



## **HB 49 Testimony – Steven W. Schierholt, Executive Director**

Chairman Romanchuk, Ranking Member Sykes and members of the House Finance Subcommittee on Health and Human Services, thank you for the opportunity to provide testimony on the State of Ohio Board of Pharmacy’s Fiscal Year 2018 & 2019 budget proposal.

My name is Steve Schierholt and I am the Executive Director of the State Board of Pharmacy. The Board of Pharmacy was established by the legislature in May of 1884 and consists of nine members, including 8 pharmacists, who are appointed by the Governor for terms of four years. The Board currently has a staff of sixty-eight employees 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
- 3796. – Medical Marijuana Control Program
- 4729. – Pharmacy Practice Act & Dangerous Drug Distribution Act

In enforcing these chapters, the Board licenses and regulates more than 45,000 pharmacists, pharmacy interns and sites where dangerous drugs are purchased and stored prior to delivery to a patient. The site licenses include, but are not limited to, retail pharmacies, wholesalers, hospitals, prescriber offices, veterinary clinics, nursing homes, prisons and jails, emergency medical service organizations, medical gas distributors and pain management clinics.

Beginning in FY 18, the Board will also begin licensing an estimated 42,000 pharmacy technicians as well as prescriber offices that provide treatment of opioid addiction using buprenorphine.

### **Total Number of Active Board of Pharmacy Licenses, by FY Year**

License Type	Registered Pharmacist	Pharmacy Intern	Terminal Distributor	Wholesale Distributor	Controlled Substance Wholesaler	Total
<b>FY 2009</b>	16838	3640	16839	950	501	<b>38768</b>
<b>FY 2010</b>	17354	3845	16814	1024	540	<b>39577</b>
<b>FY 2011</b>	17877	3930	17222	1138	565	<b>40732</b>
<b>FY 2012</b>	18426	4112	17913	1092	588	<b>42131</b>
<b>FY 2013</b>	18954	4193	18646	1119	618	<b>43530</b>
<b>FY 2014</b>	19318	4263	18754	1156	655	<b>44146</b>
<b>FY 2015</b>	19933	4458	19143	1203	682	<b>45419</b>
<b>FY 2016</b>	20272	4333	18803	1168	673	<b>45249</b>



The 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 criminal prosecution and/or administrative action. In performing this duty, Board staff investigate physicians, nurses, dentists or other individuals that may not be licensed by the agency. In FY 16, 18 percent of all cases investigated by the Board involved healthcare professionals other than pharmacists who may have violated provisions of Chapters 2925. and 3719. of the Ohio Revised Code. For example, earlier this month a joint investigation between the Board and the Mahoning Valley Law Enforcement Task Force led to the indictment of a Youngstown physician on 78 felony counts, including 33 counts of drug trafficking.

The Board also operates Ohio's prescription drug monitoring program, known as the Ohio Automated Rx Reporting System (OARRS). Established in 2006, OARRS collects information on all prescriptions for controlled substances that are dispensed by pharmacies and personally furnished by licensed prescribers in Ohio. Drug wholesalers are also required to submit information on all controlled substances sold in the state. The data is reported every 24 hours and is maintained in a secure database.

OARRS serves multiple functions, including: a patient care tool; drug epidemic early warning system; and drug diversion and insurance fraud investigative tool. OARRS assists prescribers and pharmacists in avoiding potentially life-threatening drug interactions as well as identifying individuals fraudulently obtaining controlled substances from multiple health care providers, a practice commonly referred to as "doctor shopping." It can also be used by professional licensing boards to identify clinicians with patterns of inappropriate prescribing and dispensing, and to assist law enforcement in cases of controlled substance diversion.

Last year also saw the first full year of Ohio's OARRS integration initiative. Announced by Governor Kasich in October 2015, the Board is working to integrate OARRS directly into electronic medical records and pharmacy dispensing systems across the state, allowing instant work flow access for prescribers and pharmacists. Since that announcement, the Board has made significant progress, including the following highlights:

- Mount Carmel Health System became the first major health system to integrate their electronic health records with OARRS under the integration initiative. Integration allows instant access to OARRS for more than 2,300 prescribers and pharmacists in the Mt. Carmel Health System.
- The Ohio State University Wexner Medical Center and the Cleveland Clinic have recently integrated their electronic health record with OARRS.
- Discount Drug Mart completed integration in its 73 Ohio stores.
- 79 independent pharmacies in Ohio are now integrated with OARRS.

As a result of integration and efforts to enforce current laws and rules requiring the use of OARRS, the number of daily OARRS queries has increased significantly. In January 2016, the average number of weekday requests for information in OARRS was 64,042. In January 2017, that number nearly doubled to 120,914 and on Monday that number hit 222,335 requests.

## **FY 18 & 19 Appropriation**

For FY 18, the Board's proposed appropriation is \$10.6 million, an increase of 19.5 percent from FY 17. The FY 19 appropriation totals \$10.7 million, an increase of 0.8 percent from FY 18.

