



**STATE OF
OHIO**
BOARD OF PHARMACY

ANNUAL REPORT FY 2015

July 1, 2014 - June 30, 2015

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 fifty-seven employees, including 12 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 41,000 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 squads, 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



STEVEN W. SCHIERHOLT, ESQ.

The mission statement of the State of Ohio Board of Pharmacy emphasizes the “public interest.” As I have learned in the first months of my tenure as the Board’s new Executive Director, these are much more than words. Board members and staff take this promise to heart, making sure that all their daily deliberations and operations are focused on protecting the people of Ohio.

Our mission, now more than ever, is critically important. Ohio, like much of the nation, is experiencing a drug overdose epidemic. 2014 saw the highest number of unintentional drug overdose deaths on record. Most striking is that prescription drugs, such as opioid pain relievers and benzodiazepines, contributed to more than half of the reported deaths.

Prescribers and pharmacists are integral players in our efforts to combat this crisis. That is why Governor Kasich and the Board are committed to aiding the healthcare community by strengthening Ohio’s prescription drug monitoring program, the Ohio Automated Rx Reporting System (OARRS). OARRS is a web-based tool created to track the dispensing and personal furnishing of controlled prescription drugs to Ohio patients.

Through collaborative partnerships, FY 2015 saw significant progress towards improving OARRS. Such progress included expanding access to the system, additional training resources for healthcare and law enforcement and continued efforts to promote integration of the system with electronic medical records and pharmacy dispensing systems. These efforts have shown great promise, as OARRS use is at an all-time high and there has been a significant decline in controlled substance prescribing.

During this time, the Board also made important strides towards improving efforts at educating our licensees. As an integral part of these efforts, the agency went through a process of rebranding, rebuilding and enhancing our websites. Now all Board information has the same look, and is easier to access. We want our website to be a one-stop shop for information for our stakeholders and the public, especially when it comes to the implementation of new laws and regulations.

A LETTER FROM THE EXECUTIVE DIRECTOR

Our education efforts also include regular interaction with the organizations representing our licensees. As such, the Board holds frequent meetings with other healthcare regulatory boards, professional associations and schools of pharmacy. These meetings are important to ensure that we are maximizing all avenues to help our licensees maintain compliance with Ohio law.

Finally, the Board made substantial progress in our efforts to ensure regulatory consistency. Our recently introduced electronic inspections program represents a major step forward in standardizing our inspections of pharmacies and other licensed facilities. Through this system, licensees can expect consistency no matter what part of the state they are located.

In closing, the goals of the State of Ohio Board of Pharmacy will continue to reflect the mission statement we strive to fulfill. By working together with professionals and the public, we will continue this agency's long history of protecting the citizens of Ohio.

Sincerely,

A handwritten signature in black ink that reads "Steven W. Schierholt". The signature is written in a cursive, flowing style.

Steven W. Schierholt, Esq.

Executive Director

State of Ohio Board of Pharmacy

LICENSING

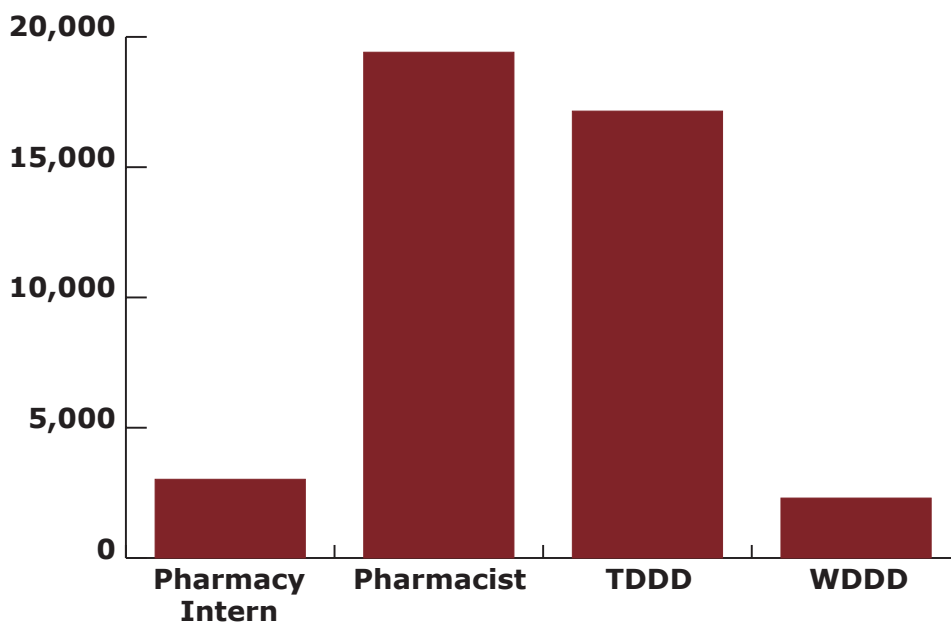
The Licensing Department's responsibilities include processing of all licensure applications, all verifications of good standing, organization of all reciprocity reviews and support to all field agents and specialists. The Board licenses all of the following:

