

The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health 250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER Governor KARYN E. POLITO Lieutenant Governor MARYLOU SUDDERS Secretary

MONICA BHAREL, MD, MPH Commissioner

> Tel: 617-624-6000 www.mass.gov/dph

Janurary 15, 2021

Steven T. James House Clerk State House Room 145 Boston, MA 02133

Michael D. Hurley Senate Clerk State House Room 335 Boston, MA 02133

Dear Mr. Clerk,

Pursuant to Section 35X of Chapter 10, Section 24A of Chapter 94C, and Sections 9G, 25, 43, and 78 of Chapter 112 of the Massachusetts General Laws, please find enclosed a report from the Department of Public Health entitled "*Bureau of Health Professions Licensure Annual Report*."

Sincerely,

Monica Bharel, MD, MPH Commissioner Department of Public Health

Charles D. Baker Governor

Karyn Polito Lieutenant Governor



Marylou Sudders Secretary

Monica Bharel, MD, MPH Commissioner

Bureau of Health Professions Licensure Annual Report

Fiscal Year 2019



Massachusetts Department of Public Health

Table of Contents

Legislative Mandate	2
Executive Summary	4
Introduction	6
Bureau of Health Professions Licensure – Shared Resources and Initiatives	7
Board of Certification of Community Health Workers	13
Board of Registration in Dentistry	15
Board of Registration of Genetic Counselors	19
Board of Registration in Naturopathy	21
Board of Registration in Nursing	23
Board of Registration of Nursing Home Administrators	27
Board of Registration of Perfusionists	29
Board of Registration in Pharmacy	31
Board of Registration of Physician Assistants	39
Board of Registration of Respiratory Care	42
Drug Control Program	45
Prescription Monitoring Program	56
Conclusion	63
Contact Us/Feedback	64
Appendices	65

Legislative Mandate

The following report is hereby issued pursuant to Chapters 10, 94C and 112 of the General Laws as follows:

Section 35X of Chapter 10 of the Massachusetts General Laws:

Section 35X. (a) There shall be established upon the books of the commonwealth a separate fund to be known as the Quality in Health Professions Trust Fund to be expended, without prior appropriation, by the department of public health. The fund shall consist of 50 per cent of the fee revenue collected in accordance with subsection (b) of this section or subsection (b) of section 35V by the various boards serving within the department under section 9 of chapter 13 excluding the board of registration in medicine. The fees shall be in addition to any existing fees collected for obtaining and renewing a license, certificate, registration, permit or authority as determined by the secretary of administration and finance under section 3B of chapter 7. The commissioner shall make necessary expenditures from this account for the shared administrative costs of the operations and programs of the department related to health board licensing. The commissioner shall further direct that funds from this account shall be expended to provide services in an amount reasonably related to the cost of each board's or unit's administrative and regulatory mandates with consideration to revenue generated from each board or unit. The department may incur expenses, and the comptroller may certify for payment, amounts in anticipation of expected receipts, but no expenditure shall be made from the fund that would cause the fund to be in deficit at the close of a fiscal year. Moneys deposited in the fund that are unexpended at the end of the fiscal year shall not revert to the General Fund. The commissioner shall report annually on March 1 to the house and senate committees on ways and means: (i) the revenue credited to the fund; (ii) the amount of fund expenditures that are attributable to the shared administrative costs of the department related to health board licensing and an explanation of why such administrative costs are necessary; (iii) an itemized list of the amount of funds expended by board or unit; and (iv) an analysis of the services provided based on fund expenditures by board or unit, including the manner in which the fund expenditures assist the department in meeting its regulatory mandates related to health board licensing.

Section 24A(k) of Chapter 94C of the Massachusetts General Laws:

SECTION 24A(k). The department shall submit an annual report on the effectiveness of the prescription monitoring program with the clerks of the house and senate, the chairs of the joint committee on public health, the chairs of the joint committee on health care financing and the chairs of the joint committee on public safety and homeland security.

Sections 9G, 25, 43, and 78 of Chapter 112 of the Massachusetts General Laws:¹

SECTION 9G. The board shall keep a record of the names and addresses of all persons registered by it and all programs approved by it and a duplicate thereof shall be open to inspection in the office of the state secretary. The board shall make an annual report on the status of physician assistants in the commonwealth to the governor and the general court.

SECTION 25. The board shall keep a record of the names of all persons examined and registered by it, of all persons to whom permits are issued under section thirty-nine, and of all money received and disbursed by it, and a duplicate thereof shall be open to public inspection in the office of the state secretary. The board shall make an annual report of the condition of pharmacy in the commonwealth.

SECTION 43. The board of registration of dentistry, herein and in sections forty-three A to fiftythree, inclusive, called the board, shall examine applicants for registration in dentistry, and shall investigate all complaints of violations of sections forty-four, forty-nine, fifty-two, fifty-two A, fifty-two C and sixty-five. In aid thereof, the board may make, and shall publish, such rules and regulations as it deems necessary. If, as a result of such investigation, the board has reasonable cause to believe that a violation has occurred, it shall forthwith file a written report of the same with the attorney general who shall, within three months following receipt of such report, notify the board in writing of the action taken with respect to such violation. The board may also bring a petition in equity in the superior court to enjoin the continuation of such violation. Five members of the board shall constitute a quorum for the transaction of business. The board shall keep a full record of its proceedings and a registry of all persons registered by it, which shall be public records open to inspection. A transcript of any of the entries in such record, certified by its secretary, shall be competent evidence of the facts stated therein. The board shall make a full and accurate annual report.

SECTION 78. The board shall keep records of the names of all persons registered and licensed by it and of all money received and disbursed by it and duplicates thereof shall be open to public inspection in the office of the state secretary. It shall make an annual report of the condition of nursing in the commonwealth.

NOTE:

There is no legislative mandate for an annual report for the Boards of Registration of Genetic Counselors, Nursing Home Administrators, Perfusionists, Respiratory Care, Naturopathy or the Board of Certification of Community Health Workers, or the Drug Control Program. To advance public interest and transparency, all 10 Bureau of Health Professional Licesure (BHPL) Board reports, the Prescription Monitoring report, the Drug Control Program report, and all Bureau expenditure reports are included herein.

¹ Use of the term "board" in Section 9G refers to the Board of Registration of Physician Assistants; in Section 25, it refers to the Board of Registration in Pharmacy; and in Section 78 it refers to the Board of Registration in Nursing.

Executive Summary

The Massachusetts Department of Public Health's (DPH) Bureau of Health Professions Licensure (BHPL) consists of 10 Boards of Registration and Certification, the Drug Control Program (DCP), and the Prescription Monitoring Program (PMP).

BHPL is pleased to submit this report of fiscal year 2019 (FY19) regulatory, policy, licensure and enforcement activities.² This report summarizes and highlights statistics and accomplishments undertaken to fulfill the BHPL mandate to protect the public health, safety, and welfare in Massachusetts. The report reflects a commitment to establishing and improving practice standards for the health professions under the oversight of BHPL and providing transparency of drug control and prescription monitoring activities.

The mission of DPH is to prevent illness, injury, and premature death, assure access to high quality public health and health care services, and promote wellness and health equity for all people in the Commonwealth.

BHPL is charged with evaluating the qualifications of applicants and granting licenses, permits, registrations and certifications to those who qualify, as well as setting standards for the and handling of pharmaceuticals by health care providers, manufacturers and distributers. The BHPL boards, PMP, and DCP establish rules and regulations to ensure the integrity and competence of licensees and registrants and promote public health, welfare, and safety by ensuring that licensed and registered professionals and entities meet statutory requirements, including the promotion of access to safe and effective pharmaceutical care services in Massachusetts.

The Governor signed several pieces of legislation in the 189th and 190th legislative session that BHPL continues to implement, including Chapter 52 of the Acts of 2016 – An Act relative to substance use, treatment, education and prevention (The STEP Act) and Chapter 208 of the Acts of 2018 – An Act for prevention and access to appropriate care and treatment of addiction (The Care Act). This report will discuss milestones of the ongoing implementation efforts.

² Beginning in FY17, the *Bureau of Health Professions Licensure Annual Report* replaced the following separate annual reports to the legislature historically submitted by the Drug Control Program and the Division of Health Professions Licensure: "Prescription Monitoring Program Annual Report", "Annual Report for Quality in Health Professions Trust", and "Division of Health Professions Licensure Annual Report".

Significant Accomplishments of FY19

The Massachusetts Prescription Awareness Tool (MassPAT) was launched in 2012 as the online version of the Prescription Monitoring Program (PMP) and was significantly upgraded in response to the opioid epidemic in 2016. In FY19, prescriber searches in MassPAT topped 7,410,000, an increase of over 1 million searches from FY18. Electronic Health Records (EHR) integrations contributed significantly to this increase. By the close of FY19, over 150 provider organizations, accounting for more than half of the prescribers registered in the Commonwealth, have one-click access to a patient's PMP report directly from the patient's EHR.

The Massachusetts Controlled Substances Registration program (MCSR), with the support of BHPL staff, completed the initial phase of the MCSR transition to the BHPL licensure database from the existing paper-based process in FY19. Applications for new and renewal MCSRs can now be completed online. Additionally, members of the public, including healthcare credentialing staff, can now take advantage of the online Check-A-License website to verify the status of issued MCSRs.

In FY19, The CHW Board began processing certification applications. By the close of FY19, 111 Community Health Workers had obtained certification from the CHW Board.

The Naturopathy Board submitted proposed draft regulations, 273 CMR 2.00-8.00, for administrative review in FY19.

In FY19, the Drug Stewardship Program (DSP) gave final approval of MED-Project's Drug Stewardship Plan (Plan), which provides statewide collection and disposal of unwanted medications in partnership with over 150 manufacturers of benzodiazepines and Schedule II and III opioids distributed in the Commonwealth. This first-in-the-nation statewide Plan ensures funding and support of drug take-back programs at law enforcement agencies throughout the Commonwealth and provides resources and information for in-home disposal, contributing to the safety and security of drugs that contribute to public health risk.

During FY19, BHPL received and responded to 879 public record requests within the statutory 10-day response deadline or other timeframe agreed to by the requestor.

The number of prescriptions for opioids continued to fall. Prescriptions for Schedule II opioids fell by 9% in FY19 compared to FY18. Overall there has been a 38.8% decline in Schedule II opioid prescriptions since the first quarter of 2015.

Introduction

BHPL is comprised of the DCP, the PMP and 10 boards of health profession registration and certification:

- Board of Certification of Community Health Workers,
- Board of Registration in Dentistry,
- Board of Registration of Genetic Counselors,
- Board of Registration in Naturopathy,
- Board of Registration in Nursing,
- Board of Registration of Nursing Home Administrators,
- Board of Registration of Perfusionists,
- Board of Registration in Pharmacy,
- Board of Registration of Physician Assistants, and
- Board of Respiratory Care.

BHPL Mission Statement

Our mission is to protect the public health, safety, and welfare by issuing licenses, registrations, permits and certifications to qualified health care professionals, services, and facilities through the fair and consistent application of statutes, regulations, and policies. Through our 10 boards of registration and certification, the DCP and the PMP, we develop, implement, and enforce regulations and policies, through open meetings and public process, that ensure and promote the safe practice of those we regulate.

