

ANNUAL REPORT 2014 July 1, 2013 - June 30, 2014



MISSION

The Ohio State 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 Ohio State Board of Pharmacy is the single state agency in Ohio responsible for administering and enforcing laws governing the legal distribution of drugs. The Board consists of nine members who are appointed by the Governor for terms of four years. Eight of the members are licensed pharmacists who represent, to the extent practicable, each phase of pharmacy practice. One member represents the public. The Board has a staff of forty-six employees that are responsible for carrying out the day-to-day operations and responsibilities of the Board.



Since the State Board of Pharmacy is responsible for administering and enforcing the drug laws of Ohio, the Board licenses:

- Pharmacists, (O.R.C. Chapter 4729.)
- Pharmacy Interns, (O.R.C. Chapter 4729.)
- Terminal and Wholesale Distributors of Dangerous Drugs (both in-state and out-of-state), (O.R.C. Chapter 4729.) and
- Manufacturers and Wholesalers of Controlled Substances (O.R.C. Chapter 3719.).

The Board is also responsible for regulating the legal distribution of dangerous drugs in Ohio and ensuring the quality of all drugs administered, prescribed, dispensed by prescription, or sold over-the-counter (O.R.C. Chapter 3715.). The State Board of Pharmacy can discipline its licensees and registrants for violations of both federal and state laws governing the legal distribution of drugs. The Board has the responsibility of investigating and presenting evidence of violations of any of the federal or state drug laws by any person to the appropriate court (federal, state, or municipal) for prosecution of the offender (O.R.C. Chapter 2925.).

A LETTER FROM THE EXECUTIVE DIRECTOR



I am excited as the Executive Director to publish our 2014 Annual Report. This report is designed to share pertinent operational statistics and accomplishments of the Ohio State Board of Pharmacy. The following primary strategies drove our strategic planning in 2014:

- **1. Culture:** Continue to improve and foster a culture of trust, professionalism and service to internal and external customers.
- **2. Improve Operations:** Provide enhanced and improved service by leveraging I.T. enhanced process redesign.
- **3. Improve the PMP:** Continue to improve our prescription monitoring program (PMP), the Ohio Automated Rx Reporting System (OARRS), to better serve our end users and the public.
- **4. Fiscal Responsibility:** Continue to operate the Agency at a surplus of revenues over expenses, utilizing zero GRF funding.

Culture

The leadership team and staff at the Ohio State Board of Pharmacy are dedicated to improving the morale and culture of our agency, inside and out. Culture is king. A healthy culture drives motivation that is sustainable and essentially drives all listed strategies and processes. We have done this through intentional design: leading by example, placing the right people in the right positions with the right skill sets and creating a system of rewards to acknowledge employees for a job well done. A culture of trust and professionalism is demanded by leadership and not only expected between employees, it's expected to be shown to our licensees and citizens. And I'm proud to say I know this has improved from a number of positive correspondences from staff, citizens, licensees, other state agency department leaders, legislators, law enforcement partners, associations and interested parties.

Improve Operations

It's been no secret that from the beginning of my tenure, this has been an essential identified need for the agency. I have made it a top priority to use I.T. to streamline processes and produce a better product. You'll see from most of the sections the improvements and accomplishments made, many of which are tied directly to these strategies, have enabled us to do more with less while improving morale. This strategy also has allowed us to offer new additional services in compliance (such as the SPIDR program) and vast improvements in the licensing processes benefitting the agency and the end user.

Improve Ohio's PMP (OARRS)

We're fortunate to have an incredible staff that continually works with leadership to improve this nationally recognized clinical program. Our new M.E.D. (Morphine Equivalent Dosing) initiatives, not only met a need from the Governor's office but took this request and expanded upon it, making it a much improved patient-care tool for our end users. The OARRS program offers functionality that is unparalleled, as I learned presenting these enhancements at the National Association of Boards of Pharmacy annual meeting this past year. It is no surprise that the group behind the scenes for this product also have developed some incredible enhancements for operational needs across the agency as well. There are more enhancements in the pipeline that are going to be pretty incredible for OARRS, so please stay tuned.

Fiscal Responsibility

Fiscal accountability is obviously crucial for any organization. Though the Ohio State Board of Pharmacy is part of the "rotary fund" for boards and commissions, we pride ourselves as being a donator to this fund, operating totally on the fees from our licensees and fines from cases, thus taking zero dollars from Ohio's General Revenue Fund. All initiatives are challenged with this strategy prior to implementation and, as you'll see, we continually meet this fiscal goal while running a nationally leading PMP program that is primarily funded by federal grants.

In conclusion, The Ohio State Board of Pharmacy is dedicated to our mission. We're also dedicated to improvement. These primary strategies evolved into many specific operational improvement projects developed from our yearly strategic planning leadership meeting. The following Annual Report is broken down by major sections of the agency and list pertinent operational and fiscal statistics as well as accomplishments. I'm proud and greatly appreciate all of Leadership Team, Office Staff, Field Agents and Compliance Specialists, as these accomplishments could not have occurred without their dedication to excellence that makes the Ohio State Board of Pharmacy a national leader.

Sincerely,

Kyle W. Parker, M.B.A., R.Ph., Executive Director

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Ohio State Board of Pharmacy

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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.



FY 2014 Accomplishments

Supporting Our Veterans

- Adoption of veteran and military family licensure and renewal policies.
- Publishing a dedicated veteran and military family web site: www.pharmacy.ohio.gov/veterans.

