



STATE OF
OHIO
BOARD OF PHARMACY

ANNUAL REPORT FY 2018

July 1, 2017 - June 30, 2018

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

4752. – Home Medical Services

4729. – Pharmacy Practice Act & Dangerous Drug Distribution Act

In enforcing these chapters, the Board licenses and regulates more than 66,000 pharmacy professionals, including pharmacists, pharmacy interns and technicians, 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, home medical equipment service providers, hospitals, wholesalers, prescriber offices, 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 the Fiscal Year 2018 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 - In June 2018, the Board approved 56 provisional licenses for medical marijuana dispensaries located across the state. The Board also launched the medical marijuana toll-free helpline. More information about the program and its progress towards implementation, can be found on the program's website: www.medicalmarijuana.ohio.gov.



Implementation of Prescribing Rules for Acute Pain - In August 2017, the Board, working with the state's prescriber boards, helped implement new rules for the treatment of acute pain. In general, the rules limit the prescribing of opioid analgesics for acute pain to no more than seven days for adults and five days for minors. To help enforce these new rules, the Board implemented new rules making it the first state in the country to require mandatory reporting of ICD-10 diagnosis codes to its prescription drug monitoring program for every controlled substance prescription.

Wholesaler Reclassification - The biennial budget (HB 49 - 132nd General Assembly) modified the wholesaler license category and created five separate license types for the manufacture and distribution of dangerous drugs, as follows:

- Wholesale Distributors of Dangerous Drugs
- Manufacturers of Dangerous Drugs
- Outsourcing Facilities
- Repackagers of Dangerous Drugs
- Third-Party Logistics Providers

OARRS Enhancements - Ohio became the first state in the nation to upgrade to the NarxCare platform. This upgrade featured scores that calculate a patient's possible risk of overdose and addiction, and red flags to alert prescribers of a potential patient safety issue. These enhancements provide another tool to assist prescribers in combatting Ohio's drug overdose epidemic.

A LETTER FROM THE EXECUTIVE DIRECTOR

Pharmacy Technicians - Ohio's Opiate MBR (SB 319 - 131st General Assembly), signed by Governor Kasich in January 2017, included a provision requiring the Board to register all pharmacy technicians by April 6, 2018. Registration ensures all technicians are subject to comprehensive background checks and uniform training standards. By the end of Fiscal Year 2018, the Board successfully registered more than 20,000 pharmacy technicians.

Office-Based Opioid Treatment Facilities - To ensure drugs containing buprenorphine are appropriately prescribed and to increase the success of this form of treatment, Ohio's Opiate MBR required facilities where prescribers treat more than 30 individuals to obtain licensure by the Board.

Thank you for taking the time to review the State of Ohio Board of Pharmacy's Fiscal Year 2018 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 licensure and registration applications, verifications of good standing, organization of all reciprocity reviews and support field staff. The Board licenses/registers all of the following:

- Pharmacists, pharmacy interns, and pharmacy technicians.
- Terminal Distributors of Dangerous Drugs: Sites where dangerous drugs (i.e. prescription 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 who are engaged in the manufacture or sale of dangerous drugs at wholesale. A drug distributor 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.
- Home Medical Equipment Service Providers: Sites who are engaged in the sale, delivery, installation, maintenance, replacement, or demonstration of home medical equipment.

FY 2018 Accomplishments

- The licensing department onboarded 4 new license types and 8 different classifications.
- Nearly 25,000 additional license and registration applications were processed.
- The Board's licensing system was upgraded to a fully electronic and paperless platform.

Current and New Active Licenses/Registrations by Type, FY 2018

Type of License	FY 2018 Active	FY 2018 New
Registered Pharmacist	20,349	933
Pharmacy Intern	3,449	866
Pharmacy Technician	20,648	20,648
Terminal Distributor of Dangerous Drugs	19,591	2,185
Drug Distributors	1,736	184
Home Medical Equipment Service Provider	661	95
Total Licenses Issued	66,434	24,911

COMPLIANCE AND ENFORCEMENT

The primary responsibility of the Compliance & Enforcement 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 2018 Accomplishments

- The Board immediately suspended the licenses of several compounding pharmacies and practitioners for engaging in practices that posed immediate and serious harm to the public.
- The conviction of a physician indicted on 29 felony counts, including drug trafficking, illegal processing of drug documents, and workers compensation fraud who was sentenced to 60 months in prison.
- A physician was found guilty at jury trial on 3 felony counts of drug trafficking, 1 felony count of drug possession, and 1 misdemeanor count of drug possession. The physician was sentenced to 6 months in county jail, 6 months in a corrections center, and 5 years' probation.
- The indictment of a pharmacist for multiple felonies and misdemeanors, including tampering with drugs, illegal processing of drug documents, and misbranding of drugs. The pharmacist permanently surrendered his license to practice pharmacy and plead guilty to 5 counts of illegal possession of drug documents.

