



STATE OF
OHIO
BOARD OF PHARMACY

ANNUAL REPORT FY 2020

July 1, 2019 - June 30, 2020

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, eight 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 ninety-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 Laws

3719. – Controlled Substance Act

3796. – Medical Marijuana Control Program

4729. – Pharmacy Practice Act & Dangerous Drug Distribution Act

4752. – Home Medical Equipment Services Providers

In enforcing these chapters, the Board licenses and regulates more than 87,000 professionals, including pharmacists, pharmacy interns and pharmacy technicians, and sites where drugs and home medical equipment 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 services providers, 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 charged with preventing, detecting, and investigating the diversion of dangerous drugs, including controlled substances. The Board investigates and presents evidence of violations of drug laws by any person and refers them for prosecution and/or administrative action. In these efforts, the Board works collaboratively with other state prescriber boards and law enforcement to conduct investigations of healthcare professionals (pharmacists, physicians, dentists, nurses, etc.) who may be in violation of Ohio law.

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 2020 (FY 20) Annual Report. Some notable highlights from FY 20 include:

Duty to Report Rules – In an effort to promote better reporting of violations of Ohio laws and rules, the Board implemented new duty to report rules. The rules require pharmacists, pharmacy interns, and pharmacy technicians to report to the Board certain types of conduct of which the licensee/registrant has knowledge. The Board spent several months working with stakeholders to implement these important rules aimed at safeguarding Ohioans.



Coronavirus Efforts – As part of the state’s coronavirus response, the Board issued 36 waivers to assist pharmacists, terminal distributors, and other licensees meet unique operational challenges during the pandemic.

Inspection Guides – To assist licensees in complying with all applicable rules, the Board began publishing inspection guides for each license type. The inspection guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to ensure compliance. The guides are available on the [terminal distributor licensing page](#).

Medical Marijuana Dispensaries – In FY 20, the Board issued 32 dispensary certificates of operation, with a total 52 dispensaries now operating across the state. The Board had previously awarded 19 certificates of operation in FY 19.

Patient and Caregiver Registry – In FY 20, the MMCP announced that over 100,000 patients and caregivers had registered with the state’s patient and caregiver registry. By the end of FY 20, the MMCP reported over 116,497 registered patients with 91,330 unique patients having purchased medical marijuana products (as reported to OARRS by licensed dispensaries).

Thank you for taking the time to review the State of Ohio Board of Pharmacy’s Fiscal Year 2020 Annual Report. The Board remains as committed as ever to protecting the health and safety of all Ohioans.

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

LICENSING

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

- Pharmacists, pharmacy interns, and pharmacy technicians.
- 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.
- Drug Distributors: Sites that are engaged in the sale of dangerous drugs at wholesale.
- Home Medical Equipment Services Providers (HME): Sites that are engaged in the sale, delivery, installation, maintenance, replacement, or demonstration of home medical equipment.
- Medical marijuana dispensaries and dispensary employees.

FY 2020 Accomplishments

- Transitioned pharmacist and pharmacy intern license types to a biennial renewal cycle.
- Implemented continuing education (CE) requirements for pharmacists to align all pharmacists to the same CE reporting period with their license renewal.
- As part of the state's coronavirus response efforts, the Board issued a waiver to allow for the temporary reinstatement of lapsed or expired Ohio pharmacist licenses. As a result, the Licensing Department reinstated 28 pharmacists.

Current and New Active Licenses/Registrations by Type, FY 2020

Type of License	FY 2020 Active	FY 2020 New
Pharmacist	21,843	1,064
Pharmacy Intern	4,397	867
Pharmacy Technician	34,372	7,539
Terminal Distributor	21,813	2,048
Drug Distributor	2,028	216
HME Services Providers	1,011	122
Medical Marijuana Dispensary Employees	1,533	800
Dispensary - Provisional	34	2
Dispensary - Certificate of Operation	51	32
Total	87,082	12,690

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 criminal investigations involving prescription drugs.

