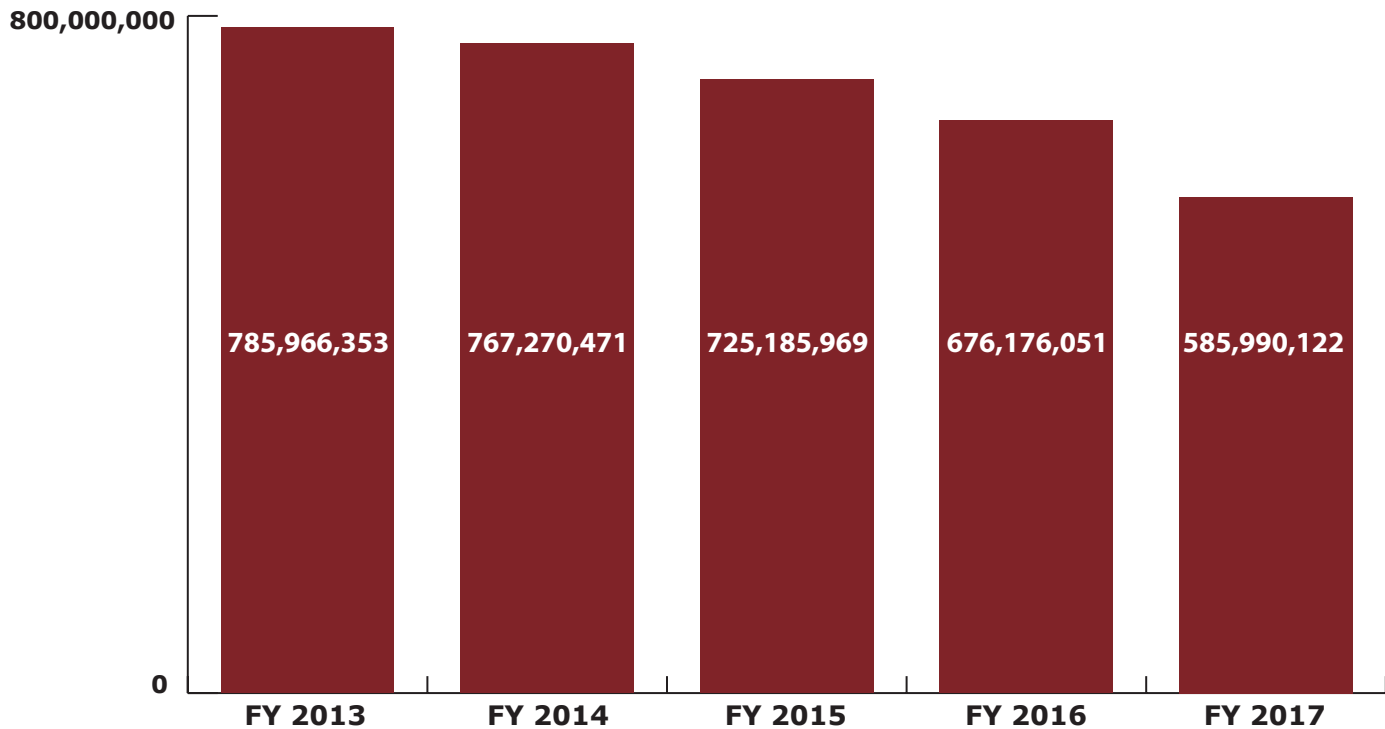
controlled substances (a one non-controlled drug, gabapentin) dispensed by Ohio-licensed pharmacies and personally furnished by licensed prescribers in Ohio. Drug wholesalers are also required to submit information on all controlled substances sold to an Ohio licensed pharmacy or prescriber. The data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

OARRS serves multiple functions, including: patient care tool; drug epidemic early warning system; and drug diversion and insurance fraud investigative tool. As the only statewide electronic database that stores all controlled substance dispensing and personal furnishing information, OARRS helps prescribers and pharmacists avoid potentially life-threatening drug interactions as well as identify individuals fraudulently obtaining controlled substances from multiple healthcare providers, a practice commonly referred to as "doctor shopping." It can also be used by professional licensing boards to identify or investigate clinicians with patterns of inappropriate prescribing and dispensing, and to assist law enforcement in cases of controlled substance diversion.