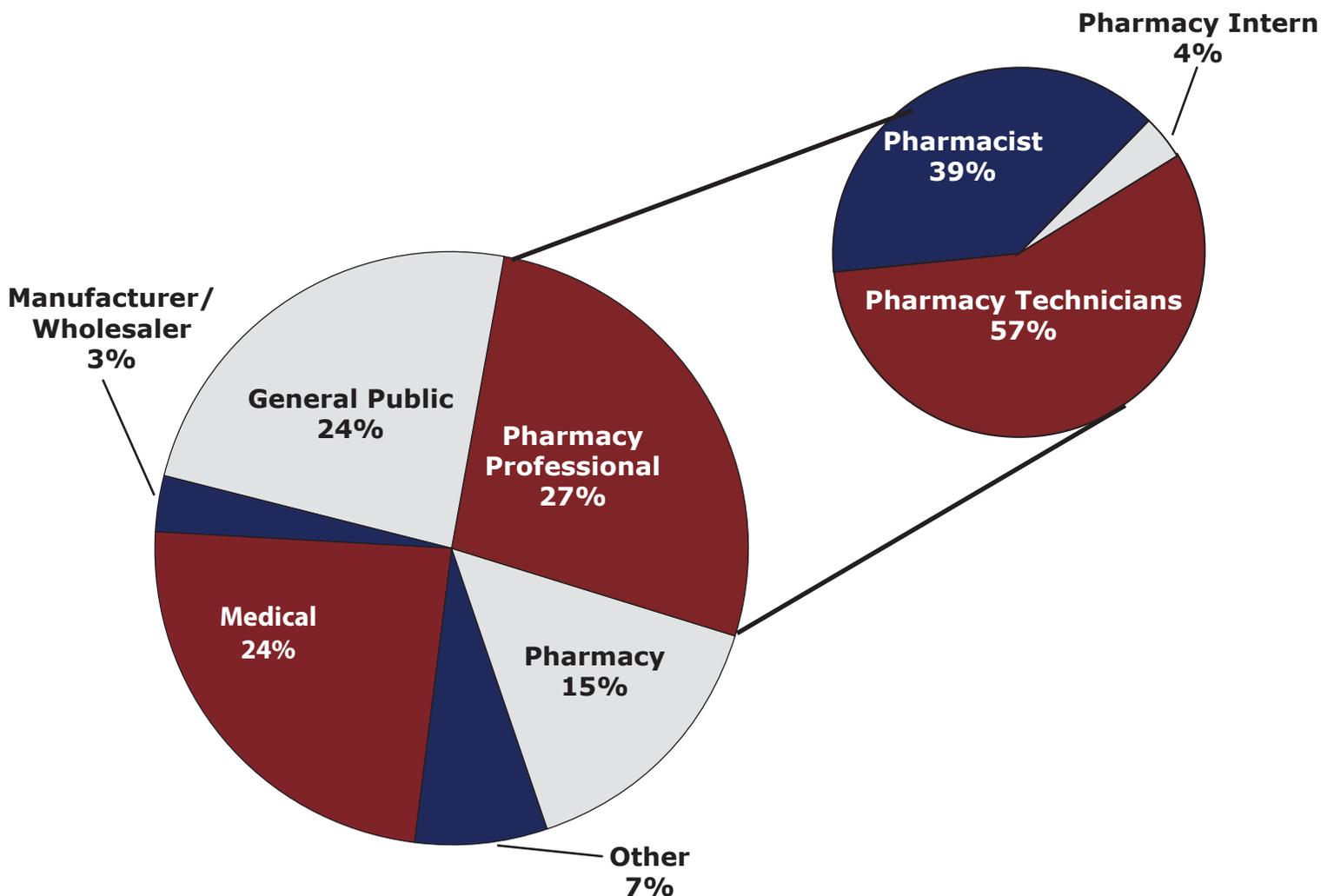
New Cases by Type (Top 10), FY 2018

Background Investigation	452
Deception to Obtain Dangerous Drugs	356
Theft of Drugs	288
Consumer Complaint	239
Unprofessional Conduct/Gross Immorality	163
Error in Dispensing	117
Falsification	102
Questionable Prescribing	81
Minimum Qualifications	78
Late Renewal of License	74

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. Suspension and probation are also utilized, particularly in cases of substance abuse where rehabilitation is deemed possible.

ADMINISTRATIVE ACTIONS IN FY 2018	
Citations Issued	48
Proposals to Deny License (New, Reciprocal or Renewal)	25
Settlement Agreements	72
Summary License Suspensions	13
Suspensions	6
License Revocations	2
Pharmacists Currently Serving Terms of Probation	29
Medical Marijuana Case Citations Issued/Proposals to Deny	322

Case Suspects by Type, FY 2018



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 2018 Accomplishments

Adoption of legislation allowing for the following:

- Biennial renewal of licenses.
- Access to OARRS by drug court judges, coroners and hospital peer review committees.
- Expanding the retention of OARRS data from three to five years.

Successful development and implementation of administrative rule packages, including:

- Acute pain prescribing in coordination with the other prescriber boards;
- Reporting diagnosis codes to OARRS;
- Updated emergency medical service organization rules;
- Pharmacist consult agreements; and
- Pharmacy technician registration.