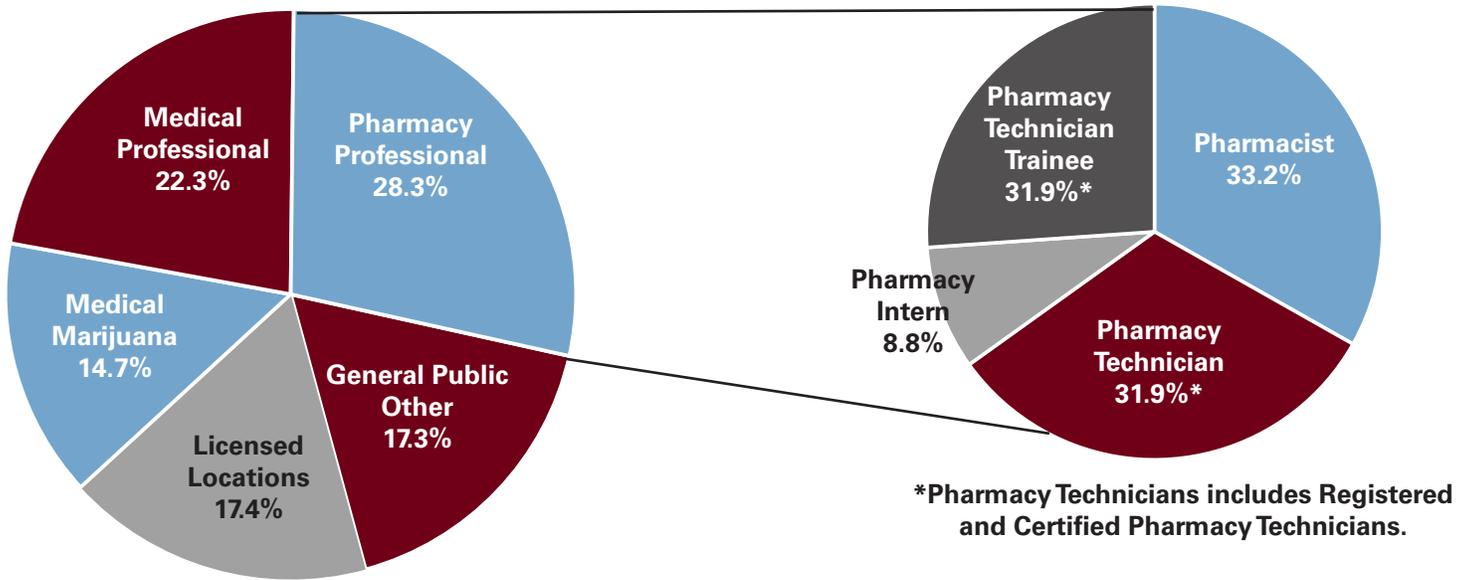
FY 2020 Accomplishments

- In Northeast Ohio, Board agents investigated an error in dispensing at a retail pharmacy when they uncovered 144 fraudulent prescriptions for Schedule II controlled substances including oxycodone and morphine. The investigation revealed a diversion of 10,003 pills between March 2018 and August 2019. It was determined that a pharmacist was responsible for creating false prescriptions using fictitious patient names. The pharmacist's license was summarily suspended, and the case is pending criminal prosecution for illegal processing of drug documents and deception to obtain a dangerous drug.
- After a joint investigation with federal law enforcement, the Board assisted in securing the indictment of an Ohio physician for Illegally Dispensing a Controlled Substance, Fraud, Coercion, and Sex Trafficking by Force. The physician permanently surrendered their DEA registration, medical license, and Terminal Distributor of Dangerous Drug license and is currently awaiting trial.
- Board staff conducted a total of 2,144 inspections and issued 312 written warnings.

New Cases by Type (Top 10), FY 2020

Case Type	# of New Cases
Theft of Drugs	320
Background Investigation	216
Suspicious Purchases	200
Minimum Qualifications of TDDD/WDDD	199
Error in Dispensing	142
Late Renewal of TDDD/WDDD	114
Deception to Obtain Dangerous Drugs	110
Medical Marijuana Background Investigation	72
Questionable Prescribing	63
Questionable Dispensing	58

Case Suspects by Type, FY 2020



Administrative actions taken against a licensee 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 table below and on the next page provide a summary of administrative actions taken by the Board in FY 2020.

ADMINISTRATIVE ACTIONS IN FY 2020 PHARMACY	
Summary Suspensions* (Total)	58
Summary Suspensions (Pharmacy Technicians)	34
Summary Suspensions (Pharmacists)	18
Summary Suspensions (Interns)	1
Summary Suspensions (TDDD)	4
Summary Suspensions (Drug Distributors)	1
Summary Suspensions (OARRS)	0
Citations Issued (Includes Summary Suspensions)	245
Proposals to Deny Licensure/Registration	44
Settlement Agreements	123
License Revocations	13
Pharmacist Probation	63

*A summary suspension is a method of immediately suspending a license or registration. It is utilized if the alleged offense presents "a danger of immediate and serious harm to others." Licensees and registrants that are summarily suspended are still entitled to a full hearing by the Board in accordance with Chapter 119. of the Revised Code.