- 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 agencies and pain management clinics.
- Wholesale Distributors of Dangerous Drugs (WDDD): Sites who are engaged in the sale of dangerous drugs at wholesale.

FY 2015 Accomplishments

- 58 pharmacist and pharmacy intern veteran fee waivers issued.
- Online system implemented to allow for paperless submission of required licensing documents.
- Increase in electronic renewal notifications resulted in a significant reduction in the number of paper reminder mailings for terminal and wholesaler licensing renewal.

Current Active Licenses by Type, FY 2015



Total Active
Licenses for
FY 2015

41,885

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 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 2015 Accomplishments

- Introduction of new program, Matrix Inspector, to improve the consistency, efficiency and timeliness of inspections.
- To improve coordination of investigations, the Board initiated monthly meetings among investigators of healthcare regulatory boards.
- Compliance Agent Jesse Wimberly received the President's Award for his exceptional performance, leadership, and service to the Board.

Administrative Actions

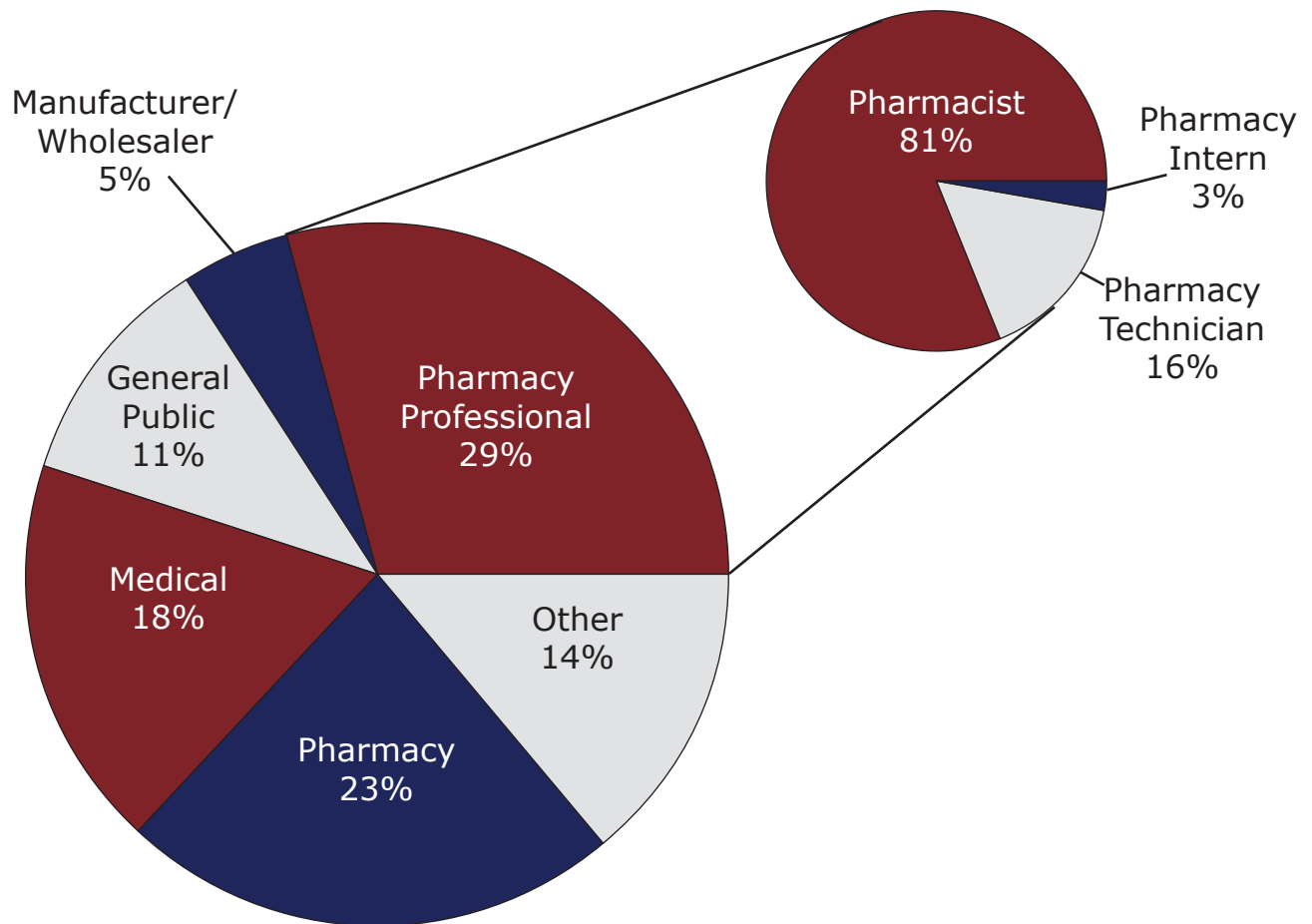
Administrative actions taken against a licensee can range from permanent revocation to imposition of fines or, for pharmacists and interns, additional continuing education requirements. Suspensions and probations are also utilized, particularly in cases of substance abuse where rehabilitation is deemed possible. The following numbers represent administrative actions taken by the Board in FY 2015.