Regulation Changes

A number of changes were made to the Ohio Revised Code and Ohio Administrative Code in order to streamline the licensing process:

- ORC 4729.54 Terminal distributor licenses: annual renewal date changed to March 31.
- OAC 4729-3-03 Application for registration as a pharmacy intern: documentation needed for verification of college work changed.
- 4729-7-02 Requirements for renewal of a pharmacist identification card: C.E.U. eligibility date
 to coincide with renewal cycle (September 15); military consideration for education, training and
 experience as well as extension of deadlines for military personnel called to active duty.
- 4729-7-03 Evidence of continuing pharmacy education experiences: documentation needed for verification of C.E.U.s obtained changed.

Staffing

A reorganization of personnel has led to increased productivity and reduced wait time on licensing applications. Such a reorganization includes the addition of the following staff:

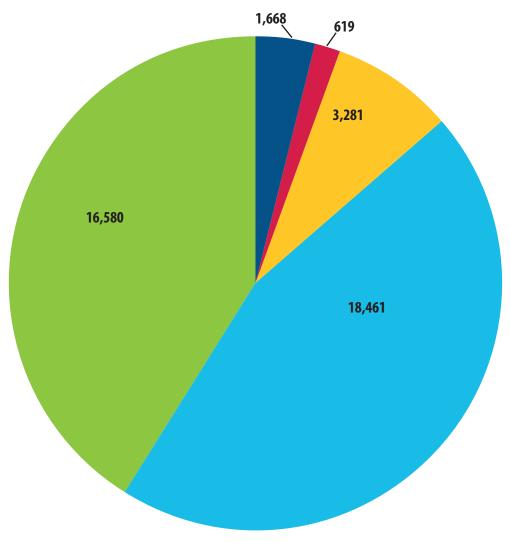
- Certification/Licensing Examiner 2- Pharmacist Focus.
- Certification/Licensing Examiner 2- Terminal Distributor Focus.

Technology

A major push was made to make as much of the licensing process as possible available online and via self-service. Such changes include:

- Terminal distributor of dangerous drugs limited licensee drug list approval and access program.
- Pharmacist and intern 2013 paperless renewal process.
- Terminal distributor non-resident pharmacy compounding survey program.
- Wholesale distributor of dangerous drugs licensee ability to print own license.











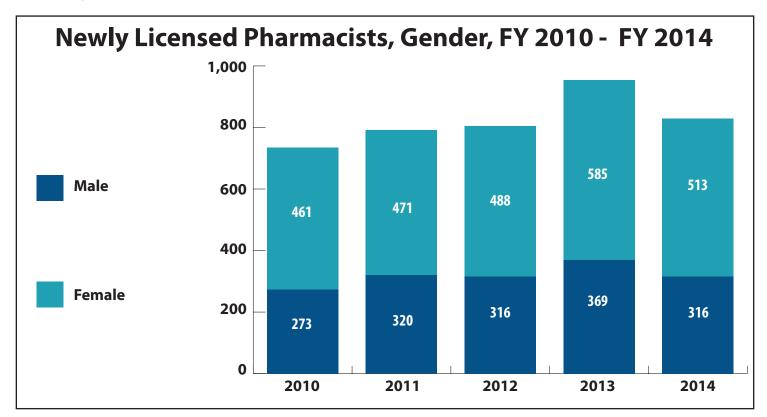


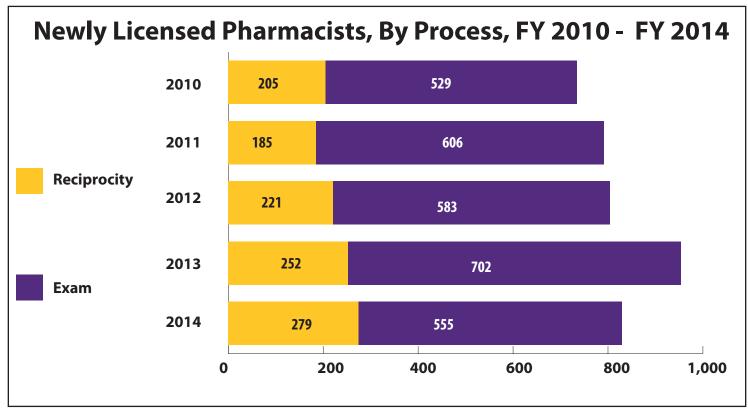


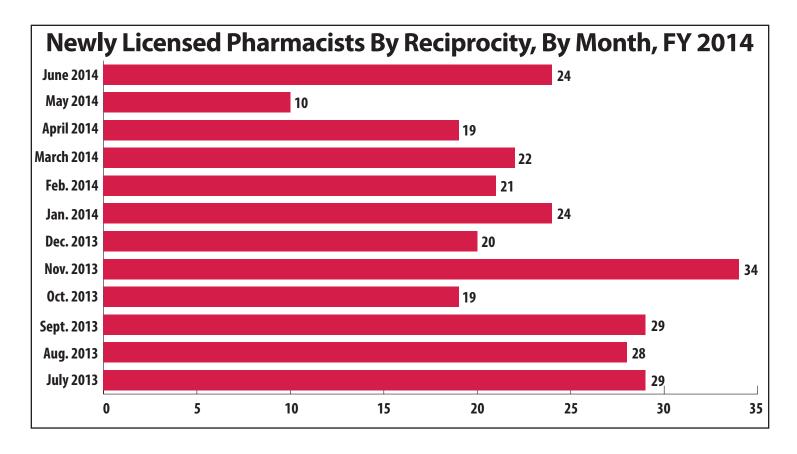
Total Active Licenses for FY 2014 40,609

Pharmacists:

- Gender distribution of newly licensed pharmacists continues to favor females.
- FY 2014 newly licensed pharmacist applicants saw a notable decrease (13.1% YOY).
- Roughly 1 out of 4 newly licensed pharmacists become licensed through reciprocity.
- An average of 23 newly licensed pharmacists became licensed through reciprocity each month during FY 2014.