Vision Statement

- I. We believe that the citizens of Massachusetts deserve the highest quality of health care provided by qualified health care professionals who practice, and by facilities that operate, with the highest degree of ethics and integrity.
- II. We recognize and value the contributions of our volunteer board members, staff, licensees, permit holders, and registrants, and appreciate their diversity, professional experience, and knowledge.
- III. We believe that continued competency is important and support initiatives that address the need for life-long learning in a rapidly changing health care environment.
- IV. We believe that partnerships with educators, other governmental agencies, law enforcement, and organizations that advocate for patients and/or providers enhance our ability to promote and ensure quality of care and safe practices to achieve better outcomes for patients.
- V. We believe that health care consumers, employees, licensees, registrants, applicants, and others who rely on our data to make health care and employment decisions expect, and should have easy access to, timely, accurate, and relevant information.

The following pages give a more comprehensive perspective of how the DCP, the PMP, and the 10 boards at BHPL work on behalf of the Commonwealth of Massachusetts.

Bureau of Health Professions Licensure – Shared Resources and Initiatives

Budget

As of June 30, 2019, BHPL licensed, registered, certified, or authorized 226,059 health care professionals and businesses. The staffing level of BHPL was comprised of 120 full-time equivalent active staff.

BHPL and its 10 boards of registration and certification receive funding from a combination of three state appropriations and the Quality in Health Professions Trust Fund.³

- I. Line item 4510-0721⁴ is appropriated to the Board of Registration in Nursing.⁵
- II. Line item 4510-0722⁶ is appropriated to the Board of Registration in Pharmacy.⁷

The FY19 budget supported pharmacy inspections and investigations with a total of \$1.19M appropriated to the Board of Registration in Pharmacy. This funding was used by the Board of Registration in Pharmacy towards the performance of inspections and monitoring of sterile and non-sterile compounding pharmacies, including unannounced inspections of all pharmacies in the Commonwealth.

- III. Line item 4510-0725 is appropriated to ⁸ the remaining eight boards: Community Health Workers, Dentistry, Genetic Counselors, Naturopathy, Nursing Home Administrators, Perfusionists, Physician Assistants, and Respiratory Care.⁹
- IV. The Quality in Health Professions Trust Fund, account 4510-0727¹⁰, is applied towards the operations of all 10 boards, and specifically towards expenditures that are not covered by the appropriations. Currently, the three appropriations cover approximately 20% of the boards' expenditures; the remaining 80% are paid for through the trust. The trust is funded by a complex statutory formula that directs a portion of each license fee to be deposited in the trust. Unexpended collected trust revenue can be carried forward at the end of each fiscal year. Due to license renewal cycles set by statute, BHPL collects more trust revenue during even fiscal years than odd fiscal years. Sufficient trust roll-forward balances from the even fiscal years are needed to fund expenses in the odd fiscal years.

³ See Appendix A: BHPL FY19 Board Funding.

⁴ See Appendix B: BHPL FY19 Board of Registration in Nursing Expenditures Overview.

⁵ See Appendix C: BHPL FY19 Board of Registration in Nursing Expenditures Detail.

⁶ See Appendix D: BHPL FY19 Board of Registration in Pharmacy Expenditures Overview.

⁷ See Appendix E: *BHPL FY19 Board of Registration in Pharmacy Expenditures Detail.*

⁸ See Appendix F: BHPL FY19 Boards of Registration and Certification Expenditures Overview.

⁹ See Appendix G: *BHPL FY19 Boards of Registration and Certification Expenditures Detail.*

¹⁰ See Appendix H: BHPL FY19 Quality In Health Professions Trust Fund Expenditures Overview.

Administration and support services for the 10 boards of registration and certification are centralized within BHPL and shared among the boards to provide economies of scale, promote consistency in the application and enforcement of requirements, and permit streamlined and efficient operations for the issuance of licenses, registrations and certifications, the collection of revenue, the provision of information technology services, enforcement, investigations, legal services, and adjudicatory hearings, and budget and accounting functions. All funds expended from the trust fund are attributed to the shared administrative, licensing and enforcement activities of the 10 boards.¹¹

The following is a summary of Board accounts 4510-0721, 4510-0722, and 4510-0725:

- a. FY19 Board Appropriations \$ 2,147,098
- b. FY19 Expenditures \$ 2,410,689.06

The following is a summary of the Trust account 4510-0727 (showing even year revenue):

- a. FY19 Trust Revenue \$9,406,877
- b. FY19 Uncommitted Balance \$4,181,506

DCP and PMP are supported by four appropriation and retained revenue accounts. The accounts have no carry forward of end of year balances.

- I. Retained revenue account 4510-0616 supports¹² DCP. In FY19, DCP was authorized to retain \$1,037,750 of the revenue generated by Controlled Substance Registrations. Most Programs encompassed by DCP, including DSP and the Medication Administration Program (MAP), which is primarily funded through interagency service agreements with the Department of Mental Health and the Department of Developmental Services, rely on the central DCP account, 4510-0616, for operational funding.¹³
- II. Retained revenue account 4510-0040 supports¹⁴ the Pharmaceutical and Medical Device Code of Conduct Program (PCOC). In FY19, PCOC was authorized to retain \$73,734 of the revenue generated by PCOC.¹⁵
- III. Account 4510-0643 supports¹⁶ the PMP through federal grant.¹⁷

The following is a summary of DCP account 4510-0616:

- a. FY19 DCP Revenue Collections \$4,859,650
- b. FY19 BHPL Retained Revenue \$ 1,037,750
- c. FY19 Expenditures \$ 941,125

¹¹ See Appendix I: BHPL FY19 Quality In Health Professions Trust Fund Expenditures Detail.

¹² See Appendix J: BHPL FY19 Drug Control Program Expenditures Overview.

¹³ See Appendix K: BHPL FY19 Drug Control Program Expenditures Detail.

¹⁴ See Appendix L: *BHPL FY19 PCOC Expenditures Overview*.

¹⁵ See Appendix M: *BHPL FY19 PCOC Expenditures Detail.*

¹⁶ See Appendix N: BHPL FY19 PMP Expenditures Overview.

¹⁷ See Appendix O: BHPL FY19 PMP Expenditures Detail.

The following is a summary of revenue and expenditure for PCOC - 4510-0040

- a. FY19 DCP Revenue Collections \$ 1,430,000
- b. FY19 BHPL Retained Revenue \$73,734
- c. FY19 Expenditures \$ 20,963

Compliance Monitoring

The compliance activities of BHPL are essential to its mission. BHPL conducts inspections and investigations of licensees and registrants, prosecutes cases, and takes disciplinary action against the licenses and registrations of individuals and/or businesses who engage in conduct that may pose a threat to the health, safety, and welfare of the public.

During FY19, the BHPL Boards collectively resolved 563 formal complaints against health professional/facility licenses. Of the 563 formal complaints, 44%, or 288, were resolved by imposition of disciplinary action.

Probation Department

The Probation Department at BHPL monitors licensees whose practice is subject to conditions or who must fulfill requirements, either as part of a formal disciplinary probation or as a nondisciplinary resolution of a complaint. The Probation Department monitors the compliance of licensees with the specific terms of their respective Consent Agreement or Final Decision and Order when their license is subject to Stayed Probation, Probation, Suspension, or Surrender followed by Probation, or Stayed Suspension. As of June 30, 2019, the Probation Department was monitoring 151 participants.

In FY19, the scope of matters handled by the Probation Department increased to include dental assistants. The Board of Registration in Dentistry began licensing dental assistants in FY14 and during FY19 began to address instances of unlicensed practice or failure to complete continuing education by this new group of licensed professionals.

Monitoring Licensees with a Substance Use Disorder

There are two programs operating within BHPL that monitor the return to practice by licensees struggling with a substance use disorder. Each program is mandated by a separate, specific statute; each statute limits the scope of the program to a particular board and its licensees, and each statute requires specific staffing requirements and subcommittees.

The Substance Abuse Rehabilitation Program

The Substance Abuse Rehabilitation Program (SARP) is a voluntary, non-disciplinary approach to substance use disorder recovery among licensed nurses. Established by M.G.L. c. 112, §80F, SARP is an abstinence-based program to assist nurses, whose competency has been impaired by substance use disorders, to return to nursing practice. The program takes 5 years to successfully complete. SARP is designed to protect the public health, safety, and welfare by establishing adequate safeguards to maintain professional standards of nursing practice, while monitoring and supporting the ongoing recovery of participants and their return to safe nursing practice.

As of June 30, 2019, SARP was monitoring the compliance of 112 participants. During FY19, SARP admitted 19 new participants, terminated 19 participants for non-compliance with the program, and discharged 30 participants after successful completion of the program.

The Pharmacy Substance Use Disorder Program

The Pharmacy Substance Use Disorder Program (PSUD) was established in 2016 by M.G.L. c. 112, §24H. PSUD is a non-disciplinary, confidential approach to substance use disorder recovery for licensed pharmacists, pharmacy technicians, and pharmacy interns. This program allows the Board of Registration in Pharmacy to monitor pharmacists, pharmacy technicians, and pharmacy interns with the goal of returning to safe pharmacy practice.

As of June 30, 2019, PSUD was monitoring the compliance of 15 participants. During FY19, PSUD admitted 5 new participants, terminated 1 participant for non-compliance with the program, and discharged 1 participant after successful completion of the program.

Information Technology

In FY19, the Information Technology Department of BHPL (ITD) made multiple modifications and improvements to MyLicense Office (MLO), the licensure database utilized by BHPL, to improve efficiency in various licensure processes. These modifications and improvements are vital to BHPL becoming more data focused.

In FY19, ITD completed the first data migration for the Massachusetts Controlled Substance Registration (MCSR) Automation project. ITD staff successfully migrated nearly 50,000 Massachusetts physicians, dentists, advance practice nurses, physician assistants and pharmacists from the legacy controlled substance registration system to the BHPL online licensing platform. ITD staff also completed the new Community Health Worker Certification for the Board of Certification of Community Health Workers.

Lastly, in FY19, ITD staff continued preparation for a new cloud environment and new application system updates for MLO that will be deployed in FY20.

Quality Improvement

The Quality Improvement Department (QID) of BHPL consists of dedicated staff that analyzes BHPL data to make informed decisions and recommendations for improvements of BHPL operations, and oversees all BHPL improvement initiatives. QID staff is focused on making BHPL data more accurate and accessible. The QID works with BHPL ITD to develop technological solutions that meet business requirements to increase workflow efficiency.

In FY19, the QID collaborated with IT staff to develop several new license types in MLO, including the Community Health Worker, and the roll out of the initial phase of the

Massachusetts Controlled Substance Registration transition. The QID also worked with IT staff to develop an internal online system to manage and prioritize new project requests. This new IT intake system will be introduced to BHPL staff in early FY20.

The QID monitors BHPL staff training and encourages staff to become trained in methods of quality improvement. In FY19, two BHPL staff successfully completed DPH Lean Six Sigma Black Belt training and six BHPL staff successfully completed DPH Lean Six Sigma Green Belt training. Additionally, three BHPL staff successfully completed the Commonwealth's Core Management program.

The QID is also responsible for oversight of BHPL public record requests. BHPL received and responded to 879 public record requests within the statutory 10-day response deadline or other timeframe agreed to by the requestor, during FY19. BHPL led the total number of requests for bureaus and offices within DPH by approximately 200 requests in FY19.

