



**STATE OF
OHIO**
BOARD OF PHARMACY

ANNUAL REPORT FY 2016

July 1, 2015 - June 30, 2016

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 sixty-eight 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 in 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

In enforcing these chapters, the Board licenses and regulates more than 43,000 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, 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 State of Ohio Board of Pharmacy, I am pleased to present the Fiscal Year 2016 Annual Report. This year, the Board continued its efforts to protect the citizens of Ohio by providing consistent and effective oversight of the pharmacy profession and the distribution of dangerous drugs.

A central theme of our efforts is our ongoing commitment to combatting Ohio's drug overdose epidemic. In FY 2016, the Board implemented a number of strategies to address this public health crisis, including:

- OARRS Integration - Governor Kasich announced an investment of up to \$1.5 million a year to integrate the Ohio Automated Rx Reporting System (OARRS) directly into electronic medical records and pharmacy dispensing systems across the state, allowing instant access for prescribers and pharmacists. This investment is the first of its kind in the country and makes Ohio a national leader in promoting the use of its prescription monitoring program to combat prescription drug abuse.
- OARRS Rules for Pharmacists - In addition to work-flow integration, the Board implemented an enhanced regulation (OAC 4729-5-20) requiring pharmacists to check OARRS. The rule, implemented in February 2016, requires a pharmacist to review a patient's OARRS history prior to dispensing a new controlled substance prescription. The rule also requires a pharmacist to review a patient's report every twelve months and to query OARRS if the patient presents any red flags of abuse or diversion.
- Ohio's Opiate MBR (SB 319) - Introduced in April 2016, this important piece of legislation proposes new initiatives aimed at reducing prescription drug diversion, expanding access to naloxone and promoting responsible opioid addiction treatment. It includes proposals allowing for the registration of pharmacy technicians, licensure of facilities providing office based opioid treatment, licensure of all prescriber practices that possess controlled substances, and expanding access to naloxone to any facility that may interact with at-risk opioid users.
- Promoting Naloxone Availability at Ohio Pharmacies - The Board actively promoted the implementation of Ohio HB 4 (131st General Assembly), which allows pharmacies to dispense naloxone without a prescription. The Board developed a dedicated web page that includes resources to assist pharmacies in offering this important service.

A LETTER FROM THE EXECUTIVE DIRECTOR

- "Sometimes We Just Have to Say No" Campaign - The Board developed a campaign for pharmacists to educate them on the importance of corresponding responsibility. The campaign, entitled "Sometimes We Just Have to Say No", was released in conjunction with updates to the OARRS rule for pharmacists. It includes online continuing education and information that can be provided to patients on when a prescription is not considered valid, explains a pharmacist's corresponding responsibility under the law, and includes information on where patients and families can get a referral to addiction treatment.
- Drug Overdose Death Investigations - The State of Ohio Board of Pharmacy linked data from OARRS to overdose death data provided by the Ohio Department of Health to identify prescribers who may have prescribed controlled substances to drug overdose decedents. In FY 2016, the Board worked closely with prescriber regulatory boards to conduct joint investigations of these prescribers for violations of criminal and administrative law.

FY 2016 also saw the Board's ongoing commitment towards improving efforts at educating our licensees. This included roundtable and pharmacy law presentations for pharmacists held throughout the state. Additionally, the Board's communication staff also implemented a monthly news update to provide licensees important information on law and rules changes as well as important agency initiatives.

The State of Ohio Board of Pharmacy, like the practice of pharmacy, continues to grow and evolve with each passing year. As we meet these challenges, we will never lose sight of our core mission to promote and protect the health and safety of all Ohioans.

Sincerely,



Steven W. Schierholt, Esq.