FY 2017 Accomplishments

- Nearly 18,000 prescribers and pharmacists obtained integrated access to OARRS.
- Use of OARRS continued to break records in FY 2017. During this time period, user requests of OARRS data increased by more than 270 percent.
- To ensure compliance with laws requiring prescriber use of the system, OARRS staff provided monthly referrals to prescriber licensing boards of clinicians who may have failed to use the system as required.
- Awarded \$399,365 grant by U.S. Department of Justice to hire additional compliance agents that are specifically assigned to review OARRS data to identify and investigate those who may be in violation of Ohio's drug laws.

Opioid Doses* Dispensed to Ohio Patients, FY 2013 - 2017



**Solid Oral Doses Only.*

OARRS Requests by Month, FY 2017

Month	Total Requests	Average Daily Requests
June 2017	7,366,622	245,554**
May 2017	7,202,982	232,354**
April 2017	3,650,967	121,698**
March 2017	4,935,900	218,087*
February 2017	4,002,892	180,835*
January 2017	2,896,981	120,914*
December 2016	2,660,464	110,733*
November 2016	2,533,177	106,031*
October 2016	2,231,644	95,830*
September 2016	1,748,016	83,544*
August 2016	2,048,814	82,310*
July 2016	1,976,042	83,064*

**Average Weekday Requests*

*** Average Daily Requests (including weekends)*

STATEMENT OF ACTIVITIES

FOR STATE FISCAL YEAR 2017 (JULY 1, 2016 - JUNE 30, 2017)

FY 2017 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.	\$7,323,188
Fund 4A50 (Drug Law Enforcement) Fines and bail or property forfeitures collected as a result of the Board's drug law enforcement efforts.	\$0
Fund 3EB0 (OARRS Improvements) Harold Rogers Prescription Monitoring Program grant distributed by the U.S. Department of Justice, Office of Justice Programs.	\$126,547
Fund 3CT0 (Developing/Enhancing PMP) Prescription Drug Monitoring Program Electronic Health Record (EHR) Integration and Interoperability Expansion grant distributed by the U.S. Department of Health and Human Services.	\$1,975
Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grant distributed by the U.S. Department of Justice, Office of Justice Programs.	\$89,500
Fund 5SG0 (Drug Database) Donations and grant subawards from other state agencies to make improvements to OARRS as authorized in ORC 4729.83.	\$143,331
Fund 5SY0 (Medical Marijuana Control Program) Implement the Medical Marijuana Control Program required under ORC Chapter 3796. Program will be sustained by fees paid by dispensaries and patients.	\$13,334
TOTAL REVENUE FY 2017	\$7,697,875

FY 2017 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).	\$7,616,849
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.	\$35,155
Fund 3EB0 (OARRS Improvements) Used for the purpose of planning, implementing, or enhancing Ohio's prescription drug monitoring program known as the Ohio Automated Rx Reporting System (OARRS).	\$133,166
Fund 3CT0 (Developing/Enhancing PMP) Prescription Drug Monitoring Program Electronic Health Record (EHR) Integration and Interoperability Expansion grant distributed by the U.S. Dept. of Health and Human Services.	\$4,493
Fund 5SG0 (Drug Database) Implement a memorandum of understanding between the Ohio Department of Health and the State Board of Pharmacy to make improvements to OARRS as part of a grant distributed by the Centers for Disease Control and Prevention (CDC).	\$127,221
Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grant distributed by the U.S. Department of Justice, Office of Justice Programs.	\$72,059
Fund 5SY0 (Medical Marijuana Control Program) Used by the Board to implement the Medical Marijuana Control Program under ORC Chapter 3796.	\$775,624
TOTAL EXPENSES FY 2017^{[1] [2]}	\$8,764,567

[1] Pursuant to section 119.092(E), the State of Ohio Board of Pharmacy paid the following fees to a prevailing eligible party in Fiscal Year 2017: \$7,603.00 for the payment of attorney's fees to a prevailing party as resolution of matter while pending appeal.

[2] Approximately \$35,000 in FY17 expenses have been encumbered but not yet paid. As these are paid, actual FY17 expenses will increase accordingly.



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

Megan E. Marchal, Pharm.D., R.Ph., President
Fred M. Weaver, B.S., R.Ph., Vice-President
Joshua M. Cox, Pharm.D, BCPS, R.Ph.
Michael A. Moné, B.S., R.Ph., J.D.
Richard J. Newlon, Public Member
Curtis L. Passafume, Jr. MBA, R.Ph.
Jennifer M. Rudell, R.Ph.
Shawn C. Wilt, 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