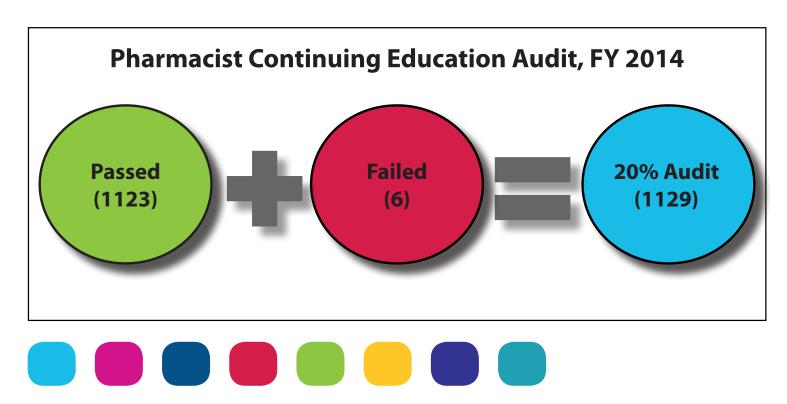






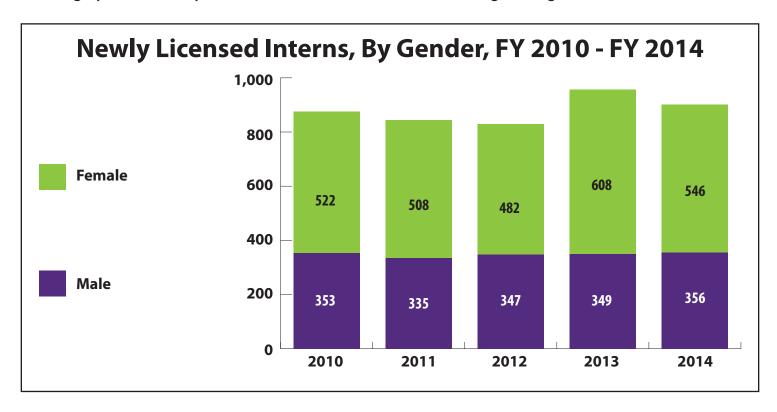
Pharmacist Continuing Education Audits:

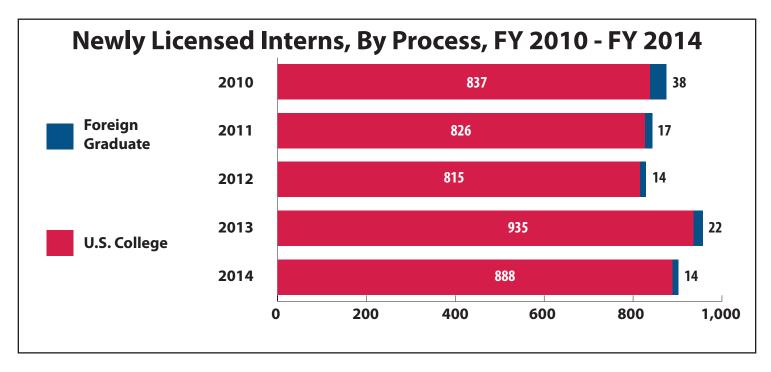
Ohio Pharmacists are required to complete six C.E.U.s (60 hours) of approved continuing education every three years. The Ohio State Board of Pharmacy conducts an annual audit of 20 percent of licensees that are required to submit their continuing education. In FY 2014, less than 1% of pharmacists audited in failed their C.E.U. requirements.



Pharmacy Interns:

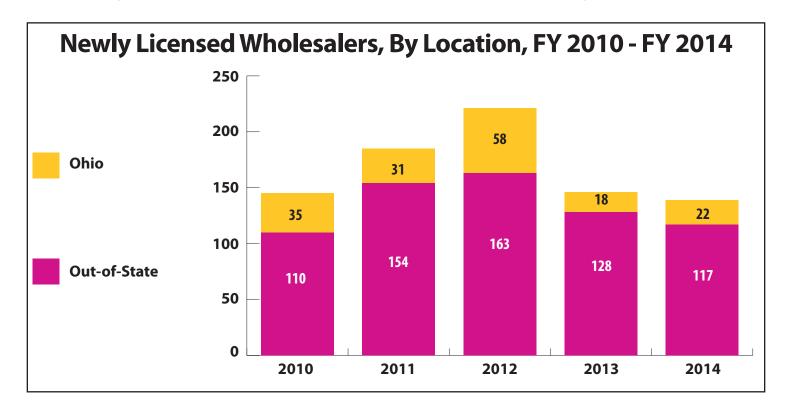
- Gender distribution of newly licensed interns continues to favor females.
- FY 2013 newly licensed intern applicants saw a notable increase (13.4% YOY).
- Roughly 1 in 50 newly licensed interns matriculated from foreign colleges in FY 2014.

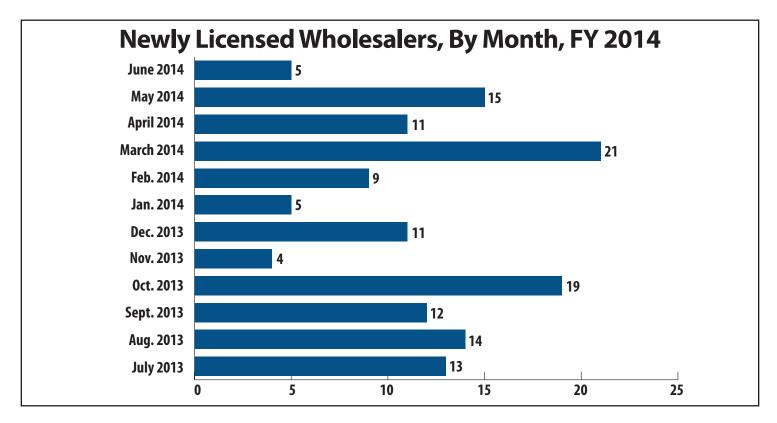




Wholesale Distributors of Dangerous Drugs:

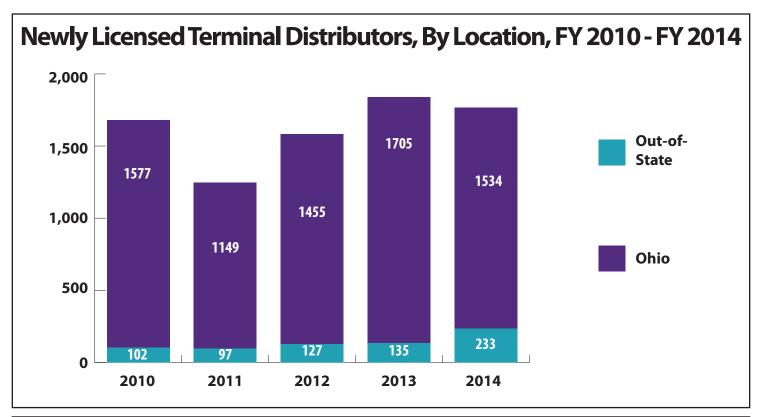
- Location distribution of newly licensed wholesalers continues to favor out-of-state locations.
- FY 2014 newly licensed wholesaler applicants were at their lowest in 5 years.
- On average, 12 new wholesaler licenses were approved each month during FY 2014.

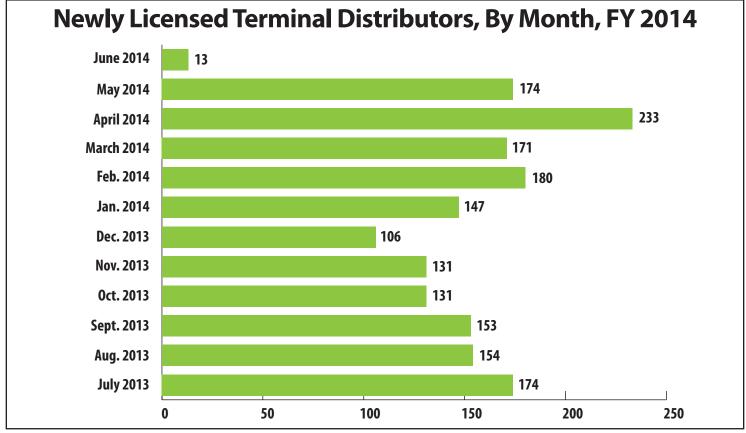




Terminal Distributors of Dangerous Drugs:

- FY 2014 terminal distributor out-of-state applicants saw a significant increase (172.6% YOY).
- More than 1,700 new Terminal Distributor licenses were approved during FY 2014.
- Pharmacy Supplied Contingency Stock licenses (such as long-term care facilities) and Clinic Category licenses continue to dominate the total of newly issued Terminal Distributor licenses.





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

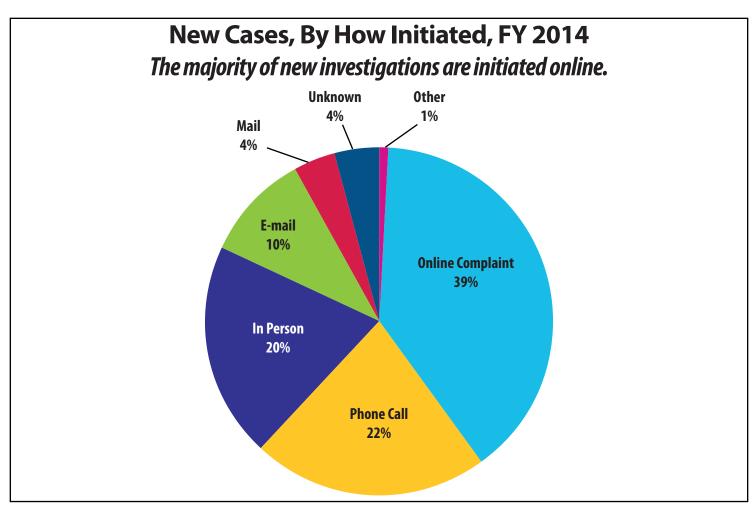


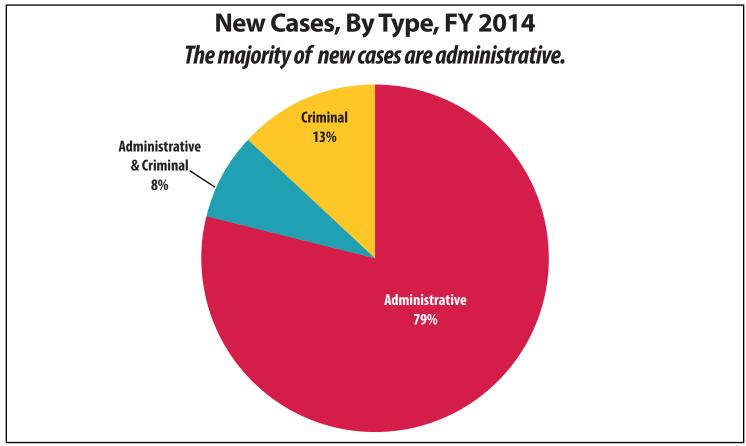
crimes committed by health care professionals and the general public. Department staff also perform pharmacy inspections; train pharmacy, medical, and law enforcement personnel; and assist outside agencies with prescription drug crime investigations.