Executive Director

State of Ohio Board of Pharmacy

LICENSING

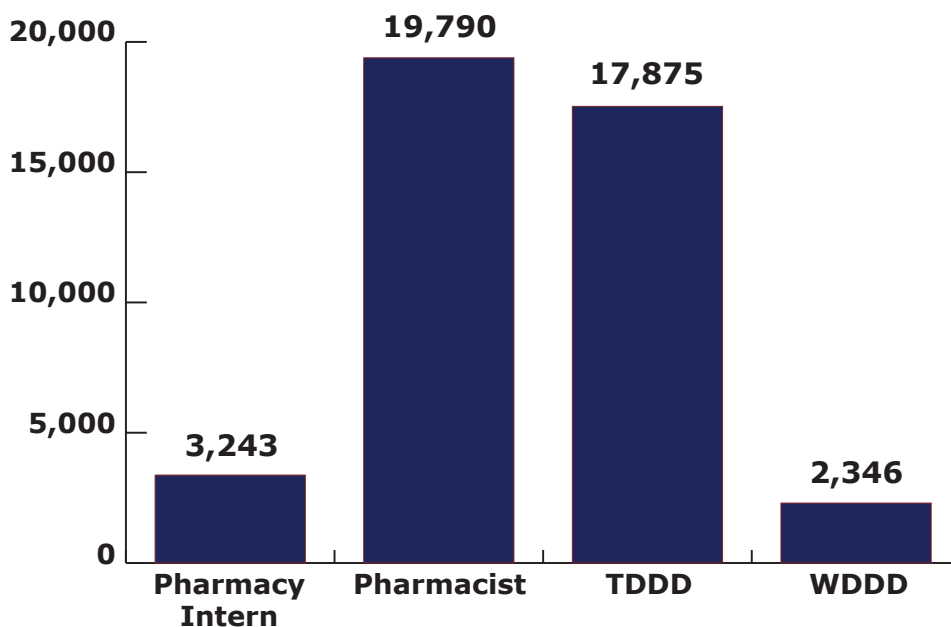
The Licensing Department's responsibilities include processing of all licensure applications, all verifications of good standing, organization of all reciprocity reviews and support to all field agents and specialists. The Board licenses all of the following:

- 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 2016 Accomplishments

- 72 pharmacist and pharmacy intern veteran fee waivers issued.
- A Kaizen process improvement event that resulted in an 82 percent decrease in process steps, an 83 percent decrease in decision points, a 78 percent decrease in the length of an initial application and a 76 percent decrease in application processing time.

Current Active Licenses by Type, FY 2016



**Total Active
Licenses for
FY 2016**

43,254

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 prescription drug crime investigations.

FY 2016 Accomplishments

- A Kaizen process improvement event that resulted in a 48 percent decrease in process steps, a 45 percent decrease in decision points and an estimated time savings of five months.
- Andrea Wagner, Compliance Administrative Assistant, received the Board's Customer Service Award.
- A realignment of the Board's investigative staff territories and supervisors.
- The development of an internal review committee to streamline and prioritize the assignment of cases to field staff.

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.

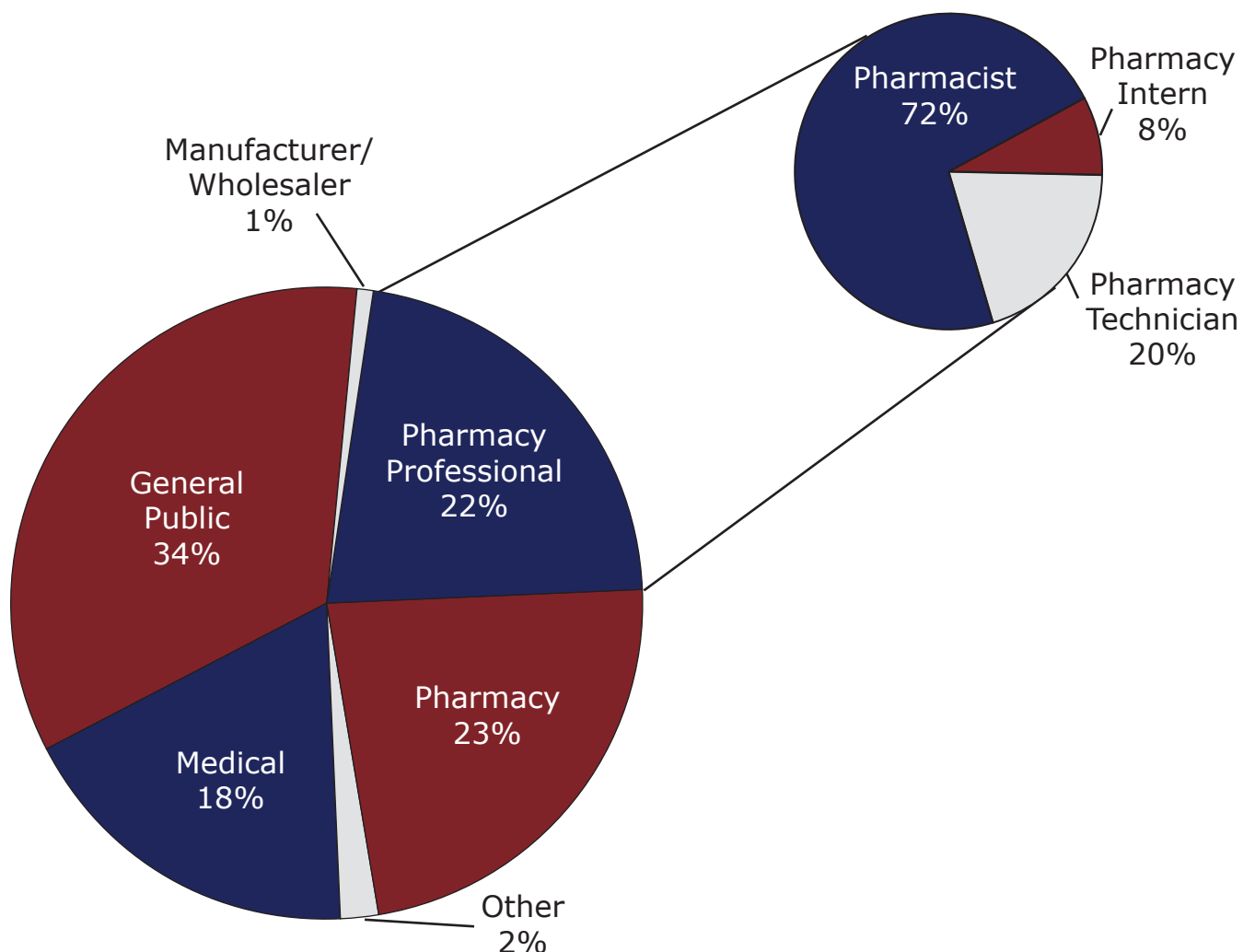
The following numbers represent administrative actions taken by the Board in FY 2016.