**Please be aware that this appropriation is entirely funded through fees assessed on licensees and no GRF funds will be used to meet these proposed funding levels.**

The budget appropriation will allow the Board to meet the following three priorities:

### **Priority 1: Implement Pharmacy Technician Registration (SB 319)**

Ohio SB 319 (131<sup>st</sup> General Assembly) implemented a number of policy changes that would greatly expand the Board's scope and authority over the regulation of the pharmacy profession, including the registration of an estimated 42,000 pharmacy technicians. This will nearly double the number of licensees overseen by the Board.

Part of the rationale for the registration of technicians is that they are consistently identified as a significant source of controlled substance diversion. Between 2013 and 2015, the Board initiated 140 cases on technicians related to theft of prescription drugs. More than one-third (36 percent) of all drug theft cases investigated by the Board between 2013 and 2015 involved a pharmacy technician.

To meet the expected demands on our compliance staff to investigate technicians, the Board will hire four additional agents over the biennium. Additionally, the Board will need to hire an attorney and contract with a hearing examiner to ensure timely processing of all technician administrative hearings.

### **Priority 2: Ensure Routine Inspections and Enhance Capacity to Conduct Administrative and Criminal Investigations**

The proposed FY 18 and 19 appropriation will be used to ensure all licensed locations are routinely inspected and the Board has the necessary staff capacity to meet its statutory obligations to perform both administrative and criminal investigations.

Currently, Board agents and specialists are charged with conducting inspections as well as investigations of individuals and entities in violation of Ohio laws and rules. While this dual role for staff was sustainable in the past, the increasing number of drug diversion and other complaints received by the Board in the past few years has resulted in an overall decrease in the number of routine inspections. A recent analysis conducted by the Board, found that the number of cases investigated by the Board's agents and specialists rose from 1,102 in 2013 to 1,496 in 2016.

This 36 percent increase in caseload has limited the time available to conduct routine inspections. The number of inspections completed decreased from 2,281 in 2013 to 1,273 in 2016, a 44 percent decrease. At the same time, the number of in-state facility licenses during

this period increased from 16,968 in 2013 to 18,992 in 2016. Thus, the Board was only able to inspect 6.7 percent of all Ohio facilities storing dangerous drugs in 2016.

Routine inspections allow Board staff to review facilities to ensure they comply with security, recordkeeping and other rules designed to deter and detect the diversion of prescription drugs, including opioids. Routine inspections provide the opportunity to correct problems before they escalate to a complaint requiring a more time-intensive investigation.

It should also be noted that the Board will experience an increase in the number of high-risk licensees due to the passage of SB 319 (Ohio’s Opiate MBR). These entities include 1,035 prescriber offices that purchased more than 3 million doses of opioids in 2015 and clinics that provide addiction treatment using controlled substances.

The FY 18 and 19 appropriation will be used to add four inspectors that will solely focus on conducting routine inspections of facilities that store dangerous drugs. By adding these inspectors, the Board will free up time for specialists and agents to conduct investigations of drug diversion and other crimes as well as allow specialists, who are licensed pharmacists, to focus on inspections of highly technical facilities requiring their specialized training and expertise.

The criminal cases investigated by the Board are often time consuming and complex. The effort necessary to conduct multiple undercover visits, search warrants, interviews, expert reviews, prosecutor consultations, criminal adjudication (including providing testimony) can often mean cases take a significant amount of time to complete. Hiring inspectors frees up the time agents currently dedicate to inspections and allows the Board to devote additional hours to working these complex cases as well as taking on additional cases to stop those engaged in criminal behavior who are contributing to Ohio’s drug overdose epidemic.

To make certain that the Board of Pharmacy takes in the necessary revenue to cover all proposed expenses, the agency is requesting the following fee increases in FY 18 and 19:

<b>License Type</b>	<b>Current Fee</b>	<b>Proposed Fee</b>
<b>Wholesaler<sup>1</sup> (Non-Controlled)</b>	\$750.00	\$950.00
<b>Wholesaler (Controlled)</b>	\$787.50	\$1,000
<b>Terminal Distributor<sup>2</sup> (Category II)</b>	\$112.50	\$160.00
<b>Terminal Distributor (Category III)</b>	\$150.00	\$220.00
<b>Veterinarian Terminal Distributor</b>	\$40.00	\$60.00
<b>Pharmacist</b>	\$97.50	\$125.00

<sup>1</sup>Wholesalers are typically large companies, including a number who rank on the Fortune 500, that wholesale and manufacture drugs. They also include entities such as outsourcing facilities. These operations typically require more time to inspect. This relates to their size (a traditional wholesaler is often a large multi-building warehouse) or their complexity (outsourcing facilities and manufacturers must meet certain federal requirements for the safe production of drugs).

<sup>2</sup>Terminal Distributors include a wide range of facilities that store dangerous drugs, including: hospitals, retail pharmacies, nursing homes, veterinarian clinics, EMS organizations, physician offices, etc. The license is site-specific and covers all drugs stored at the physical location. For example, a hospital building may have many locations where they store drugs but only one Terminal Distributor license.