FY 2014 Accomplishments

- Compliance Agent Trey Edwards and Compliance Secretary Yolanda Freeman recognized by the Board for outstanding service.
- Institution of electronic submission of DEA-106 forms streamlined the drug diversion reporting process.
- First annual Retail Roundtable brought together key retail pharmacy stakeholders and Board of Pharmacy employees for discussion and training.
- New computer-generated pharmacy inspection reports improved communication with pharmacy professionals.
- Creation of the Shared Prescription Investigation Deconfliction Resource (SPIDR) to reduce investigation overlap among involved law enforcement and regulatory agencies.

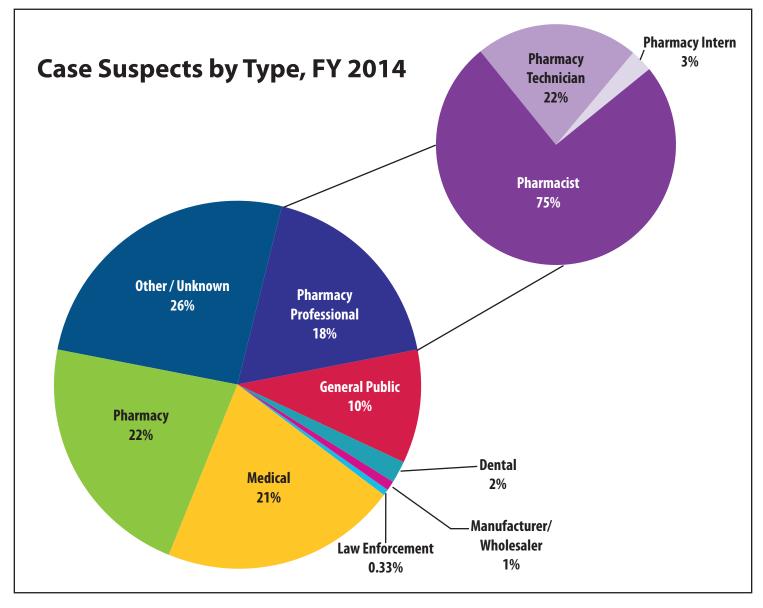






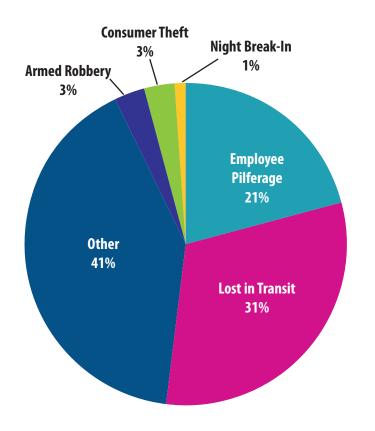
New Cases by Type (Top 10), FY 2014

| Consumer Complaint | 173 |
|---|-----|
| Theft of Drugs | 166 |
| Questionable Dispensing | 125 |
| Error in Dispensing | 124 |
| Questionable Prescribing | 98 |
| Deception to Obtain Drugs | 98 |
| Background Investigation | 77 |
| Illegal Processing of Drug Documents | 64 |
| Illegal Drug Purchases | 61 |
| OARRS Complaints | 53 |



Drug Theft or Loss

DEA form 106 documents prescription drug theft and loss. The Board of Pharmacy compiles and analyzes these forms, which include information on type and location of loss. The following data was derived from the forms submitted for FY 2014.



DEA 106 Reports by County (Top 5)

| , | | | | |
|------------|-------|--------------------|--|--|
| County | Total | % of Total Reports | | |
| Franklin | 311 | 33.95% | | |
| Hamilton | 81 | 8.84% | | |
| Montgomery | 58 | 6.33% | | |
| Cuyahoga | 49 | 5.35% | | |
| Lucas | 38 | 4.15% | | |

Administrative Actions

Not every case that goes before the Board of Pharmacy results in administrative action. The following numbers represent the actions taken by the Board in FY 2014.

| Citations Issued | 100 |
|--|-----|
| Proposals to Deny License (New, Reciprocal or Renewal) | 31 |
| Settlement Agreements | 17 |
| Summary License Suspensions | 15 |
| License Revocations | 1 |

Administrative actions taken against a pharmacist's license 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 following numbers represent a snapshot of suspended and probationary licenses at the end of FY 2014.

| Pharmacists Currently Serving Terms of Probation | 31 |
|--|----|
| Suspended Pharmacists Currently Reporting to Rehabilitation Programs | 18 |
| Severed Rehabilitation Contracts (Contracts Terminated Early) | 2 |

LEGISLATIVE AFFAIRS

The Office of Legislative Affairs (OLA) is responsible for the development and implementation of strategies to advance the Board's legislative initiatives and other interests relating to the General Assembly. OLA serves to:

 Articulate the Board's position on legislation proposed by the General Assembly.



- Facilitate 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.
- Coordinate the Board's responses to legislative committee requests and other inquiries from individual members and general assembly staff.
- Assist with the implementation of legislative and regulatory changes.
- Provide updates and guidance to stakeholders and the general public on recent policy changes.