VALOR Act to Assist Active Military, Military Spouses, and Veterans

Under Chapter 108 of the Acts of 2012 (VALOR Act), and Chapter 62 of the Acts of 2014 (VALOR Act II), the following statutory provisions were implemented:

- I. Each of the BHPL boards will accept relevant education, training, and service completed by a license applicant as a member of the armed forces or the military reserves toward the qualifications required for licensure pursuant to M.G.L. c. 112, §1B(b);
- II. The license of an active duty service member remains valid until he or she is released from active duty, and for 90 days thereafter pursuant to M.G.L. c. 112, §1B(c);
- III. BHPL expedites the licensure process for military spouses who are licensed in other states and have left employment there to accompany a spouse relocated to the Commonwealth due to a military transfer pursuant to M.G.L. c. 112, §1B(d); and
- IV. BHPL waives the Commonwealth's portion of the initial application and licensure fees for all licenses issued pursuant to the VALOR Act pursuant to M.G.L. c. 112, \$1B(g).

In FY19, BHPL received 19 licensure applications subject to the VALOR Act, comprised of 7 active duty service members, 9 spouses of active duty service members and 3 veterans.¹⁸

In FY19, BHPL manually renewed 24 active duty service licensees, but had to reverse 4 due to the U.S. Department of Defense deeming any license where the fee is waived as restricted. Appendix Q shows the distribution of active service duty licensees, with the greatest concentration among Army dentists.¹⁹

¹⁸ See Appendix P: *FY19 VALOR Act Licensure Applications*.

¹⁹ See Appendix Q: FY19 Active Service Duty Licensees.

The BHPL <u>website</u> contains additional information and forms that VALOR Acts applicants must submit. Active military, military spouses, and veterans must identify themselves as such in order to obtain these benefits. A Bureau-wide staff action policy adopted by all BHPL boards, authorizes the processing of license applications and renewals under the VALOR Acts in an efficient and consistent manner.

Implementation of Uniform Staff Action Policies

As many of the boards within BHPL perform similar, routine licensing and enforcement functions, BHPL has developed operating protocols that can be implemented through the adoption of uniform staff action policies. Adoption of these policies promotes consistent handling of similar situations across the boards and license types, and like cross-trianing, it enables staff to be better able to cover vacancies and staffing needs across the boards. During FY19, the following uniform staff action policies were adopted or updated by the boards that had not yet done so:

Social Security Numbers and Department of Revenue License Actions 17-01: authorizes staff action to implement statutory requirements set forth in M.G.L. c. 30A §13A and M.G.L. c. 119A §16, relating to the collection of social security numbers, reporting of licensee data to the Department of Revenue and processing of license suspensions and reinstatements pursuant to Department of Revenue notices.

Valor Act Implementation 14-01: facilitates staff action for the implementation of M.G.L. c.112, §1B to assist active military, military spouses, and veterans on behalf of the Board.

Routine Responses 18-02: authorizes staff responses to routine correspondence and requests for extensions.

Delegation of Signatory Authority 18-03: enables the Executive Director to effectuate actions that have been authorized by the Board where such actions require an authorized signature.

Petition for Retirement Status 17-03: facilitates timely processing of petitions for "Retired" certification status by Board staff.

The Board of Certification of Community Health Workers

M.G.L. c. 13, §§9, 106-108; M.G.L. c. 112, §§259-262

I. Administration

About the Board

The Board of Certification of Community Health Workers (CHW Board) was created as a result of state health care reform and is intended to help integrate Community Health Workers (CHWs) into the health care and public health systems in order to promote health equity, cost containment, quality improvement, and management and prevention of chronic disease.

The CHW Board consists of 11 members. It is chaired by the Commissioner of Public Health or her designee. The Governor appoints 10 members consisting of the following: 4 CHWs, 1 CHW training organization representative, 1 community-based CHW employer, 1 Massachusetts Association of Health Plans representative, 1 Massachusetts League of Community Health Centers representative, 1 Massachusetts Public Health Association representative, and 1 public member. 6 members are required to be present to constitute a quorum.

CHW Board Members

Clair Santarelli, Commissioner of DPH Designee, Chair Joanne Calista, CHW training organization representative, Vice Chair Henrique O. Schmidt, CHW member, Secretary Sheila Och, CHW member Hugo Santos, CHW member Catherine Bourassa, Community-based CHW employer member Margaret Hogarty, Massachusetts Public Health Association representative Denise Lau, Public member

FY19 CHW Board Meetings

July 10, 2018 September 11, 2018 October 9, 2018 January 8, 2019 March 12, 2019 May 4, 2019

II. Accomplishments of the CHW Board

Processing Certification Applications and Issuing Certifications: The CHW Board began accepting applications on October 26, 2018. To assist CHWs in completing the application, the CHW Board developed an application checklist, Frequently Asked Questions, and a CHW Certification Fact Sheet.

Training Program Applications: In FY19, the CHW Board finalized the Training Program Application which will be used by organizations to apply to become a CHW Board Approved Training Program.

Stakeholder Engagement: The CHW Board Chair and Executive Director presented at the 10th Annual Community Health Worker/Patient Navigator Conference on May 16, 2019.

Board Composition: CHW Board staff continued to focus on filling CHW Board seats during FY19. In FY19, two new CHW Board members were appointed.

III. Regulations and Policies

Suitability for Certification Policy 18-01: At its July 10, 2018 meeting, this policy was adopted outlining the criteria the CHW Board will use to establish the suitability of Community Health Worker applicants seeking Certification. The assessment includes a criminal record check in order to provide a standard level of vetting for work in the human services field.

At its July 10, 2018 meeting, the CHW Board also adopted the following uniform staff action policies:

- Social Security Numbers and Department of Revenue License Actions 17-01
- Valor Act Implementation 14-01

Routine Responses 18-02

- Delegation of Signatory Authority 18-03
- Petition for Retirement Status 17-03

IV. License and Licensee Statistics

Biennial certification	111	Community Health Worker
TOTAL	111	

V. Compliance: Disciplinary Statistics

Due to its recent establishment, the CHW Board took no disciplinary action in FY19.

The Board of Registration in Dentistry

M.G.L. c. 13, §§9, 19-21; M.G.L. c. 112, §§43-53

I. Administration

About the Board

The Massachusetts Board of Registration in Dentistry (Dentistry Board) is responsible for the licensure and registration of dentists, dental hygienists, and dental assistants for practice in the Commonwealth. The Dentistry Board also issues limited intern and faculty dental licenses, facility and practitioner permits for the administration of anesthesia and sedation, and permits for portable dental operations and mobile dental facilities. The Dentistry Board establishes rules, regulations, and policies governing the practice of dentistry, dental hygiene and dental assisting, and investigates complaints against licensed dental professionals.

The Dentistry Board oversees the practice of dentistry, dental hygiene and dental assisting to ensure services comply with statutory and Dentistry Board regulations and policies, including ethical standards of practice. The Dentistry Board is made up of 11 voting members (6 dentists, 2 dental hygienists, 1 dental assistant and 2 public members) and 2 non-voting dental assistant advisors. By statute, 5 voting members must be present to constitute a quorum.

Dentistry Board Members

Dr. Paul Levy, dentist member, Chair Jacyn Stultz, RDH, MS, dental hygienist member, Secretary Dr. Stephen DuLong, faculty dentist member Dr. John Hsu, dentist member Dr. Patricia Wu, dentist member Dr. Cynthia M. Stevens, dentist member Dr. Michael Scialabba, dentist member Dr. Seema Jacob, dentist member Stacy Haluch, RDH, dental hygienist member Kathleen Held, dental assistant member Ailish M. Wilkie, CPHQ, public member

FY19 Dentistry Board Meetings

July 18, 2018 September 5, 2018 October 3, 2018 November 7, 2018 December 5, 2018 January 23, 2019 February 20, 2019 March 6, 2019 May 1, 2019 June 5, 2019

II. Accomplishments of the Dentistry Board

Community Outreach: Dentistry Board members and staff participated in the Yankee Dental Congress in January 2019, hosting a one-hour continuing education course on current Dentistry Board licensure requirements, regulations and policies. In July 2018, Executive Director Barbara A. Young participated in the second annual Mobile Dental Resource Day in Shrewsbury, MA and offered a presentation on the Dentistry Board's current regulations regarding mobile and portable dentistry. In FY19, Executive Director Barbara A. Young also presented an ethics course to the current dental, dental hygiene and/or dental assisting students at the MCPHS/Forsyth School of Dental Hygiene and Quinsigamond Community College.

Board Composition: Dentistry Board staff continued to maintain representative membership during FY19.

III. Regulations and Policies

Regulatory Review Workgroup: The Dentistry Board Regulatory Review Workgroup completed its comprehensive review of the Board's regulations at 234 CMR. All proposed changes to the Dentistry Board's regulations were submitted to the Dentistry Board for its consideration and future promulgation. The Workgroup met on the following dates during FY19:

July 25, 2018 October 24, 2018

Clinical Competency Examinations: The Dentistry Board reaffirmed its policy of July 2017 at its March 2019 meeting, maintaining that applicants for initial dental licensure who submit scores on the WREB (Western Regional Examination Board) clinical competency exam must include passing scores on the now optional prosthodontic and periodontic sections of the WREB and 2 restorative procedures in the operative section of the WREB.

At its December 5, 2018 meeting, the Dentistry Board adopted the BHPL uniform staff action policy **Petition for Retirement Status 17-03**.

Radiation Health and Safety Training: At its February 20, 2019 meeting, the Dentistry Board approved a radiation health and safety continuing education course as taught by the dental hygiene staff at the Springfield Technical Community College in Springfield, MA for those dental assistants who need to complete such training for initial licensure or are seeking to improve their current skills.

Local Anesthesia Administration by Dental Hygienists: At its June 5, 2019 meeting, the Dentistry Board issued an advisory ruling on its regulations at 234 CMR 6.00 regarding the level of supervision required of dental hygienists during their administration of local anesthesia by a supervising dentist. The Dentistry Board determined that a dentist must be present in the dental

practice or facility where a hygienist is administering local anesthesia from the time of initial administration until such time the patient is discharged from the practice setting.

Biennial licensure,	7,114	Dentists	
Biennial	6,971	Dental Hygienists	
Biennial	9,684	Dental Assistants	
Biennial	3,581	Dental Hygienists - Anesthesiology Permits	
Annual	471	Limited and Faculty License	
Biennial	724	Facility Permits	
Biennial	261	General Anesthesia Permits	
Biennial	795	Nitrous Oxide Permits	
Biennial	332	Conscious Sedation Permits	
Biennial	51	Portable Dental Operation and Mobile Dental Facility	
		Permits	
TOTAL	29,984		

IV. License and Licensee Statistics

V. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	Number of Staff Assignment Investigations Closed	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Opened</u>	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Resolved</u>	Number ofFormalComplaintsResolved withDisciplineImposed	% of Formal Complaints Resolved w/Discipline Imposed
146	111	218	79	19	24%

The Board of Registration of Genetic Counselors

M.G.L. c. 13, §§9, 103-105; M.G.L. c. 112, §§252-258

I. Administration

About the Board

The Board of Registration of Genetic Counselors (GC Board) is charged with evaluating the qualifications of applicants for licensure, granting licenses to qualified applicants and establishing rules and regulations to ensure integrity and competence of licensees.

Genetic Counselors (GCs) are health professionals with specialized graduate degrees and experience in medical genetics and counseling. They enter the field from a variety of disciplines, including biology, genetics, nursing, psychology, public health, and social work.

GCs work as members of a health care team, providing information and support to families who have members with birth defects or genetic disorders, or may be at risk for inherited conditions. GCs identify families at risk, investigate the families' issues, interpret information about the disorder, analyze inheritance patterns and risks of recurrence, and review available options with families. GCs also provide supportive counseling to families, advocate for patients, refer individuals and families to community or state support services, and serve as educators and resource contacts for other health care professionals and the general public.