ADMINISTRATIVE ACTIONS IN FY 2015	
Citations Issued	69
Proposals to Deny License (New, Reciprocal or Renewal)	20
Settlement Agreements	75
Summary License Suspensions	11
License Revocations	10
Pharmacists Currently Serving Terms of Probation	51

New Cases by Type (Top 10), FY 2015

Consumer Complaint	164
Error in Dispensing	142
Theft of Drugs	131
Questionable Dispensing	98
Questionable Prescribing	90
Background Investigation	71
Deception to Obtain	41
Illegal Processing of Drug Documents	41
Falsification	34
Illegal Drug Sales	30

Case Suspects by Type, FY 2015



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 2015 Accomplishments

- Development of a human trafficking continuing education course for pharmacists.
- Adoption of new rule chapters on drug compounding (OAC 4729-16) and drug take back programs (OAC 4729-8).
- Protecting the public by requiring licensure of all entities that store compounded drugs and drugs used to treat opioid addiction.
- Implementation of new legislation expanding the ability of pharmacists and pharmacy interns to administer immunizations.
- Development and dissemination of guidance document on new Drug Enforcement Administration regulations allowing pharmacies to take back unused or expired drugs.
- Creation and dissemination of educational resources for prescribers to assist in the implementation of Ohio HB 341 (Smith), which requires registration and use of the Ohio Automated Rx Reporting System.