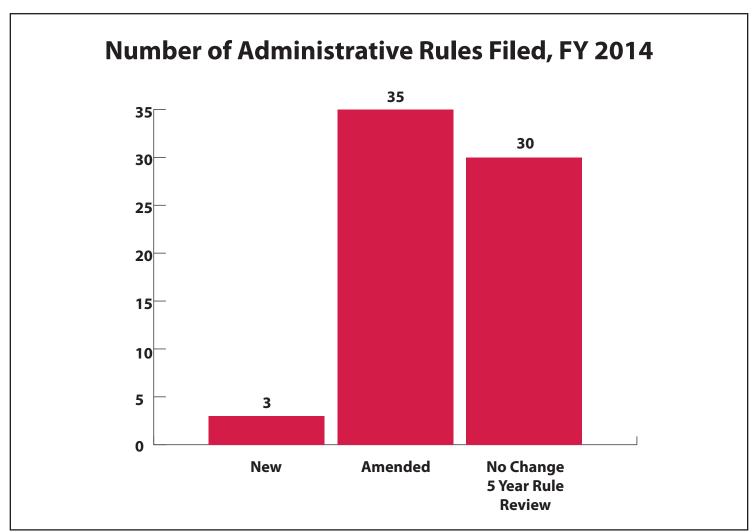
FY 2014 Accomplishments

- Enactment of legislation requiring registration and use of the Ohio Automated Rx Reporting System (HB 341 Smith).
- Adding tramadol as a Schedule IV Controlled Substance (OAC 4729-11-03).
- Requiring daily reporting to the Ohio Automated Rx Reporting System (OAC 4729-37-07).
- Adding synthetic cannabinoids (i.e. synthetic marijuana) and cathinones (i.e. bath salts)
 as Schedule I Controlled Substances (OAC 4729-11-02).
- Authorizing pharmacists to provide the Measles, Mumps and Rubella (MMR) vaccination (OAC 4729-5-38).

Administrative Rules

The Office of Legislative Affairs filed 68 rules with the Joint Committee on Agency Rule Review (JCARR) in FY 2014. Highlights of the new and amended rules filed in FY 2014 include:

- Adding tramadol as a Schedule IV Controlled Substance (OAC 4729-11-03).
- Requiring daily reporting to the Ohio Automated Rx Reporting System (OAC 4729-37-07).
- Authorizing pharmacists to provide the Measles, Mumps and Rubella (MMR) vaccination (OAC 4729-5-38).
- Removing the prescription requirement for pharmacist administration of the Herpes Zoster (Shingles) vaccine (OAC 4729-5-38).
- Authorizing the use of protocols for administration of vitamin K for prevention of vitamin K deficient bleeding in newborns and administration of erythromycin for the prevention of ophthalmia neonatorum (OAC 4729-5-01).
- Adding synthetic cannabinoids (i.e. synthetic marijuana) and cathinones (i.e. bath salts) as Schedule I Controlled Substances (OAC 4729-11-02).



Legislation

The Ohio State Board of Pharmacy works closely with members of the General Assembly on a number of issues to protect the health and safety of Ohioans. Below are some highlights of the Board's work with the Ohio General Assembly:

Promoting Registration and Use of the Ohio Automated Rx Reporting System

HB341 – OARRS CHECKS (SMITH R)

- Prohibits an opioid analgesic or benzodiazepine from being prescribed or dispensed without review of patient information in the State Board of Pharmacy's Ohio Automated Rx Reporting System.
- Requires that certain prescribers, as well as pharmacists, when renewing their professional licenses, certify to their licensing boards that they have access to OARRS and subjects the licensees to possible disciplinary action for false certifications.

Increasing Access to Naloxone to Prevent Unintentional Drug Overdose Deaths

HB170 - NALOXONE (JOHNSON T, STINZIANO M)

• Permits a licensed health professional authorized to prescribe naloxone to prescribe, administer, dispense, or furnish naloxone to a person who is, or a person who is in a position to assist a person who is, apparently experiencing or who is likely to experience an opioid-related overdose.

Preparing for Public Health Emergencies

HB44 – PUBLIC HEALTH EMERGENCIES (MCCLAIN J)

• Requires the Director of Health to develop one or more protocols regarding the availability of drugs during a public health emergency that authorize pharmacists and pharmacy interns to dispense limited quantities of certain dangerous drugs without a prescription or record of a prescription.

Increasing Operational Efficiencies and Oversight of Compounded Drugs

HB483 – MBR-OPERATION OF STATE PROGRAMS (AMSTUTZ R)

- Moves the terminal distributor of dangerous drugs license renewal date from December 31st to March 31st.
- Removes restrictions on using licensure fees from terminal distributors, pharmacists and pharmacy interns to support OARRS.
- Requires, beginning April 1, 2015, certain business entities that are exempt from holding a terminal
 distributor license under current law to hold a terminal distributor license from the State Board
 of Pharmacy to possess and distribute dangerous drugs that are compounded or used for the
 purpose of compounding.

Supporting Our Veterans

HB488 – MBR-HIGHER EDUCATION-MILITARY VETERANS (DOVILLA M, LANDIS A)

Authorizes the Board to waive licensing fees for veterans.



OHIO AUTOMATED RX REPORTING SYSTEM

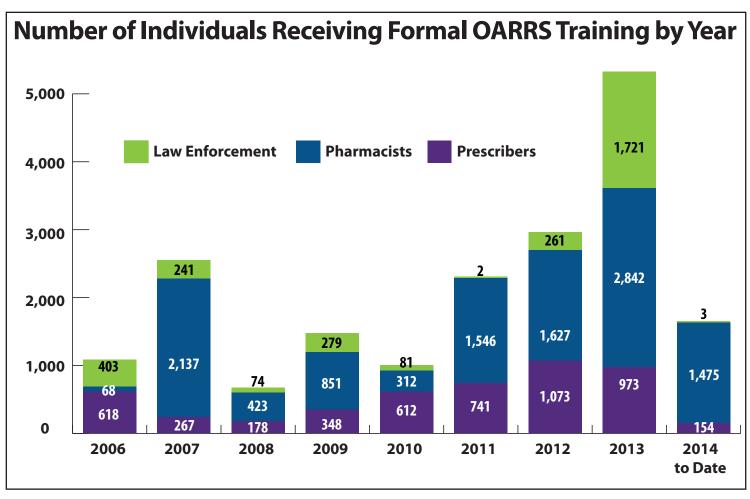
The Ohio Automated Rx Reporting System (OARRS) is the State of Ohio's Prescription Monitoring Program. OARRS is a clinical tool to assist in the treatment of Ohio patients. The Board collects information on all prescriptions for controlled substances that are dispensed in Ohio. This information is then available to prescribers when they treat patients and pharmacists when presented with prescriptions from patients. Law enforcement can also be granted access to the system during active investigations.