ADMINISTRATIVE ACTIONS IN FY 2020 MEDICAL MARIJUANA

Summary Suspensions (Total)	29
Summary Suspensions - Dispensary Employees	15
Summary Suspensions - Patients	11
Summary Suspensions - Caregivers	3
Citations (Total)*	2
Citation Issued - Dispensary Employees	1
Citation Issued - Patients	1
Citation Issued - Caregivers	0
Proposals to Deny Licensure/Registration	18
Proposal to Deny - Dispensary Employees	5
Proposal to Deny - Patients	0
Proposal to Deny - Caregivers	13
Citations Issued Total (Includes Summary Suspensions)	49
License Revocations	6
Dispensary Settlement Agreements	9

* Indicates discipline against a licensee, does not include summary suspensions.

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 2020 Accomplishments

- Coordinated the Board's coronavirus response. This included the implementation of 36 waivers to assist licensees in meeting operational needs. The full list of waivers issued by the Board can be accessed here: www.pharmacy.ohio.gov/COVID
- As part of the Board's coronavirus efforts, the Policy and Communications Department sent more than 2 million update emails to licensees since March 2020.
- Secured \$1,726,497 in federal grant funding from the U.S. Department of Justice. This grant will continue to support Board agents charged with investigating controlled substance diversion using OARRS data.
- Successful development and implementation of new rules governing pain management clinics, first aid departments, animal shelters, office-based opioid treatment facilities, clinics and prescriber offices, veterinary clinics, opioid treatment programs, non-limited facilities, and limited facilities.
- To assist licensees in complying with all applicable rules, the Board began publishing inspection guides for each license type. The inspection guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to ensure compliance. The guides are available on the [terminal distributor licensing page](#).

OHIO AUTOMATED RX REPORTING SYSTEM



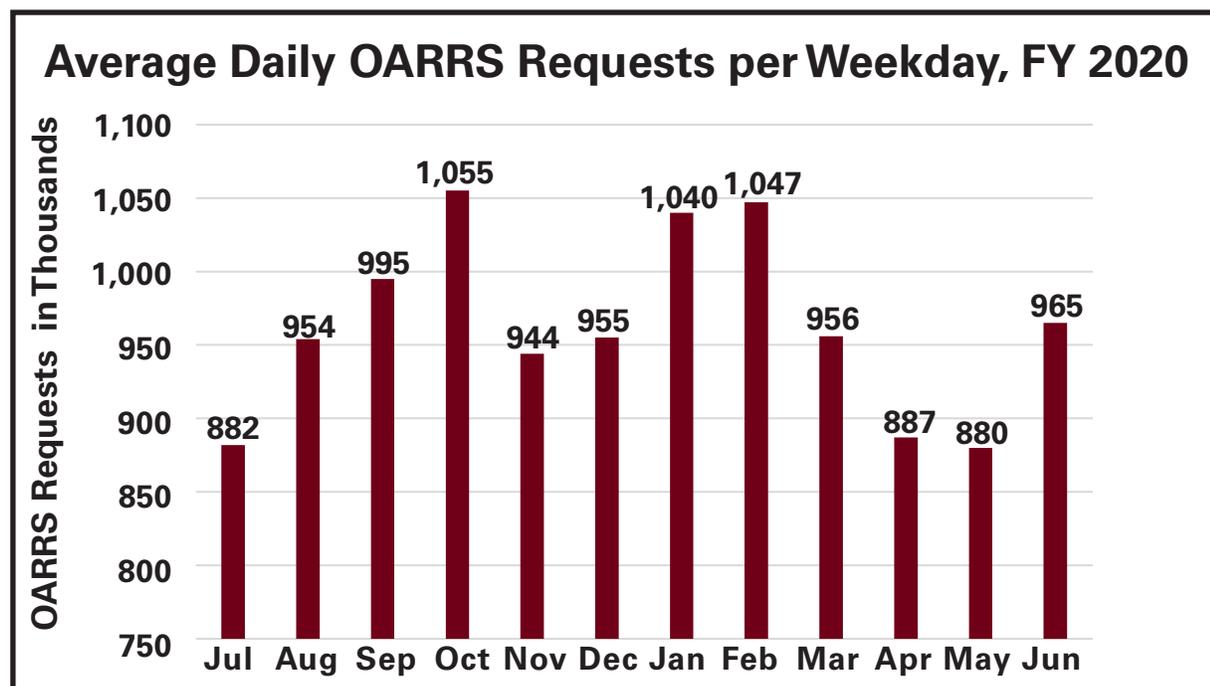
OHIO AUTOMATED RX REPORTING SYSTEM

non-controlled drugs, gabapentin and naltrexone) 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 for controlled substances (and two

FY 2020 Accomplishments

- Ohio has made significant progress in promoting integration of OARRS into electronic health records and pharmacy dispensing systems. Over 60,000 pharmacists and prescribers now have direct access to OARRS as part of their workflow.
- As a result of integration, OARRS averaged 965,000 requests per weekday at the end of FY 20 (see chart below). This included three months that exceeded over a million daily requests.