The GC Board promotes public health, welfare, and safety by ensuring that licensed GCs have proper training and experience, complete an accredited degree program, and meet other GC Board requirements. The GC Board is made up of 5 members, including 4 GCs and 1 public member. A quorum requires 3 members to be present.

GC Board Members

Kayla Sheets, MS, LGC, GC member, Chair Shelley Rose McCormick, MS, LGC, GC member Allison L. Cirino, MS, GC member Jillian Fleming, Public member

FY19 GC Board Meetings

July 26, 2018 October 4, 2018 February 7, 2018 April 4, 2019

II. Accomplishments of the GC Board

Constituent Feedback: In FY19, the GC Board reviewed constituent feedback on statutory language found at M.G.L. c. 112 §255, which expires a provisional license 30 days after the licensee fails the American Board of Genetic Counseling or American Board of Medical Genetics certification examination.

Board Composition: GC Board staff continued to focus on GC Board seats during FY19. During FY19, one new candidate was appointed to the GC Board, and two new candidates were recommended for appointment.

III. Policies

Issuance and Renewal of Licenses pursuant to M.G.L. c. 112 §255: This policy was amended at the October 4, 2018 meeting. The updated policy allows GC Board Staff to extend provisional licenses, based on outlined criteria.

Board Staff Authority to Post Information on Board's Webpage: This policy gives the GC Board staff authority to make routine postings to the Board's webpage. It was approved at the October 4, 2018 meeting.

Petition for Retirement Status 17-03: At the February 7, 2019 meeting, the GC Board voted to adopt an update to this uniform staff action policy, removing the age requirements for a "retired" license status.

License Reinstatement Following License Discipline: This policy was rescinded at the February 7, 2019 meeting. It was deemed no longer necessary, as now all Consent Agreements and Final Decision and Orders include licensee reinstatement requirements.

Unlicensed Practice: At its April 4, 2019 meeting, the GC Board amended and renamed this existing policy, formerly known as "Board Staff Disposition of Selected Complaints," which sets forth staff action for the disposition of complaints related to unlicensed practice.

IV. License and Licensee Statistics

Biennial licensure	359	Genetic Counselors
	9	Provisional Genetic Counselors
TOTAL	368	

V. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	Number of Staff Assignment Investigations Closed	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Opened</u>	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Resolved</u>	Number ofFormalComplaintsResolved withDisciplineImposed	% of FormalComplaintsResolvedw/DisciplineImposed
0	2	1	0	0	0%

The Board of Registration in Naturopathy

M.G.L. c. 13, §109; M.G.L. c. 112, §§266-274

I. Administration

About the Board

The Board of Registration in Naturopathy (Naturopathy Board) was created by statute and became effective on September 1, 2017. The Naturopathy Board regulates the practice of naturopathic doctors and establishes rules and regulations to ensure the integrity and competence of its licensees. It is charged with evaluating the qualifications of applicants for licensure and granting licenses to those who qualify.

Naturopathic doctors obtain medical degrees at accredited graduate-level medical schools and must pass a national Board exam. Naturopathic doctors seek to understand each patient's lifestyle, with special attention to diet, exercise and stress, and treat patients using natural approaches.

The Naturopathy Board promotes public health, welfare, and safety by ensuring that licensed Naturopathic doctors have proper training and experience, have completed an accredited degree program, and meet other requirements set forth by the Board. The Naturopathy Board is made up of 5 members, including 2 naturopathic doctors, 1 physician, 1 clinical pharmacologist and 1 public member. A majority of appointed members are required to be present to constitute a quorum.

Naturopathy Board Members:

Paul Herscu, N.D., Chair Anne Frances Hardy, N.D., Vice-Chair Mattia Migliore, Clinical Pharmacologist, Secretary Maria Maccario, Public Member

FY19 Board Meetings:

July 24, 2018 August 28, 2018 September 25, 2018 October 23, 2018 February 26, 2019 March 26, 2019

II. Accomplishments of the Naturopathy Board

Regulations: In FY19, the Naturopathy Board submitted the following draft regulations for administrative review:

- 273 CMR 2.00: Purpose, Definitions, and Severability;
- 273 CMR 3.00: Licensure of Individual Naturopathic Doctors;
- 273 CMR 4.00: Scope of Practice;
- 273 CMR 5.00: Professional and Ethical Standards of Conduct;

- 273 CMR 6.00: Continuing Education;
- 273 CMR 7.00: Investigations, Complaints and Board Actions; and
- 273 CMR 8.00: Reporting Requirements.

Licensure Application: At the February 26, 2019 meeting, the Naturopathy Board approved the final draft of the Naturopathic Doctor Licensure.

III. License and Licensee Statistics

Due to its recent establishment, the Naturopathy Board did not process any applications for licensure in FY19.

IV. Compliance: Disciplinary Statistics

Due to its recent establishment, the Naturopathy Board took no disciplinary action in FY19.

The Board of Registration in Nursing

M.G.L. c. 13, §§9, 13-15D; M.G.L. c. 112, §§74-81C

I. Administration

About the Board

The Board of Registration in Nursing (Nursing Board) protects the health, safety and welfare of the citizens of the Commonwealth through the fair and consistent application of the statutes and regulations governing nursing practice and education. The Nursing Board issues nursing licenses to qualified individuals and authorizes practice in advanced roles. The Nursing Board verifies licensure status of licensees, investigates and acts on complaints concerning the performance and conduct of licensed nurses, and approves and monitors nursing education programs. The Nursing Board participates in workforce initiatives and strives to promote a culture of safety through community outreach and partnerships.

The CARE Act (Chapter 208 of the Acts of 2018) reconfigured the Nursing Board's membership during FY19 to include representatives with expertise in nursing education at the graduate and post-graduate levels, a registered nurse (RN) providing direct care to patients with substance use disorder, a RN providing direct care to patients in an outpatient/community-based/behavioral setting and a RN providing direct care to patients living with chronic pan.

As a result, the Nursing Board is now made up of 17 members including 11 registered nurses, 2 licensed practical nurses, 1 physician, 1 pharmacist, and 2 consumers. By statute, 9 members are required to be present to constitute a quorum.

Nursing Board Members

Barbara Levin, RN, BSN, ONC, CMSRN, LNCC, RN direct care member, Chairperson Lori Keough, PhD, CNP, advanced practice direct care member, Vice Chairperson Linda Kelly, DNP, CNP, advanced practice direct care member Eleonor Pusey-Reid, DNP, pre-licensure level nursing education member Gayle Gravlin, EdD, RN, post-graduate level nursing education member Karen Crowley, DNP, CNP, graduate level nursing education member Anthony Alley, MSN, RN, NE-BC, RN, nursing service administrator member Mary Keohane, RN, RN direct care member Lisa Wu, RN, direct care for substance use disorder member Colleen LaBelle, BSN, RN, direct care in outpatient/community/behavioral health member Diane Nikitas, BSN, RN, direct care for chronic pain Gail Cutillo, LPN, LPN in community health member Kelly Barnes, JD, RPH, pharmacist member Deborah Drew, MBA, consumer member

FY19 Nursing Board Meetings

July 11, 2018 August 8, 2018 September 12, 2018 October 10, 2018 November 14, 2018 December 12, 2018 December 19, 2018 January 9, 2019 February 13, 2019 March 13, 2019 April 10, 2019 May 8, 2019 June 12, 2019

II. Accomplishments of the Nursing Board

Nurse Education Programs: M.G.L. c. 112, §§81A and 81C authorize the Nursing Board to establish regulations governing the approval and operation of registered nurse and practical nurse education programs located in the Commonwealth of Massachusetts.

As of June 30, 2019, there were 75 Nursing Board-approved registered nurse and practical nurse education programs:

- 24 practical nurse programs:
 - Pre-requisite approval: None
 - Initial approval status:
 - Quincy College, Practical Nursing Program, Quincy, MA
 - Quincy College, Practical Nursing Program, Plymouth, MA
 - Approval with warning status: None
 - Withdrawal of approval:
 - Roxbury Community College, Practical Nursing Program
 - Full approval: all other practical nurse programs (22)
- 20 registered nurse associate degree programs:
 - Pre-requisite approval status: None
 - Initial approval status:
 - Quincy College, Associate Degree Registered Nurse Program, Quincy, MA
 - Quincy College, Associate Degree Registered Nurse Program, Plymouth, MA
 - Approval with warning status:
 - Berkshire Community College, Associate Degree Nursing Program
 - Cape Cod Community College, Associate Degree Nursing Program
 - Withdrawal of approval:
 - Roxbury Community College, Associate Degree Nursing Program
 - Full approval status: all other associate degree programs (16)
 - 24 registered nurse baccalaureate degree programs with full approval:
 - Pre-requisite approval status: None
 - Initial approval status:
 - o Assumption College, Baccalaureate Degree Registered Nurse Program
 - o Emmanuel College, Baccalaureate Degree Registered Nurse Program
 - Merrimack College School of Health Sciences, Baccalaureate Degree Registered Nurse Program
 - Full approval status: all other baccalaureate degree (pre-licensure only) programs

- 1 registered nurse hospital-based diploma program with full approval
- 6 registered nurse entry-level graduate degree programs with full approval

New Program Administrator Orientation: The Nursing Board hosted its annual New Program Administrator Orientation in September 2018 and January 2019, introducing 15 new nurse administrators and administrative staff to the Nursing Board's regulations at 244 CMR 6.00, *Approval of Nursing Education Programs and the General Conduct Thereof*, including the regulatory requirements for Massachusetts nurse licensure by examination.

III. Regulations and Policies

Issued Revised Advisory Ruling: Pursuant to M.G.L. c. 30A, §8, the Nursing Board may issue an Advisory Ruling with respect to the applicability of a statute or regulation that it enforces or administers. The Nursing Board's Nursing Practice Advisory Panel reviews each advisory at three-year intervals to ensure each reflects evidence-based standards of practice and makes recommendations to the Nursing Board for changes. During FY19, the Nursing Board updated AR 08-01: Nursing Practice & Cardiopulmonary Resuscitation.

Policy Review: In FY19, the Nursing Board took the following actions in accordance with its systematic policy review schedule:

Reviewed:

Discipline Policy 07-01: Board Delegated Authority Related to the Standard Conditions of a Probation Agreement of Order

Revised:

Discipline Policy 15-02: Delegation of Authority to Authorize the Issuance of an Order Summary Suspension

Discipline Policy 16-01: Complaint Committee

- Licensure Policy 17-01: Board Delegation to Board Staff to Make Final Determination of Good Moral Character
- SARP Policy 06-001: Management of SARP Participants' Relapse in Substance Use Recovery

SARP Policy 99-04: SARP Medical Waiver

SAPR Policy 13-01: SARP Eligibility Criteria for Nurses Prescribed

SARP Policy 18-01: Reentry into Monitored Practice

SARP Policy 18-03: Eligibility Criteria for Initial Admission

SARP Policy 19-01: Staff Action to Resolve Selected SARP Matters

Adopted:

- Education Policy 19-01: Staff Action Authority to Approve the Clinical Components of Out of State Nursing Education Programs
- SARP Policy 18-02: Re-Admission for SARP Participation Post Surrender and Discipline Based on SARP Program Non-Compliance

Decision Making Guidelines for Offering/Ordering Probation and Reprimand

Education Guideline 244 CMR 6.05 Procedure for the Establishment and Continuing Operation of Out of State Nursing Education Programs Retired: Discipline Policy 13:01: WIN Initiative for Nursing Quad SARP Policy 99-06: Board Staff Action to Implement Substance Abuse Rehabilitation Evaluation Committee (SAREC) Recommendations

Biennial licensure	119,626	Registered Nurses (RN)			
	507	RN Nurse Midwives			
	10,303	RN Nurse Practitioners			
	644	RN Psychiatric Clinical Nurse Specialists			
	70	RN Clinical Nurse Specialists			
	1,323	RN Nurse Anesthetists			
	20,497	Licensed Practical Nurses (LPN)			
TOTAL	152,970				

IV. License and Licensee Statistics

V. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	Number of Staff Assignment Investigations Closed	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Opened</u>	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Closed</u>	Number ofFormalComplaintsClosed withDisciplineImposed	% of Formal Complaints Resolved w/Discipline Imposed
82	105	310	321	192	60%

The Board of Registration of Nursing Home Administrators

M.G.L. c. 13, §§9, 73-75; M.G.L. c. 112, §§108-117

I. Administration

About the Board

The principal mission of the Board of Registration of Nursing Home Administrators (NHA Board) is to protect the health and safety of nursing home residents by ensuring that nursing home administrators (NHAs) are competent and perform their responsibilities properly. NHAs provide sub-acute and long-term care services to residents of facilities in Massachusetts.