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

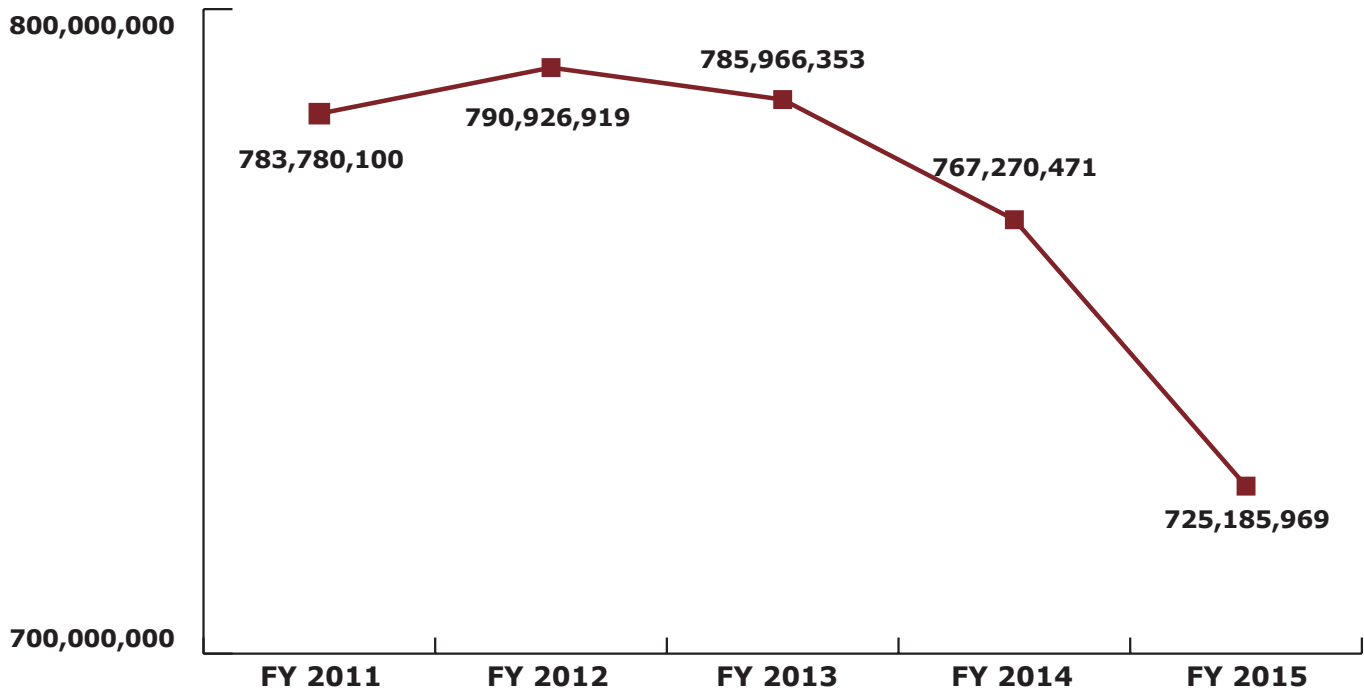
outpatient prescriptions for controlled substances dispensed by Ohio-licensed pharmacies and personally furnished by licensed prescribers in Ohio. Drug wholesalers are also required to submit information on all controlled substances sold to an Ohio licensed pharmacy or prescriber. The data is reported every 24 hours 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.