Reorganization of the Board's rules to divisions based on license type.

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 one non-controlled drug, gabapentin) dispensed by Ohio-

OHIO AUTOMATED RX REPORTING SYSTEM

licensed pharmacies and personally furnished by licensed prescribers in Ohio. Drug wholesalers are also required to submit information on all controlled substances and gabapentin 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 2018 Accomplishments

- As a result of ongoing efforts to promote integration, more than 20,000 prescribers and pharmacists have direct access to OARRS as part of their workflow.
- Use of OARRS continued to break records in FY 2018. June 2018 was the first month on record to average over 500,000 daily OARRS requests.
- In November 2017, Ohio became the first state in the country to upgrade to Appriss Health's Care® platform. The platform offers several new features including:
 - Narx Scores
 - Overdose Risk Score
 - Additional Risk Indicators
 - RxGraph
 - Medication Assisted Treatment (MAT) Provider Locator

MEDICAL MARIJUANA CONTROL PROGRAM



As one of the three state agencies charged with the implementation of the Ohio Medical Marijuana Control Program (MMCP), the Board is responsible for the oversight of the patient and caregiver registry, retail dispensaries, and the toll-free helpline.

In developing the plan for dispensaries, the Board examined geographic diversity and patient access, as required by law. This resulted in the initial 56 provisional licenses being assigned in 28 dispensary districts across the state.

The Board also operates the state's medical marijuana patient and caregiver registry. Patients and caregivers are required to be registered with the state annually. Under Ohio law, all of the following are identified as qualifying medical conditions for the program: AIDS, amyotrophic lateral sclerosis, Alzheimer's disease, cancer, chronic traumatic encephalopathy, Crohn's disease, epilepsy or another seizure disorder, fibromyalgia, glaucoma, hepatitis C, inflammatory bowel disease, multiple sclerosis, pain that is either chronic and severe or intractable, Parkinson's disease, positive status for HIV, post-traumatic stress disorder, sickle cell anemia, spinal cord disease or injury, Tourette's syndrome, traumatic brain injury, and ulcerative colitis.

The Board is responsible for licensing all dispensary employees. The licensing structure is broken into three types of employees: 1) associated key employees, 2) key employees, and 3) support employees.

FY 2018 Accomplishments

- Developed and implemented rules for dispensaries, patients and caregivers, and forms and methods of administration.
- Developed and released the Request for Applications (RFA) to operate medical marijuana dispensaries. The application submission period opened on November 3, 2017 and closed on November 17, 2018 and reopened for an amendment period from December 18, 2018 to December 20, 2018. The Board received in total 376 applications.
- All 376 applications were reviewed and scored by Board evaluators. In June, the Board awarded 56 provisional dispensary licenses. Applications were not submitted in 2 of the 31 districts and 1 district did not have a viable applicant.
- In June 2018, the Board launched the Ohio Medical Marijuana Control Program Toll-Free Helpline. The Toll-Free Helpline responds to inquiries from patients, caregivers, and health professionals regarding adverse reactions to medical marijuana, and provides information about available services and additional assistance as needed.

STATEMENT OF ACTIVITIES

FOR STATE FISCAL YEAR 2017 (JULY 1, 2017 - JUNE 30, 2018)

FY 2018 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.	\$10,040,708
Fund 4A50 (Drug Law Enforcement) Fines and bail or property forfeitures collected as a result of the Board's drug law enforcement efforts.	\$76,510
Fund 3EB0 (OARRS Improvements) Harold Rogers Prescription Monitoring Program grants distributed by the U.S. Department of Justice, Office of Justice Programs.	\$10,496
Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grants distributed by the U.S. Department of Justice, Office of Justice Programs.	\$248,600
Fund 3HH0 (OARRS Intergration HITECH) Grant money recieved from the Ohio Department of Medicaid to support OARRS intergration with medical record systems.	\$1,546,076
Fund 5SG0 (Drug Database) Donations and grant subawards from other state agencies to make improvements to OARRS as authorized in ORC 4729.83.	\$104,798
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.	\$1,920,383
TOTAL REVENUE FY 2018	\$13,947,571

FY 2018 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).	\$8,712,315
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.	\$16,911
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).	\$54,706
Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grants distributed by the U.S. Department of Justice, Office of Justice Programs.	\$251,058
Fund 3HH0 (OARRS Integration HITECH) Grant money recieved from the Ohio Department of Medicaid to support OARRS integration with medical record systems.	\$1,546,076
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 5SY0 (Medical Marijuana Control Program) Used by the Board to implement the Medical Marijuana Control Program under ORC Chapter 3796.	\$2,111,650
TOTAL EXPENSES FY 2017^[1] [2]	\$12,820,489

[1] Expenses reflect actual cash disbursements during FY 2018 and include some expenses budgeted with FY 2017 appropriation. Similarly, some expenses budgeted with FY 2018 appropriation will be disbursed in FY 2019 and reflected on that year's annual report.

[2] 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 2018.



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

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