The NHA Board is made up of 14 members including the Commissioner of Public Health or their designee, the Commissioner of Transitional Assistance or their designee, the Secretary of Elder Affairs or their designee, and 11 appointed members including 4 NHAs, 1 NHA employed by a non-proprietary nursing home, 1 educator, 1 physician, 1 registered nurse, 1 hospital administrator, and 2 public members. By statute, 8 members are required to be present to constitute a quorum.

NHA Board Members

William Graves, BS, NHA member, Chair
Sherman Lohnes, Commissioner of DPH Designee, Vice-Chair
Mary Katherine Moscato, MBA, hospital administration member, Secretary
Nancy Lordan, NHA member
Roxanne Webster, RN, registered nurse member
Mary McKenna, Executive Office of Elder Affairs representative
Mary Ellen Coyne, MassHealth Office of Long-Term Services & Supports, Commissioner of DTA designee
Sr. Jacqueline M. McCarthy, CSJ, RN, NHA memberPatrick J Stapleton, MS, non-proprietary NHA member
Dan Gebremedhin, MD, MBA, physician member
Naomi Prendergast, NHA member

FY19 NHA Board Meetings

July 20, 2018 September 21, 2018 November 16, 2018 January 18, 2019 February 15, 2019 March 15, 2019 April 26, 2019 May 17, 2019

II. Accomplishments of the NHA Board

Board Composition: NHA Board staff continued to focus on filling NHA Board seats in FY19. During FY19, one new NHA Board member was appointed, and Board staff is actively recruiting for three vacant seats.

Governor's Citation: At its September 21, 2018 meeting, the NHA Board recognized former Board Member Michael Baldassarre for an outstanding six years of service. Mr. Baldassarre received a Governor's Citation and Commissioner's Citation.

III. Policies

Petition for Retirement Status 17-03: At its February 19, 2019 meeting, the NHA Board voted to adopt an update to this uniform staff action policy, removing the age requirements for a "retired" license status.

Board Staff Authority to Post Information on Board's Webpage: This policy gives the NHA Board staff authority to make routine postings to the NHA Board's webpage. It was approved at the September 21, 2018 meeting.

IV. License and Licensee Statistics

Annual licensure	833 Nursing Home Administrators	
	80	Administrators in Training (Internship)
TOTAL	913	

V. Compliance: Disciplinary Statistics

Number of StaffAssignmentInvestigationsOpened	Number of Staff Assignment Investigations Closed	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Opened</u>	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Resolved</u>	Number of Formal Complaints Resolved with Discipline Imposed	% of Formal Complaints Resolved w/Discipline Imposed
57	25	10	6	5	83%

The Board of Registration of Perfusionists

M.G.L. c. 13, §§9, 11E; M.G.L. c. 112, §§211-220

I. Administration

About the Board

The Board of Registration of Perfusionists (Perfusionist Board) is charged with evaluating the qualifications of applicants for licensure and granting licenses to qualified applicants. It establishes rules and regulations to ensure the integrity and competence of licensees. The Perfusionist Board promotes the public health, safety and welfare by ensuring that licensed perfusionists have proper training and experience through a degree program and meet the minimum requirements set forth by the Perfusionist Board.

Perfusionists are skilled health professionals, trained and educated specifically as members of an open-heart surgical team responsible for the selection, set-up, and operation of a mechanical device commonly referred to as the heart-lung machine. The perfusionist is responsible for operating the machine during surgery, monitoring the altered circulatory process closely, taking appropriate corrective action when abnormal situations arise, and keeping both the surgeon and the anesthesiologist fully informed.

In addition to the operation of the heart-lung machine during surgery, perfusionists often function in supportive roles for other medical specialties by operating mechanical devices to assist in the conservation of blood and blood products during surgery and providing extended, long-term support of the patient's circulation outside of the operating room environment.

The Perfusionist Board is made up of 7 members including 4 perfusionists, 1 anesthesiologist, 1 cardiovascular surgeon, and 1 public member. By statute, 4 members are required to be present to constitute a quorum.

Perfusionist Board Members

Kyle Spear, CCP, Perfusionist member, Chair Michelle Tozer, CCP, Perfusionist member, Vice-chair Nelson Thaemert, MD, Anesthesiologist member, Secretary Kevin Lilly, CCP, Perfusionist member Prem Shekar, MD, Cardiovascular surgeon member

FY19 Perfusionist Board Meetings

August 4, 2018 December 20, 2018 June 4, 2019

II. Accomplishments of the Perfusionist Board

Board Composition: Perfusionist Board staff continued to focus on Perfusionist Board seats in FY19. During FY19, 1 new Perfusionist Board member was appointed, and 1 candidate was submitted for appointment.

III. Policies:

Board Staff Authority to Post Information on Board's Webpage: This policy gives the Perfusionist Board staff authority to make routine postings to the Perfusionist Board's webpage. It was approved at the December 20, 2018 meeting.

IV. License and Licensee Statistics

Biennial licensure, except	123	Full Licenses
Provisional Licenses, which are		
annual.	4	Provisional Licenses
TOTAL	127	

V. Compliance: Disciplinary Statistics

The Perfusionist Board took no disciplinary action in FY19.
The Board of Registration in Pharmacy

M.G.L. c. 13, §§9, 22-25; M.G.L. c. 112, §§24-42D

I. Administration

About the Board

The Board of Registration in Pharmacy (Pharmacy Board) provides general practice standards through regulations that ensure competence and integrity of pharmacists, pharmacy interns, pharmacy technicians in a variety of healthcare settings, including retail pharmacies, hospitals, long term care facilities, and home care settings. The Pharmacy Board strives to assure that consumers are receiving quality prescription drug products from pharmacists who have graduated from accredited colleges of pharmacy.

The mission of the Pharmacy Board is to promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Massachusetts through the regulation of the practice of pharmacy, the operation of pharmacies, and the distribution of prescription drugs in the public interest. The Pharmacy Board has a leadership role in regulating the practice of pharmacy and acts in accordance with standards of ethics, accountability, efficiency, effectiveness, and transparency.

The Pharmacy Board is made up of 13 members, including 8 pharmacists, 1 pharmacy technician, 1 nurse, 1 physician, and 2 public members. By statute, 7 members are required to be present to constitute a quorum.

Pharmacy Board Members

Andrew Stein, Pharm D, RPh, independent pharmacist member, President Kim Tanzer, Pharm D, RPh, academic member, President-elect Julie Lanza, CPhT, pharmacy technician member, Secretary Michael Godek, RPh, chain pharmacist member Timothy Fensky, RPh, FACA, sterile compounding pharmacist member Patrick Gannon, RPh, hospital pharmacist member Phillippe Bouvier, RPh, independent pharmacist member Stephanie Hernandez, PharmD, BCGP, RPh, long term care member Leah Giambarresi RPh, chain pharmacist member Richard Lopez, MD, physician member Carly Jean-Francois, RN, NP, nurse member Susan Cornacchio, JD, RN, public member Dawn Perry, JD, public member

FY19 Pharmacy Board Meetings

August 2, 2018 September 6, 2018 October 4, 2018 November 1, 2018 December 6, 2018 January 10, 2019 February 7, 2019 March 7, 2019 April 4, 2019 May 2, 2019 June 6, 2019 June 27, 2019

About the Advisory Committee to the Pharmacy Board

The Advisory Committee to the Board of Registration in Pharmacy (Advisory Committee) is a panel of experts appointed by the Commissioner of Public Health and assembled to advise the Pharmacy Board on various topics, including sterile compounding best practices and emerging models of pharmacy. The Advisory Committee was established in FY15, pursuant to Chapter 159 of the Acts of 2014, and has since become a valuable resource to the Pharmacy Board and Pharmacy Board staff. In FY19, the expert members weighed in on several important pharmacy topics, including review of public comment on proposed draft regulations at 247 CMR 17.00 Sterile Compounding, review of a draft policy on a pharmacy's response to above action level environmental monitoring results and review of proposed amendments to Policy 2019-01 on Shared Pharmacy Service Models for telepharmacy practices. The Advisory Committee will continue to advise the Pharmacy Board in FY20, with expert advice on pharmacy practice issues as necessary.

The Advisory Committee is currently made up of 12 members, including the Commissioner of Public Health or their designee, 1 expert in USP Chapter 71, 1 expert in USP Chapter 795, 1 expert in USP Chapter 797, 1 expert in Pharmacoeconomics, 1 expert in Clinical Pharmacology, 1 Microbiologist, and 1 expert in cGMP for aseptic processing. At the request of the board, the Commissioner may appoint additional members knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine or related specialties. By statute, a majority of 7 members are required to be present to constitute a quorum.

Advisory Committee Members

James Lavery, Bureau Director, BHPL, Commissioner's Designee
Caryn D. Belisle, RPh, MBA, expert in USP Chapter 71
John Walczyk, PharmD, RPh, FIACP, FACA, expert in USP Chapter 795
Sylvia B. Bartel, RPh, MHP, expert in USP Chapter 797
Antoinette Lavino, RPh, BCOP, expert in USP Chapter 797
Judith T. Barr, MEd, ScD, FASHP, expert in Pharmacoeconomics
Keith B. Thomasset, BS, PharmD, MBA, BCPS, expert in Pharmacoeconomics
David H. Farb, PhD, expert in Clinical Pharmacology
Michael J. Gonyeau, BS Pharm, PharmD, Med, BCPS, FNAP, FCCP, RPh, expert in Clinical Pharmacology
Karen Byers, MS, RBP, CBSP, expert Microbiologist
Francis McAteer, expert Microbiologist
Lieutenant Commander John Mistler, PharmD, CPH, USPHS, expert in cGMP

FY19 Advisory Committee Meetings

November 29, 2018 June 20, 2019

II. Accomplishments of the Pharmacy Board

Naloxone Standing Orders: In the fall of 2018, a statewide standing order for naloxone was issued for pharmacies to more easily dispense naloxone to any persons requesting it.

Pharmacy Board Newsletter: In FY19, the Board of Pharmacy continued to publish an educational quarterly newsletter in conjunction with the National Association of Boards of Pharmacy (NABP). The newsletter consists of Board member profiles, regulatory updates and guidance regarding pharmacy practice issues.

Pharmacy Board-Approved Continuing Education Programs: The approval of continuing education programs by the Pharmacy Board staff is a valuable service provided to the pharmacy community at no charge. To provide continuing education credit for lectures provided by small groups of presenters such as pharmacy residents and interns, the Pharmacy Board approved 163 such programs in FY19.