ADMINISTRATIVE ACTIONS IN FY 2016	
Citations Issued	55
Proposals to Deny License (New, Reciprocal or Renewal)	23
Settlement Agreements	83
Summary License Suspensions	12
License Revocations	5
Pharmacists Currently Serving Terms of Probation	42

New Cases by Type (Top 10), FY 2016

Deception to Obtain Dangerous Drugs	495
Consumer Complaint	134
Theft of Drugs	118
Error in Dispensing	108
Questionable Prescribing	88
Background Investigation	86
Questionable Dispensing	68
Illegal Processing of Drug Documents	48
Intake Review	40
Unprofessional Conduct/Gross Immorality	35

Case Suspects by Type, FY 2016



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 2016 Accomplishments

- Implementation of a monthly electronic newsletter.
- Developed a dedicated naloxone web page (www.pharmacy.ohio.gov/naloxone) that features a number of resources including: guidance documents, a sample protocol and patient educational materials.
- Protecting the public by making updates to the security and control requirements for terminal distributors of dangerous drugs (OAC 4729-9-11).
- Promulgation of new licensure requirements for virtual wholesalers and third party logistics providers (OAC 4729-9-28 & 4729-9-29).
- Development of the "Sometimes We Just Have to Say No" campaign and accompanying online educational materials for the updated pharmacist OARRS rule (www.pharmacy.ohio.gov/OARRSrules).
- Updated rules to require pharmacists to complete mandatory patient safety continuing education.

OHIO AUTOMATED RX REPORTING SYSTEM



OHIO AUTOMATED RX REPORTING SYSTEM

for controlled substances 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.