MEDICAL MARIJUANA

As one of the three state agencies charged with the implementation of the Ohio Medical Marijuana Control Program (MMCP), the Board is responsible for:

- Operating the patient and caregiver registry;
- Licensing of retail dispensaries;
- Licensing of dispensary employees;
- Managing the toll-free helpline;
- Approving new forms of medical marijuana; and
- Coordinating the Medical Marijuana Advisory Committee.



The Board is also responsible for reviewing and assigning product identifications for medical marijuana products (see table below).

MMCP Products Available FY 20	
Forms	IDs Assigned
Tier I plant material	3997
Tier II plant material	1890
Metered oil or solid for vaporization	1123
Edibles for oral administration	655
Tinctures	147
Oil for oral administration	130
Capsule for oral administration	129
Lotions	80
Transdermal patches	80
Ointments	32

FY 2020 Accomplishments

- In FY 20, the Board issued 32 dispensary certificates of operation, with 52 dispensaries now operating across the state. The Board had previously awarded 19 certificates of operation in FY 19.
- By the end of FY 20, the MMCP reported over 116,497 registered patients with 91,330 unique patients having purchased medical marijuana products (as reported to OARRS by licensed dispensaries). Additional program updates can be accessed by visiting: www.pharmacy.ohio.gov/MMupdate.
- In FY 20, the MMCP reported over \$100 million in medical marijuana sales. By the end of FY 20, the MMCP had reported total product sales of \$142.7 with 17,268 pounds of plant material and 1,027,440 units of manufactured product sold.

STATEMENT OF ACTIVITIES

FOR STATE FISCAL YEAR 2020 (JULY 1, 2019 - JUNE 30, 2020)

FY 2020 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.	\$9,405,713
Fund 4A50 (Drug Law Enforcement) Fines and bail or property forfeitures collected as a result of the Board's drug law enforcement efforts.	\$500
Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grants distributed by the U.S. Department of Justice, Office of Justice Programs.	\$388,294
Fund 3HH0 (OARRS Integration HITECH) Grant money received from the Ohio Department of Medicaid to support OARRS integration with medical record systems.	\$2,067,429
Fund 3HM0 (Equitable Sharing Treasury) Money derived from the proceeds of investigations worked with federal agencies under the administrative umbrella of the Department of the Treasury	\$15,186
Fund 3HN0 (Equitable Sharing Justice) Money derived from the proceeds of investigations worked with federal agencies under the administrative umbrella of the Department of Justice	\$188,991
Fund 5SG0 (Drug Database) Donations and grant subawards from other state agencies to make improvements to OARRS as authorized in ORC 4729.83.	\$451,872
Fund 5SY0 (Medical Marijuana Control Program) Revenue comes from fees paid by dispensaries and patients.	\$6,998,229
TOTAL REVENUE FY 2020	\$19,516,214

FY 2020 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).	\$9,488,501
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.	\$76,273
Fund 3HD0 (Pharmacy Federal Grants) Harold Rogers Prescription Monitoring Program grants distributed by the U.S. Department of Justice, Office of Justice Programs.	\$379,835
Fund 3HH0 (OARRS Integration HITECH) Grant money received from the Ohio Department of Medicaid to support OARRS integration with medical record systems.	\$2,067,429
Fund 5SG0 (Drug Database) Implement memorandums of understanding with the Ohio Department of Health and the Ohio Department of Mental Health and Addiction Services to enhance OARRS.	\$445,584
Fund 5SY0 (Medical Marijuana Control Program) Used by the Board to implement the Medical Marijuana Control Program under ORC Chapter 3796.	\$3,166,115
TOTAL EXPENSES FY 2020 [1,2]	\$15,623,737

[1] Expenses reflect actual cash disbursements during FY 2020 and include some expenses budgeted with FY 2019 appropriation. Similarly, some expenses budgeted with FY 2020 appropriation will be disbursed in FY 2021 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 2020.



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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Joshua M. Cox, Pharm.D, BCPS, R.Ph., Vice-President
Trina Buettner, R.Ph.
N. Victor Goodman, Public Member
Megan E. Marchal, Pharm.D., R.Ph.
D. Rich Miller, III, B.S., R.Ph.
Shawn C. Wilt, R.Ph.

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