Pharmacy Technician Training Programs: Pursuant to Policy 2017-01, which standardized pharmacy technician training programs and licensure exams, the Pharmacy Board approved 11 pharmacy technician training programs and exams in FY19.

Pharmacy Compliance Inspections: During FY19, 12 pharmacy investigators, on behalf of the Pharmacy Board, conducted a total of 2,457 pharmacy inspections in the following categories:

- 2,021 retail compliance inspections;
- 38 non-sterile compounding inspections;
- 35 sterile compounding inspections;
- 332 site visits;
- 25 wholesale distributor inspections; and
- 6 nuclear pharmacy inspections.

Pharmacy investigators also worked to incorporate educational guidance into inspections and site visits. During FY19, a pharmacy investigator participated in the Commonwealth's MasSP Program and utilized site visits to educate new managers of record about regulatory compliance and best practices to prevent opioid misuse and abuse. The Pharmacy Board looks forward to maintaining inspection totals and a strong field presence in FY20 with a full roster of pharmacy investigators.

NAPB Participation: During FY19, Pharmacy Board members and staff continued to work collaboratively with NABP, participating in the following:

- American Pharmacists Association Institute on Alcoholism and Drug Dependencies
- Standards of care task force
- Electronic licensure transfer program task force
- NABP staff training

• Regional and national meetings with delegate seat representation

Staff Training: During FY19, two additional pharmacy investigators attended NABP sponsored sterile compounding training. Staff and investigator training continue to be a priority for the Pharmacy Board, with several trainings scheduled for FY20.

Educational Outreach: Pharmacy Board staff continued to make outreach a large focus of FY19, engaging the professional community with proposed new standards and providing guidelines following statutory changes. In FY19, Pharmacy Board staff highlighted the new Pharmacy Substance Use Disorder program and the future licensure process for institutional sterile compounding pharmacies. Outreach included participation in the following pharmacy of pharmacy programs, which attracted a wide range of licensees in a variety of pharmacy practice settings:

- Overview of the Pharmacy Board for pharmacy students at Northeastern University and Massachusetts College of Pharmacy and Health Sciences University;
- Northeastern University lecture series: "Compounding: Implementing Best Practices for Sterile and Non-Sterile Compounding 2019";
- Board of Pharmacy Regulatory udate for the MassHealth Provider Series;
- Board of Pharmacy Regulatory update at the Massachusetts Health Council;
- Board of Pharmacy Regulatory update at the Lahey Hospital & Medical Center;
- Board of Pharmacy Regulatory update at the Massachusetts Pharmacists Association;
- Board of Pharmacy Regulatory update at the Rhode Island Pharmacists Association;
- Board of Pharmacy Regulatory update at the Hospital Pharmacists of Western Massachusetts;
- Board of Pharmacy Regulatory Update at Massachusetts College of Pharmacy and Health Sciences - Reed 2019;
- Institutional Sterile Compounding and Licensure for the Massachusetts Society of Hospital Pharmacists.

Stakeholder Meetings: In FY19, Pharmacy Board staff held several meetings with stakeholders to discuss issues such as renovation/expansion of sterile compounding pharmacies and innovative pharmacy practices. In FY19, the Board participated in 59 such meetings with pharmacists, hospitals, retail pharmacies, nuclear pharmacies, technology companies, architects, and other healthcare organizations.

III. Regulations and Policies

Proposed Amendments and Additions to 247 CMR: Following the 2012 multi-state meningitis outbreak that was attributed to products from a Massachusetts-based pharmacy, sweeping pharmacy practice reform was mandated by Chapter 159 of the Acts of 2014. The Pharmacy Board immediately began the process of developing regulations to implement these statutory changes. These efforts were coordinated with regulatory review pursuant to Executive Order No. 562. Pharmacy Board staff-initiated a thorough review of current regulations, drafted and presented proposed new language, amendments and rescissions, and conducted a detailed review of each change during the open session of Pharmacy Board meetings in FY15, FY16, FY17, FY18 and FY19.

The *highlights* of the Pharmacy Board's activities in FY19 related to amending regulations and promulgating new regulations include the following:

247 CMR 17:00: Sterile Compounding	•	Board Review & Vote on Public Comment: 12/6/18
247 CMR 22.00: Fining	•	Proposed Draft Adopted by Board: 9/6/18

Advisory on the Sale of Hypodermic Syringes and Needles: In FY19, this advisory was revised to remove the age and identification requirements for purchasing these items without a prescription in accordance with updates to Massachusetts law.

Advisory on Educational Equivalency for Collaborative Drug Therapy Management (CDTM) Agreements: This advisory provides guidance to licensees on the experience that the Pharmacy Board considers to be "equivalent" under M.G.L. c. 112, § 24B¹/₂.

Advisory on Use of Technology to Check Inventory Management Activities Performed by Certified Pharmacy Technicians: Approved jointly by the Pharmacy Board and the Drug Control Program, this advisory provides the conditions under which technology may be used to check certain work products of a certified pharmacy technician.

Policy 2018-01: Permitted Prescription Changes: Updates to this policy advise pharmacists to check with prescribers on prescriptions for behavioral health and narrow therapeutic index drugs before making any quantity changes authorized by the policy.

Policy 2018-04: Naloxone Dispensing via Standing Order: As a result of the newly signed Act for Prevention and Access to Appropriate Care and Treatment, edits to this policy eliminated the pharmacist naloxone training requirement and clarified that pharmacies must report the annual number of doses dispensed.

Policy 2018-05: Requirements and Procedures for Reporting Theft or Loss of Controlled Substances: An updated policy and new electronically fillable reporting form have been developed to instruct pharmacies on how to report and manage drug losses.

Policy 2018-06: Retail Pharmacy Participation in Investigational Drug Studies: This revised policy streamlines the process a pharmacy must follow in order to participate in a drug research study.

Policy 2019-01: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing: This new policy was developed with the Advisory Committee to the Pharmacy Board to address various service models that have evolved into use in pharmacy settings.

Joint Policy 2019-02: Automated Dispensing Device Use: This joint policy with the Drug Control Program simplifies and updates the current joint guidelines for use of automated dispensing devices (ADDs) for controlled substances in health care facilities. It allows licensed

healthcare facilities with an onsite pharmacy to use ADDs to store and dispense prescription products.

Policy 2019-03: Non-Resident Pharmacy Inspection Requirements for Licensure: This policy was developed to provide an overview of inspectional requirements when non-resident licensure begins. Based on the specific license the pharmacy is applying for, the policy provides details of which inspectors and inspection forms would be accepted for either initial licensure or renewal.

Policy 2019-04: Transfer of Unfilled Prescriptions: This policy replaced Policy 2010-01: Authorizing Transfer of an Original Schedule VI Prescription Not Dispensed. The new policy permits the electronic transfer of unfilled electronic medications for all scheduled medications in accordance with DEA guidance.

Staff Action Policy 17-03: Petitions for Retirement Status: In FY19, this policy was revised to remove the minimum retirement age of 50 years old.

Staff Action Policy 17-03: Implementation of Pharmacy Substance Use Disorder (PSUD): In FY19, this policy was updated to require the PSUD supervisor to report a summary of all actions taken pursuant to this policy to the Pharmacy Board.

Staff Action Policy 18-02: Retail Pharmacy Participation in Investigational Drug Studies: This policy grants Pharmacy Board staff the ability to approve a request to participate in a research study with an affiliated researcher upon receipt of required information.

Biennial licensure,	13,189	Pharmacists	
except Wholesale	64	Nuclear Pharmacists	
Distributors, which are	10,907	Pharmacy Technicians	
annual	3,569	Pharmacy Technicians in Training	
	4,562	Pharmacy Interns	
	1,126	Retail Pharmacies	
	1,141	Retail Pharmacy Controlled Substance Permits	
	37	Certificate of Fitness Permits	
	6	Nuclear Pharmacies	
	40	Wholesale Distributors	
	40	Wholesale Distributors Controlled Substance Permits	
	2	Resident Outsourcing Facilities	
	46	Non-Resident Outsourcing Facilities	
	0	Provisional Outsourcing Facility	
	2	Outsourcing Controlled Substance	
TOTAL	34,731		

IV. License and Licensee Statistics

V. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	Number of Staff Assignment Investigations Closed	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Opened</u>	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Resolved</u>	Number of Formal Complaints Resolved with Discipline Imposed	<u>% of Formal</u> <u>Complaints</u> <u>Resolved</u> <u>w/Discipline</u> <u>Imposed</u>
163	183	105	112	71	63%

The Board of Registration of Physician Assistants

M.G.L. c. 13, §§9, 11C; M.G.L. c. 112, §§9C-9K

I. Administration

About the Board

The Board of Registration of Physician Assistants (PA Board) is charged with evaluating the qualifications of applicants for licensure and granting licenses to those who qualify. It establishes rules and regulations to ensure the integrity and competence of licensees. The PA Board protects the public health, safety, and welfare through regulation of the practice in the Commonwealth of Massachusetts in accordance with applicable statutes.

A PA may, under the supervision of a licensed physician, perform any and all services that are (a) within the competence of the PA in question, as determined by the supervising physician's assessment, and (b) within the scope of service for which the supervising physician can provide adequate supervision to ensure that accepted standards of medical practice are followed.

The PA Board is made up of 9 members: 4 PAs, 1 PA educator, 2 public members, and 2 physicians, 1 of which is a member of the Massachusetts Medical Society. By statute, 5 members are required to be present to constitute a quorum.

PA Board Members

Dipu Patel-Junankar, MPAS, PA-C, PA member, Chair Shannon Sheridan-Geldart, MS, PA-C, PA educator member, Vice Chair Paul Crehan, PA-C., PA member, Secretary Alithia Carol Monroe, PA-C, PA member Mary Kuzmeski, PA member Dr. Richard Baum, MD, Massachusetts Medical Society representative member Dr. Robert Baginski, MD, physician member

FY19 PA Board Meetings

August 9, 2018 September 13, 2018 October 11, 2018 December 13, 2018 February 14, 2019 March 14, 2019 May 9, 2019 June 13, 2019

II. Accomplishments of the Board

Board Composition: PA Board staff continued to focus on PA Board seats during FY19. During FY19, Board staff submitted 1 nominee for appointment.

Educational Outreach: In FY19, Executive Director Roberlyne Cherfils and PA Board Chair Dipu Patel-Junankar, presented an overview of the PA Board to the graduating classes of PA students at the following Massachusetts colleges and universities:

- Tufts University on August 31, 2018
- Northeastern University on April 12, 2019
- BayPath University on April 24, 2019
- Boston University on May 31, 2019

The presentation topics included the PA Board's mission, initial licensure process, license renewal, enforcement process, scope of practice issues, and continuing education requirements.

On February 14, 2019, the PA Board conducted an interactive mock Board meeting for students in the Northeastern University PA program. The mock meeting included role-playing by students, Board members, and Board staff, using fictitious cases based on common issues that come before the Board.

III. Policies

Petition for Retirement Status 17-03: At the September 13, 2018 meeting, the PA Board voted to adopt an update to this uniform staff action policy, removing the age requirements for a "retired" license status.

Board Staff Authority to Post Information on Board's Webpage: This policy gives the PA Board staff authority to make routine postings to the Board's webpage. It was approved at the October 11, 2018 meeting.