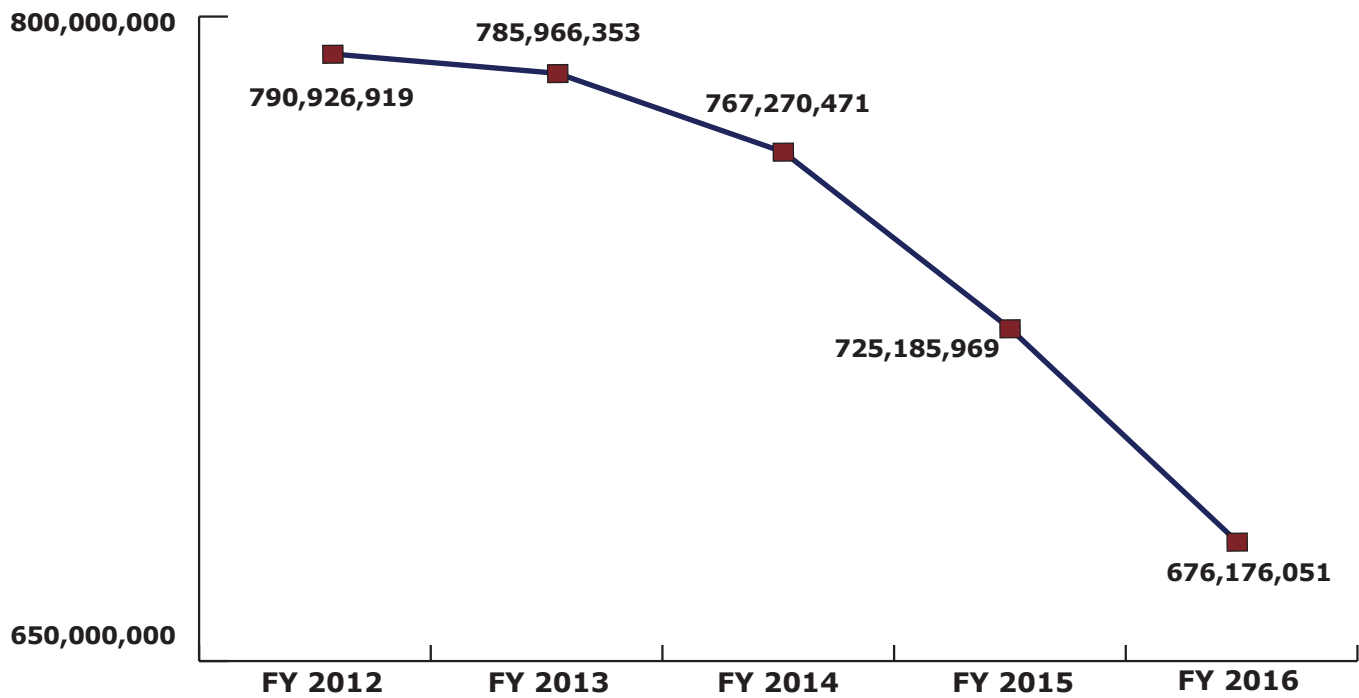
To address the growing misuse and diversion of prescription drugs, the State of Ohio Board of Pharmacy created Ohio's prescription drug monitoring program, known as the Ohio Automated Rx Reporting System (OARRS). Established in 2006, OARRS collects information on all outpatient prescriptions

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 2016 Accomplishments

- Governor Kasich announced an investment of up to \$1.5 million a year to integrate OARRS directly into electronic medical records and pharmacy dispensing systems across the state, allowing instant access for prescribers and pharmacists.
- Kroger integrated OARRS into their pharmacy computer system in their 226 Ohio stores. As a result, Kroger pharmacists increased their use of OARRS from 10 percent of all controlled substance prescriptions to 100 percent.
- Awarded \$202,687 grant by U.S. Department of Justice to develop an OARRS training system for graduate healthcare schools and residency programs.

Opioid Doses Dispensed to Ohio Patients, FY 2012 - 2016



OARRS Requests by Month, FY 2016

Month	Total Requests	Average Daily Requests*
June 2016	1,864,385	77,042
May 2016	1,730,223	76,420
April 2016	1,688,770	73,291
March 2016	1,837,621	76,159
February 2016	1,737,310	79,171
January 2016	1,496,662	64,042
December 2015	1,603,636	66,621
November 2015	1,446,057	65,020
October 2015	1,569,315	65,559
September 2015	1,495,925	65,165
August 2015	1,460,877	65,196
July 2015	1,221,048	51,824

*Weekdays only.

STATEMENT OF ACTIVITIES

FOR STATE FISCAL YEAR 2016 (JULY 1, 2015 - JUNE 30, 2016)

FY 2016 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.	\$7,044,771
Fund 4A50 (Drug Law Enforcement) Fines and bail or property forfeitures collected as a result of the Board's drug law enforcement efforts.	\$16,170
Fund 3EB0 (OARRS Improvements) Harold Rogers Prescription Monitoring Program grant distributed by the U.S. Department of Justice, Office of Justice Programs.	\$17,000
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.	\$141,054
Fund 3DV0 (Enhancing Ohio's PMP) Harold Rogers Prescription Monitoring Program grant distributed by the U.S. Department of Justice, Office of Justice Programs.	\$255,575
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). This fund also includes donations and gifts for the purpose of operating the system as authorized in ORC 4729.83.	\$100,000
TOTAL REVENUE FY 2016	\$7,574,570

FY 2016 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).	\$6,483,479
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.	\$17,644
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).	\$11,171
Fund 3CT0 (Developing/Enhancing PMP) The specific purpose of this fund is to: (1) expand the number of hospital sites and physician offices where prescribers are able to access OARRS information within their normal workflow, (2) implement access to OARRS reports from within pharmacy dispensing software, and (3) increase the number of states with which OARRS is able to share data.	\$120,380
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).	-
Fund 3DV0 (Enhancing Ohio's PMP) Harold Rogers Prescription Monitoring Program grant distributed by the U.S. Department of Justice, Office of Justice Programs.	\$211,191
TOTAL EXPENSES FY 2016*	\$6,843,865

*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 2016.



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.

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