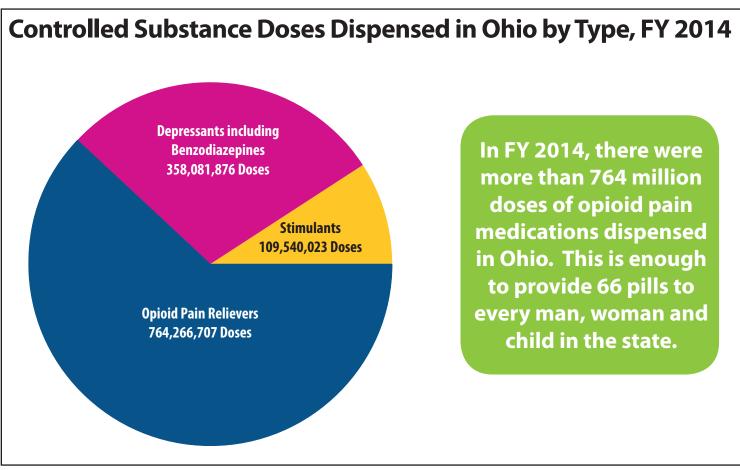


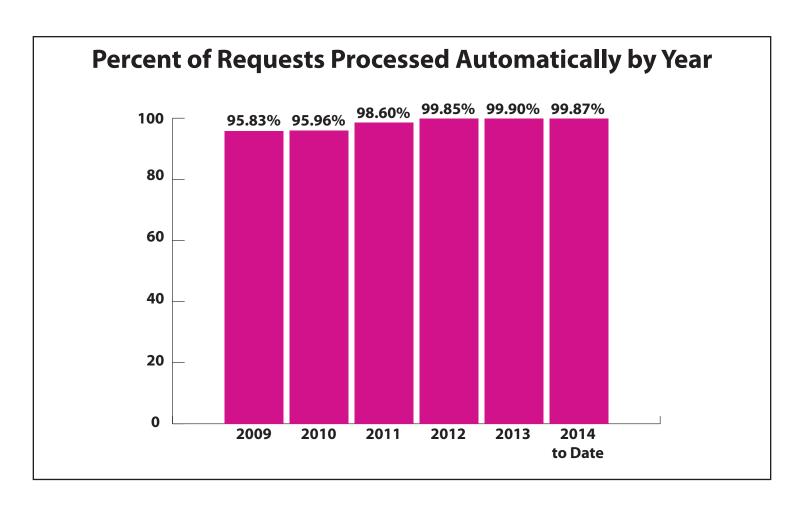
The OARRS department is primarily responsible for operating and maintaining the Ohio Automated Rx Reporting System. Additionally, the OARRS department provides technical expertise and services to the agency, as needed. For more information on OARRS, including how to register, please visit: www.ohioPMP.gov.

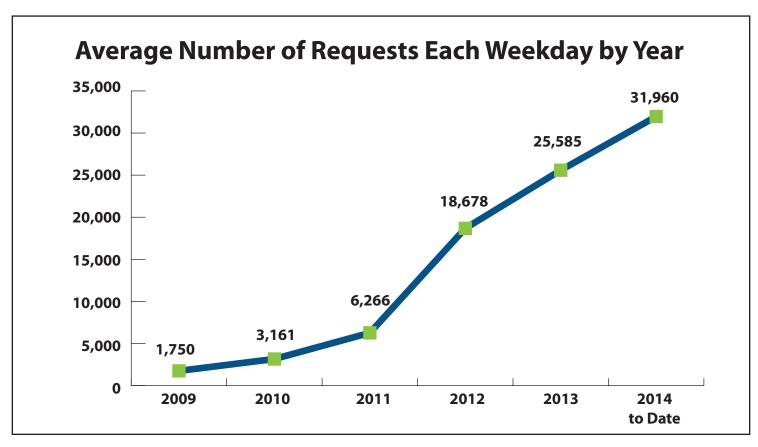
FY 2014 Accomplishments

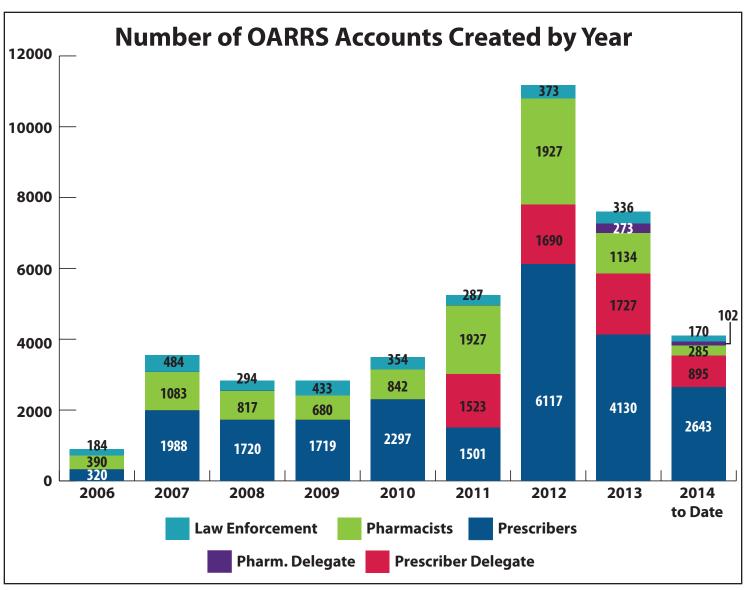
- In July, 2013, the OARRS department supported the efforts of the Governor's Cabinet
 Opiate Action Team (GCOAT) by adding the Active Cumulative Morphine Equivalent
 (ACME) score to the OARRS Patient Rx History Report. The addition of the ACME score has
 been well received as a tool for helping healthcare professionals adhere to the GCOAT
 Opiate Prescribing Guidelines.
- In January 2014, the OARRS department began providing a new report, the Practice Insight Report, to prescribers holding an OARRS account. The Practice Insight Report offers a quick glance at the prescriber's medical practice, allowing the prescriber to quickly identify patients receiving controlled substance prescriptions from multiple providers, patients receiving large doses of opioid pain medications, and possible prescription forgeries. It is the intent of OARRS to further enhance this report with specialty-specific trends and statistics once that information becomes available.