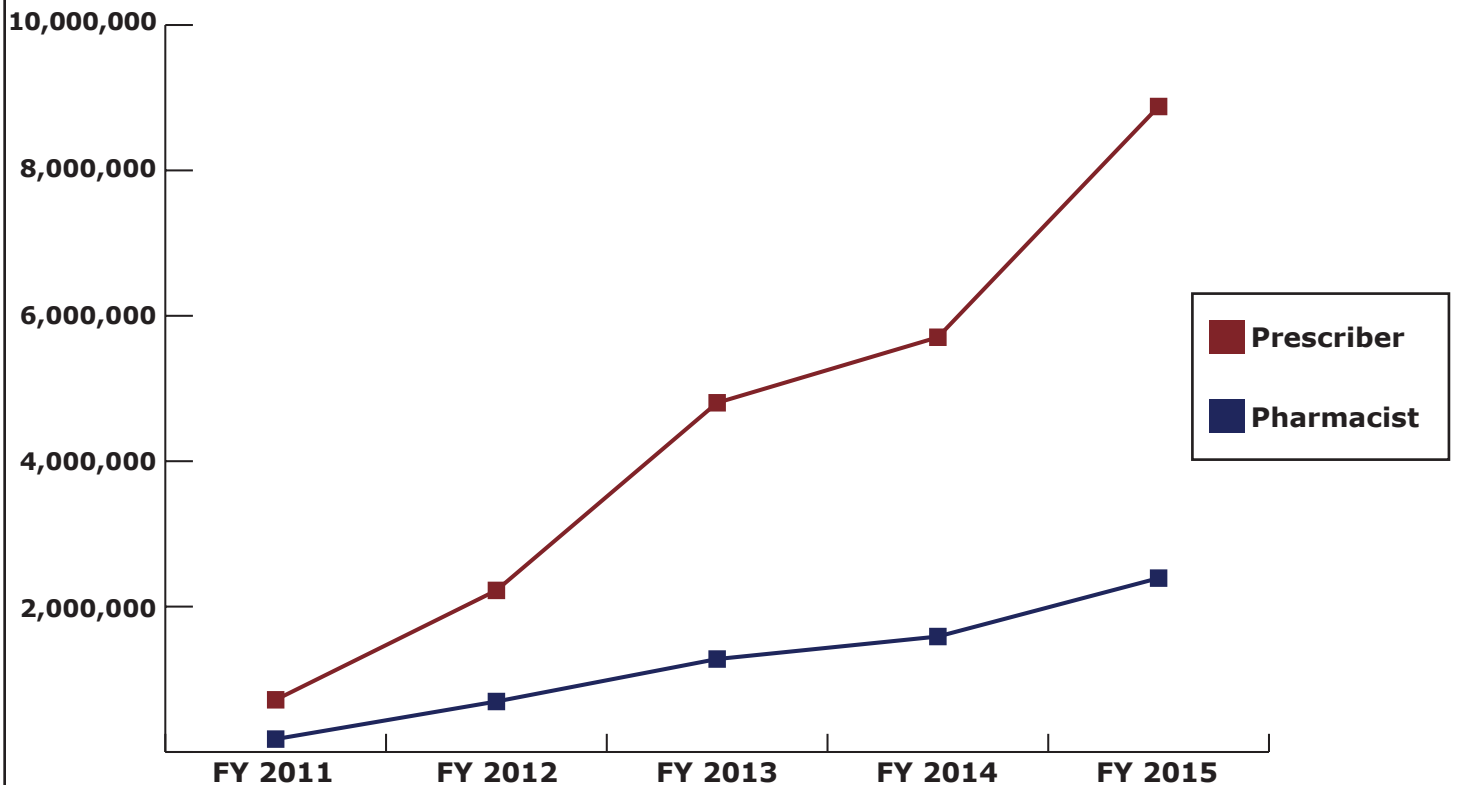
FY 2015 Accomplishments

- Awarded \$386,621 grant by U.S. Department of Justice to increase utilization of the system.
- In FY 2015, the total number of OARRS reports requested by prescribers increased by more than 3 million compared to FY 2014.
- OARRS expands access to medical and pharmacy directors of Medicaid Managed Care Organizations and physicians treating newborns diagnosed as opioid dependent.

Opioid Doses Dispensed to Ohio Patients, FY 2011 - 2015



Prescriber and Pharmacist OARRS Usage, by Number of Requests, FY 2011 - 2015



STATEMENT OF ACTIVITIES

FOR STATE FISCAL YEAR 2015 (JULY 1, 2014 - JUNE 30, 2015)

FY 2015 Revenue

Fund 4K90 (Operating Expenses) License fees and other assessments collected, as well as various fines, forfeited bonds and bail collected by the State Board of Pharmacy that are not credited to Fund 4A50.	\$6,645,706
Fund 4A50 (Drug Law Enforcement) Fines and bail or property forfeitures collected as a result of the Board's drug law enforcement efforts.	\$106,961
Fund 3BC0 (Dangerous Drugs Database) Harold Rogers Prescription Monitoring Program Grant distributed by the U.S. Department of Justice, Office of Justice Programs.	\$41,347
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.	\$155,540
Fund 3DV0 (Enhancing Ohio's PMP) Harold Rogers Prescription Monitoring Program grant distributed by the U.S. Department of Justice, Office of Justice Programs.	\$85,269
TOTAL REVENUE FY 2015	\$7,034,823

FY 2015 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).	\$6,500,474
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.	\$4,694
Fund 3BC0 (Dangerous Drugs Database) Used for the purpose of planning, implementing, or enhancing Ohio's prescription drug monitoring program known as the Ohio Automated Rx Reporting System (OARRS).	\$41,891
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.	\$158,554
Fund 3DV0 (Enhancing Ohio's PMP) Harold Rogers Prescription Monitoring Program grant distributed by the U.S. Department of Justice, Office of Justice Programs.	\$85,001
TOTAL EXPENSES FY 2015*	\$6,790,614

*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 2015.



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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