Website Alerts: In FY19, the PA Board posted 3 Alerts to its web page:

- 1. The Acts of 2014, Chapter 260, Section 9, and Domestic & Sexual Violence Training for upcoming renewal cycle.
- 2. Chapter 220 of the acts of 2018 that requires Physicians, Physician Assistants, Register Nurses, License Practical Nurses that serve adults to complete a one-time training in education under Alzheimer's disease Research and Treatment related to Dementia.
- 3. Pain Management Task Force Report on Best Practices for Treatment of Pain.

IV. License and Licensee Statistics

Biennial licensure	3,794	Full Licenses
	0	Temporary Certifications
TOTAL	3,794	

V. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	Number of Staff Assignment Investigations Closed	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Opened</u>	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Resolved</u>	Number of Formal Complaints Resolved with Discipline Imposed	<u>% of Formal</u> <u>Complaints</u> <u>Resolved</u> <u>w/Discipline</u> <u>Imposed</u>
40	16	4	2	1	50%

The Board of Respiratory Care

M.G.L. c. 13, §§9 and 11B; M.G.L. c. 112, §§23R-23BB

I. Administration

About the Board

The Board of Respiratory Care (RC Board) is charged with evaluating the qualifications of applicants for licensure and granting licenses to those who qualify. It establishes rules and regulations to ensure the integrity and competence of licensees. The RC Board protects the public health, safety, and welfare through regulation of the practice in the Commonwealth of Massachusetts in accordance with applicable statutes.

Respiratory care practitioners provide services to consumers under the direction of a licensed physician. Applying scientific principles, they identify, prevent, and rehabilitate acute or chronic dysfunction to promote optimum respiratory health and function. Respiratory care also includes teaching the patient and the patient's family, respiratory care procedures as part of the patient's ongoing program.

The RC Board is made up of 7 members, including 2 respiratory therapists, 1 nurse, 2 physicians, and 2 consumers of respiratory care services. By statute, 4 members are required to be present to constitute a quorum.

RC Board Members

Martha DeSilva, Respiratory Therapist Member, Chair Jason Moury, RRT, Respiratory Therapist Member, Vice Chair Molly Caravallo, RN, Nurse Member, Secretary Jordan Rettig, MD, Physician Member Essam Ansari, MD, Physician Member

FY19 RC Board Meetings

July 17, 2018 December 18, 2018 May 21, 2019

II. Accomplishments of the Board

Regulation Review: The RC Board voted to adopt 261 CMR 2.00, 3.00, 4.00, and 6.00, which were promulgated and effective on May 18, 2018. The Board held a second round of public hearings on 261 CMR section 5.00 on July 16, 2018 in order to review the number of continuing education credits required for license renewal.

At the December 18, 2018 meeting, the RC Board approved 261 CMR 5.00 for final administrative review and promulgation. The Board voted to increase the current CEU requirements from 15 CEUs to 20 CEUs and clarified the CEU requirements may be obtained on-line or in person.

Board Composition: During FY19, one candidate was appointed to the Board. RC Board staff continued to focus on RC Board seats in FY19.

III. Policies

Discipline Policy 15-01: At the July 17, 2018 meeting, the RC Board amended this policy adding the possibility of resolving a complaint by allowing the licensee to apply for license retirement if applicable based on the criteria outlined.

III. License and Licensee Statistics

Biennial licensure	3,001	Full Licenses
	60	Limited Permits (no renewals)
TOTAL	3,061	

IV. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	<u>Number of</u> <u>Staff</u> <u>Assignment</u> <u>Investigations</u> <u>Closed</u>	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Opened</u>	<u>Number of</u> <u>Formal</u> <u>Complaints</u> <u>Resolved</u>	Number of Formal Complaints Resolved with Discipline Imposed	% of Formal Complaints Resolved w/Discipline Imposed
7	3	3	3	0	0%

The Drug Control Program

M.G.L. c. 94c

About the Program

DCP is responsible for the oversight of the following program areas: The Massachusetts Controlled Substances Registration (MCSR), the Medication Administration Program (MAP), the Drug Stewardship Program (DSP), the Drug Formulary Commission (DFC), the Prescription Monitoring Program (the PMP) and the Pharmaceutical and Medical Device Manufacturer Code of Conduct (PCOC).

DCP has statutory responsibility to set standards for the control of possessing, prescribing, dispensing and administration of pharmaceuticals by health care providers as well as manufacturing and distribution of pharmaceuticals by health care facilities and entities. DCP undertakes initiatives to promote effective security and accountability measures and to prevent theft, tampering, misuse and abuse of drugs. DCP promotes access to safe and effective pharmaceutical care services in Massachusetts and protects consumers against fraud, deception and unsafe practices in the distribution, handling and use of pharmaceuticals and medical devices.

Massachusetts Controlled Substances Registration

M.G.L. c. 94C

I. Administration

About the Department

The MCSR Department is responsible for issuing controlled substance registrations to providers and facilities that prescribe, dispense, administer, possess, distribute, or manufacture controlled substances in Massachusetts. MCSR also issues controlled substance registrations to studies conducting research with Massachusetts controlled substances or Investigational New Drugs (INDs).

II. Accomplishments of the Department

MCSR Data Conversion: In FY19, MCSR data for BHPL licensees and physicians was converted to the BHPL licensing database, MLO. Applicants for most individual license types can now apply for MCSRs online and renew existing MCSRs online.

MCSR Virtual Drug Manufacturers & Distributors: In FY19, an MCSR was created by the CARE Act and executed by the MCSR Department for entities in the business of manufacturing or distributing a controlled substance and who have a principal place of business located in the Commonwealth but at no time take physical possession of any controlled substance in the Commonwealth. The new registration will allow Massachusetts Virtual Manufacturers and Virtual Distributors to do business in other states, as they can now demonstrate registration in their home state.

III. Registration Statistics

Annual licensure,	8,607	Advanced Practice Registered Nurses	
except Physicians,	1,149	Optometrists	
which are every three	77	Pharmacists	
years	3,455	Physician Assistants	
	36,646	Practitioners (Physicians, Podiatrists and Dentists)	
	2,351	Veterinarians	
	1,081	Research studies	
	25	Analytical Labs	
	576	Ambulances	
	833	Clinics	
	122	Drug distributors	
	82	Drug manufacturers	
	63	Drug distributors and manufacturers	
	149	Hospitals	
	256	Municipalities	
	24	Non-Municipal Public Agency	
	3	Virtual Drug Distributors	
	40	Virtual Drug Manufacturers	
	4	Virtual Drug Manufacturers & Distributors	
TOTAL	55,543		

DCP Enforcement Unit

I. Administration

About the Unit

The Enforcement Unit (EU) of DCP promotes effective security and accountability to prevent theft, tampering, misuse and abuse of prescription drugs by conducting inspections and investigations; developing policies and guidelines; and providing educational information and programs. The EU monitors and investigates the diversion of prescription pharmaceuticals (controlled substances) to illicit channels through such activities as prescription fraud (e.g., forgery, doctor/pharmacy shopping, drug theft and drug tampering) and diversion by health care professionals in and out of health care facilities. Drug diversion may result in abuse and misuse of controlled substances by health care professionals, and exposes patients to medication errors and lack of appropriate pain medications.

Compliance

DCP has statutory responsibility, in accordance with M.G.L. c. 94C, to set standards for the control of prescribing, dispensing and administration of pharmaceuticals by health care providers, as well as safe storage of pharmaceuticals by health care facilities (e.g., hospitals, clinics, long-term care) and other entities (e.g., manufacturers, distributors, ambulance services, researchers, community-based programs). In addition, M.G.L. c. 94, §189A, requires the EU to embargo adulterated or misbranded prescription and over-the-counter drug products.

The majority of EU investigations involve a licensed health care professional diverting controlled substances from a place of employment. High priority diversion investigations involve drug tampering, the substitution of a patient's controlled substance medications using a placebo, saline or other ineffective medication. The EU gathers evidence and makes referrals to or works jointly with licensing boards and state and federal law enforcement agencies towards the prosecution of diversion and tampering suspects.

Pursuant to DCP regulations, 105 CMR 700.000, registrants are required to report the loss of any controlled substances within 24 hours of discovery of the loss. All Drug Incident Reports are reviewed by a DCP Investigator before any disposition can be rendered. DCP Investigators are not regionally based and field activity is conducted throughout the Commonwealth, including the islands of Nantucket and Martha's Vineyard. The EU also receives new facility MCSR applications for investigation, including previously registered facilities that indicate, on renewal, a new address, name change, or change in controlled substance storage and accountability. During complaint investigations, routine audits of narcotic security and accountability may be conducted to improve drug security and accountability.²⁰

²⁰ See Appendix R: FY19 Drug Control Program Enforcement Unit Disciplinary Statistics.

The Medication Administration Program

105 CMR 700.003(F)

I. Administration

About the Program

MAP was codified in 1993, in response to a 1988 report of the state auditor, recommending replacement of the previously unregulated practice of medication administration by unlicensed staff working in Department of Mental Health (DMH) and Department of Developmental Services (DDS) residential settings. In 2013, DCP promulgated amendments to MAP regulations in 105 CMR 700.003(F), which enabled the Department of Children and Families (DCF) to join MAP. MAP operates under statewide standards and policies. These safeguards are in place to protect the individuals supported by MAP.

MAP makes it possible for direct care staff, who know the specific needs and concerns of each individual supported at the setting, to administer medication as a normal part of the individual's daily routine.

MAP clinical staff within DCP conduct reviews of the clinical practices in community programs, and captures reports of medication occurrences followed by medical intervention, illness, injury or death. DCP ensures medication security and accountability at MAP sites through the issuance of MCSR as well as inspections and investigations.

MAP Stakeholders

While DPH, through DCP, serves as the lead agency for oversight and coordination of MAP, the program is administered jointly through an interagency service agreement by DDS, DMH, DCF, and DPH (Agencies). The MAP Administrators Group is comprised of MAP clinical, legal, and administrative staff from the Agencies. The Administrators Group review and revise all policies and operations of MAP and its service providers. Collaboratively, the Agencies have achieved significant advances in uniformity of training and testing, and policy development and improvement.

To ensure consistency, improvement and innovation, MAP convenes a quarterly MAP Work Group, comprised of representatives from MAP service providers, who have ongoing responsibility for the management of MAP activities within the Agencies' programs. The MAP Work Group members provide input on MAP policies and practices, and enhance communication to thousands of MAP sites throughout the Commonwealth.

The community of MAP providers, stakeholders and consumers combine to form the MAP Advisory Committee, which meets on an as-needed basis to ensure effective policy communication. The MAP Advisory Group met in March 2017.

II. Accomplishments of the MAP

Curriculum: A new MAP Certified staff Training Curriculum *Responsibilities in Action*-*Understanding the Connections* was developed in FY18 and is currently being used at MAP Registered sites.

III. Regulations and Policies

After input from the MAP Administrators Group, the MAP Work Group, and the MAP Advisory Group, proposed revisions were made to the current MAP Policy Manual Version 2010-9-01 Revised 1-01-15. MAP Advisories have also been developed to enable policy and practice changes until this revised version of the MAP Policy Manual becomes effective.

Amendments to MAP regulations in 105 CMR 700.003(F), relative to requirements for stable populations and dedicated staff work, is currently in effect.

IV. MAP: MCSR Statistics

MAP requires that all medication storage sites be registered with DCP. The MAP MCSR is valid for one year. MAP Certified staff may only administer medications in sites that have a valid MAP MCSR.