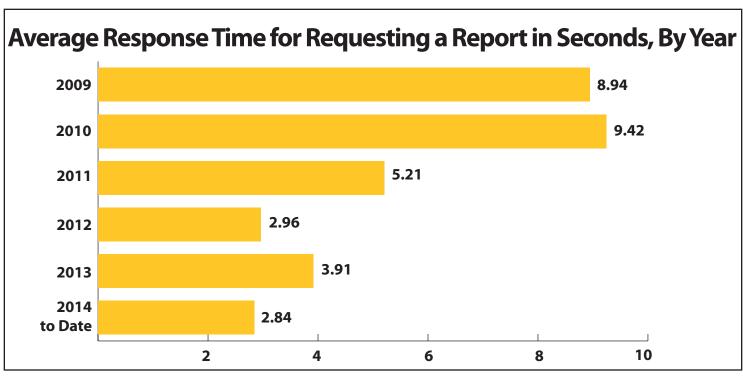










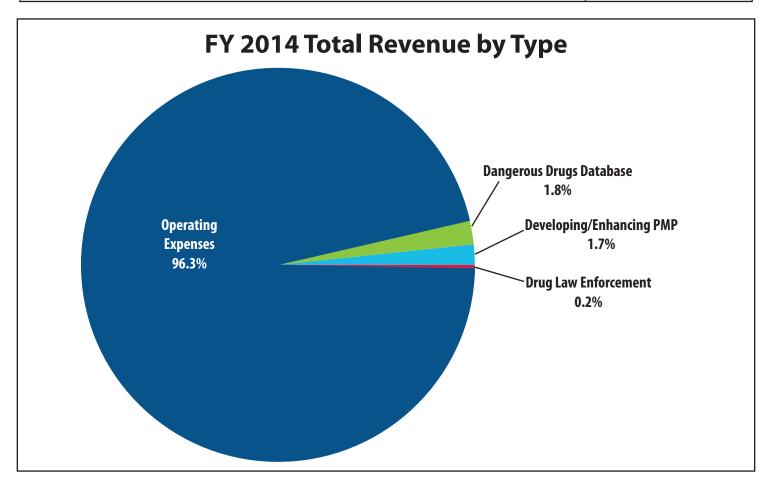


STATEMENT OF ACTIVITIES

FOR STATE FISCAL YEAR 2014 (JULY 1, 2013 - JUNE 30, 2014)

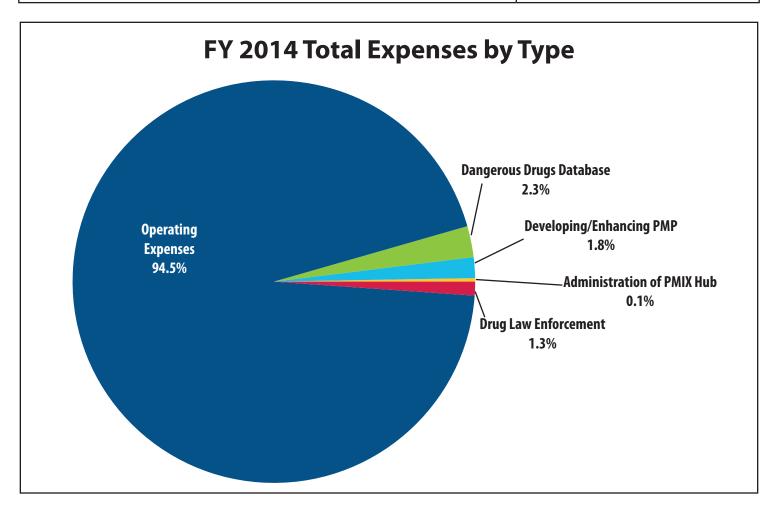
FY 2014 Revenue

| 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. | \$ 6,723,546 |
|---|--------------|
| Fund 4A50 (Drug Law Enforcement) Fines and bail or property forfeitures collected as a result of the Board's drug law enforcement efforts. | \$ 16,876 |
| Fund 3BC0 (Dangerous Drugs Database) <i>Harold Rogers Prescription Monitoring Program Grant distributed by the U.S. Department of Justice, Office of Justice Programs.</i> | \$ 122,791 |
| Fund 3CTO (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. | \$ 116,136 |
| Fund 3EYO (Administration of PMIX Hub) <i>Harold Rogers Prescription Monitoring Program grant distributed by the U.S. Department of Justice, Office of Justice Programs. (Note: Grant ended on 9/30/2013).</i> | \$ 0 |
| Total Revenue FY 2014 | \$6,979,349 |



FY 2014 Expenses

| Total Expenses FY 2014 | \$6,432,787 |
|---|--------------|
| Fund 3EYO (Administration of PMIX Hub) Used for the purpose of enhancing Ohio's prescription drug monitoring program known as the Ohio Automated Rx Reporting System (OARRS). | \$ 10,253 |
| Fund 3CTO (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. | \$ 113,102 |
| 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). | \$ 146,476 |
| 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. | \$ 86,680 |
| 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). | \$ 6,076,276 |





The Ohio State 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.

Ohio State Board of Pharmacy

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Phone: 614-466-4143

www.pharmacy.ohio.gov/contact.aspx