Please be advised that most of the Board's fees have not been adjusted since 1997 and the proposed fee increases are necessary to keep up with inflation. For example, if the terminal distributor fees were indexed for inflation, the current fees would be \$167.00 for a category II license and \$222.66 for a category III license. Similarly, if the pharmacist annual licensing fee was adjusted for inflation, the current fee would be \$144.73.

Furthermore, the proposed fees are comparable to other states. The proposed terminal distributor fee is well below the national average drug location licensing fee of \$249.31 and the pharmacist fee is as or less expensive than 26 other states. This pharmacist fee is also below the average pharmacist licensing cost in the U.S. (\$134.62).

### **Priority 3: Implement Ohio's Medical Marijuana Control Program**

The proposed budget allows the Board of Pharmacy to implement its responsibilities to license medical marijuana dispensaries and register patients & caregivers as set forth in HB 523 (131<sup>st</sup> General Assembly). The FY 18 and 19 appropriation permits the Board to develop a program that ensures: the safety of the public; access to a safe medical product; and scalability to allow the program to respond to changes in demand.

The proposed licensing fees for patients, caregivers and dispensaries are intended to cover all associated costs with operating the program. Furthermore, all fees collected will be deposited into a shared fund to ensure the solvency and sustainability of the program between the Board of Pharmacy and the Department of Commerce. The Board is working closely with OBM to ensure that any initial startup funding provided from our August 2016 Controlling Board request will be paid back once the program becomes fully operational.

The Board's FY 18 and 19 appropriation will be used to hire an additional four compliance agents to ensure that all dispensaries are operating in accordance with rules adopted by the Board. The appropriated funds will also be used to cover costs associated with the licensing of dispensaries, operation of the Ohio Medical Marijuana Advisory Committee and maintenance of the patient/caregiver registration system.

### **Policy Changes in HB 49**

Before I close, I would now like to take a moment to review several budget-related policy changes included in HB 49. These proposals include the following:

**1) Expanding Access to the Ohio Automated Rx Reporting System:** Physician and pharmacist access to the Ohio Automated Rx Reporting System (OARRS) has helped to curb the number of opioids prescribed by providing critical information about a patient's prescription history. The Board proposes making the data accessible to drug courts certified by the Ohio Supreme Court to ensure clients are adhering to terms of the program, as well as to coroners conducting drug overdose death investigations and the Department of Medicaid to incentivize responsible prescribing practices. The length of record retention for OARRS will also be extended from three to five years to provide more information on prescribing history.

**2) Strengthening Pharmacy Board Investigations:** By providing the State Board of Pharmacy confidentiality and granting subpoena authority, the Board will gain valuable tools to better fight the opioid epidemic. A confidentiality provision encourages the reporting of illegal activity because it ensures that the Pharmacy Board can protect the identity of the complainant. This budget provision also enables better coordination when conducting investigations with other state entities and allows sharing of data with federal partners such as the DEA and FDA. Confidentiality protections also allow the Board to protect the information of a pharmacist who is currently monitored by the Board's probation committee for the purposes of receiving treatment for substance abuse. Subpoena authority ensures the Board can obtain important records to help build cases and improve the timeliness of investigations.

Similar confidentiality protections are in place for most other Ohio health care regulatory boards including: Chemical Dependency Professionals Board; Chiropractic Examiners Board; Counselor, Social Worker and Marriage and Family Therapist Board; Dental Board; Medical Board; Nursing Board; Occupational Therapy, Physical Therapy & Athletic Trainers; Optometry Board; Psychology Board; and Respiratory Care Board.

**3) Promoting Efficiency by Moving to Two-Year Licensing:** The Board proposes moving from an annual license renewal cycle to a two-year license renewal cycle. Moving to a two-year licensing process for all license types creates new efficiencies by reducing resource intensive annual renewal cycles to ensure that staff can continue the timely processing of new license applications.

**4) Reducing Burden on Businesses by Harmonizing Wholesaler License Types with Federal Law:** Recent changes in federal law regarding the drug supply chain resulted in the creation of new business entities involved in the distribution and sale of prescription drugs. Currently, these facilities are licensed by the Board as wholesale distributors, which does not accurately reflect the nature of their business operation. The Board proposes creating five licensing categories to match the business entities created in federal law. This does not represent the addition of new licensees but rather a reclassification of existing licensees based on new federal definitions. By recognizing these various business types, Ohio law will sync with federal law making it easier to conduct business in the state and allow for continued oversight of the distribution of prescription drugs by the Board.

In closing, the State of Ohio Board of Pharmacy is committed to working with Governor Kasich and the General Assembly in our efforts to effectively and efficiently regulate the practice of pharmacy and enforce the drug laws of the State of Ohio. Our budget request reflects an agency that is committed to continuous quality improvement, clear and consistent regulation and safeguarding the citizens of Ohio against drug abuse and diversion.

Chairman Romanchuk and members of the subcommittee, thank you again for the opportunity to testify. I would welcome any questions you might have at this time.