Department	Number of Service Providers	Number of Sites issued MCSR
DDS	156	2780
DMH	39	543
Caring Together DMH/DCF	38	144
Youth Therapeutic Day Services	5	10
TOTAL	237	3,478

VI. Hotline Medication Occurrences Reports

MAP Registered sites are required to report any Medication Occurrence directly to DCP within 24 hours of discovery, followed by a medical intervention (e.g., lab work, tests, health care provider visit, clinic visit, ER visit, hospitalization, etc.), illness, injury or death. In FY19, there were 160 Medication Occurrence 'hotlines' reported to DCP.

The Drug Stewardship Program

M.G.L. c. 94H; 105 CMR 702.000 (draft)

I. Administration

About the Program

DSP began implementation late in 2016 as mandated by statute, M.G.L. c. 94H, as inserted by Chapter 52 of the Acts of 2016 - An Act relative to substance use treatment, education and prevention (STEP). The statute establishes a drug stewardship program, financed by pharmaceutical product manufacturers to collect, secure, transport and safely dispose of unwanted drugs in compliance with enumerated requirements. The statute ensures that retail pharmacies are not required to participate directly in the collection, securing, transport or disposal of prescription drug products.

II. Accomplishments

Stakeholder Engagement and Communication: The DSP worked closely with pharmaceutical manufacturer associations and stewardship collaboratives to develop guidance and compliance checklists. The DSP, through relationships with the Federal Food and Drug Association, developed complete lists of covered manufacturers to ensure communication, which described the DSP and outlined deadlines for compliance, reached globally to provide notice of the new requirements to all appropriate manufacturers of benzodiazepine and Schedule II and III opioid drug products that make their way into the Commonwealth.

Certification of Non-Participation: Manufacturers reached by the DSP's broad communication were provided the option of claiming non-participation. The DSP created a checklist to allow these manufacturers to provide qualified reasons for not submitting a Plan. Dozens of claims were received and confirmed, based on one of three main factors:

- 1. The manufacturer does not sell covered drugs;
- 2. The manufacturer sells covered drugs, but not in the Commonwealth; or
- 3. The manufacturer sells covered drugs in the Commonwealth, but only for exempt purposes, like veterinary care.

Plan Submission: The DSP approved 1 Plan submission from a manufacturing collaborative, called MED-Project, comprised of over 150 member manufacturers who buy into the Plan manager, MED-Project. The DSP and MED-Project have collaborated to ensure this sole statewide Plan provides a comprehensive and effective method of ensuring the safety and security of unwanted medications.

The approved Plan establishes a kiosk grant program to support the collection of unwanted medicine in the Commonwealth by current law enforcement agency kiosks. The grant program also offers kiosks to eligible law enforcement agencies not currently hosting a kiosk and replace selected existing kiosks that are not fully functional or do not meet current regulatory requirements. Through service and funding grants, MED-Project supports the collection, transport, and disposal of unwanted drugs collected in the kiosks. Finally, MED-Project created an outreach and education program for residents on usage and storage of unwanted medicines

once they are no longer needed for the purpose for which they were prescribed, and options to dispose of unwanted drugs conveniently and safely from their own homes.

MED-Project's Plan received final approval on November 26, 2018 and immediately began operation. Details and resources are available to the public on MED-Project's website: <u>https://med-project.org/locations/massachusetts/</u>.

The approved plan was negotiated to include three progress reports from MED-Project to be submitted 120 days, 240 days and 360 days from the approval date, at which time MED-Project would be permitted to seek renewal for another year.

Compliant progress reports were submitted in FY19 on March 26, 2019 and June 26, 2019.

III. Regulations and Policies

The STEP Act created the DSP as a temporary program, with a sunset date of December 31, 2021. Regulations are being developed under a new regulation number (105 CMR 702) to set penalties for noncompliance.

An alternative plan will also be established in the regulation, allowing manufacturers to opt out of creating their own plan or joining a group plan, by engaging in alternate plan activities.

IV. Participation Statistics

The DSP received and approved one Plan submission, consisting of over 150 manufacturers, prior to the July 19, 2017 deadline. The DSP has received 51 non-participation forms, of which 49 have been approved.

VI. Compliance

Regulations are necessary to ensure compliance through fines and penalties for a participating manufacturer's failure to submit and execute a Plan.

The Drug Formulary Commission

M.G.L. c. 17, §13

I. Administration

About the Program

The Drug Formulary Commission (DFC) is charged with preparing a Formulary of Chemically Equivalent Substitutions (Formulary) for opioids classified as Schedule II or III that the DFC has determined to have a heightened public health risk (HPHR opioids) due to the potential for abuse and misuse of the drug. The Formulary is intended to serve as a tool for prescribers in addressing the opioid crisis but does not mandate the substitution of specific drugs by prescribers. Pharmacists are required to make substitutions based on pairings listed on the Formulary, unless the prescriber indicates "No Substitution" on the prescription. Additionally, the DFC is required to develop and publish a list of non-opioid drug products for pain management on an annual basis.

Members of the DFC are appointed by the Governor and include practicing physicians and pharmacists, pharmaceutical researchers, addiction specialists and patient advocates. As of June 30, 219, DFC had 6 vacancies. DCP staff plan meeting agendas and develop materials in consultation with a consultant pharmacist from the University of Massachusetts Medical School.

Commission Members:

James Lavery, BHPL Director, DPH Commissioner's designee Dr. Paul Jeffrey, Director of Pharmacy, MassHealth designee Niels Puetthoff,, Bureau of Managed Care, Division of Insurance designee Dr. Joanne Doyle Petrongolo, Clinical Chemist member Dr. Jeffrey Supko, Pharmaceutical Chemist member Dr. Theoharis Theoharides, Clinical Pharmacologist member Dr. Daniel Carr, Pharmaceutical Manufacturing member Cheryl Campbell, Biologics Manufacturing member Dr. Alexander Walker, Practicing Physician member Cindy Steinberg, Public (elderly representative) member

FY19 Commission Meetings:

The Drug Formulary Commission did not hold meetings in FY19.

II. Accomplishments of the Commission

Non-Opioids for Pain Management: On August 17, 2017, the DFC approved the first annual update of the list of Non-Opioid Drug Products for Pain Management, which includes 111 drug products. The DFC is required to complete this task on an annual basis. The list was updated and published on August 16, 2018, including 144 drug products.

Regulation: On August 9, 2017, the Public Health Commission approved the revision of 105 CMR 720: *Massachusetts List of Interchangeable Drug Products*, changing its name to "*Drug Formulary Commission*" and substituting the outdated purpose of the regulation, to provide for a

means of determining which generic drugs can be substituted for brand name drugs, with the current purpose, to guide the work of the DFC and publish the Formulary. The regulation is awaiting final promulgation.

The Pharmaceutical and Medical Device Manufacturer Code of Conduct 105 CMR 970.000

I. Administration

About the Program

The Pharmaceutical and Medical Device Manufacturer Code of Conduct (PCOC) was developed as a legislative initiative, M.G.L. c. 111N, which took effect on January 1, 2009 and regulates the pharmaceutical and medical device industry in two ways:

- It requires DPH to adopt a standard marketing code of conduct for all pharmaceutical or medical device manufacturing companies that employ a person to sell or market prescription drugs or medical devices in the commonwealth, which in turn must be adopted by those companies.
- It also requires all pharmaceutical or medical device manufacturing companies that employ a person to sell or market prescription drugs or medical devices in the commonwealth to annually report bona fide payments (i.e., permissible payments under the code of conduct) made to Massachusetts-licensed health care practitioners.

II. Accomplishments

Covered Recipient List: The program must create an annual list of recipients covered by the PCOC restrictions and requirements to notify manufacturers of the recipients that will lead to reporting. This process is achieved by reaching out to relevant licensing boards for a current licensee list, and adding each licensee to current covered recipient list for manufacturer use.

Application and Renewal Process: Manufacturers register with the PCOC each year and pay an initial registration or renewal fee by check. The PCOC receives and processes applications.

Annual Disclosure Reports: The PCOC receives payment ("gift") information from manufacturers by the end of each fiscal year and compiles it in a master list. Following a submission and review process, program staff works with EHS IT to post in a searchable format on a public-facing website.

III. Regulations and Policies

Currently, the PCOC operates under state regulation (105 CMR 970.000), promulgated on December 7, 2012. The Drug Enforcement Administration (DEA) then produced its own rules on Open Payments, commonly referred to as the Sunshine Act. Open Payments is a federal program, required by the Affordable Care Act, that collects information about the payments drug and device companies make to physicians and teaching hospitals for things like travel, research, gifts, speaking fees, and meals. It also includes ownership interests that physicians or their immediate family members have in these companies. This data is then made available to the public each year on this website. <u>https://openpaymentsdata.cms.gov/</u>. The Federal rules preempt the PCOC to the extent that the recipient of the payment is also covered by Sunshine Act provisions.

Disclosure reports must be submitted to the department from July 1 and August 31 of each year. Federal Sunshine Act reports must be published by the PCOC within 90 days of receipt from the DEA.

At the end of FY18, the President signed the SUPPORT Act, which amended the Sunshine Act to include additional covered recipients. This amendment will further limit the PCOC's covered recipient list and reduce the number of payments reported to the PCOC.

IV. Registration Statistics

The PCOC staff received 47 initial registrations since in FY19 and 396 registration renewals in the same period, for a total of 443 registered drug and device manufacturers. A total of 19,240 payments were reported to 10,890 recipients. These figures do not include preempted Federal Sunshine Act payments.

V. Compliance: Disciplinary Statistics

DPH Office of General Counsel received no voluntary disclosures of PCOC violations this year. Had any been received, they would have been referred to the Attorney General for further action.

The Prescription Monitoring Program

M.G.L. c. 94C, §§24A-24B; 105 CMR 700.012

I. Administration

About the Program

The Massachusetts Prescription Monitoring Program (PMP) was established through joint regulations of DCP and the Pharmacy Board in 1992. DCP launched an online version of the PMP (MA Online PMP) in 2012, using state appropriations and grants from the Bureau of Justice Assistance (BJA).

Nationwide, PMPs are important tools to support safe and appropriate prescribing. Information provided by PMPs help prescribers and pharmacists identify individuals who may be misusing, abusing, or diverting prescription controlled substances and may need intervention, such as a treatment referral.

The PMP collects prescribing and dispensing information on Schedule II through V controlled substances, and Gabapentin, a Schedule VI drug of interest,²¹ dispensed by Massachusetts pharmacies and out-of-state pharmacies that deliver to Massachusetts residents. All Massachusetts registered pharmacies and all pharmacies that dispense Schedule II-V medications and Gabapentin to MA residents must submit this data to the PMP Clearinghouse within 24 hours or the next business day. The PMP provides critical information to prevent and detect the misuse, abuse and diversion of prescription drug products, which affect public health and safety. Data in the PMP can be queried by authorized health care providers for use as a clinical tool and has improved prescriber and pharmacies to necessary patient information for timely intervention of at-risk patients.

This prescription data is accessed through the Massachusetts Prescription Awareness Tool (MassPAT), an online tool utilized by authorized providers that supports safe prescribing and dispensing practices. MassPAT contains prescription records for the past 12 months. By viewing a patient's prescription history in the system, a provider can improve the safety of drug therapy and coordinate care by communicating with other providers to improve clinical outcomes and overall patient health. Utilization of MassPAT can also enable early identification of potential prescription drug misuse, abuse or diversion and trigger early intervention. Practitioners are required to utilize MassPAT prior to issuing a prescription to a patient for any Schedule II or III narcotic drug for the first time and prior to issuing a prescription for a benzodiazepine.

Law Enforcement and Regulatory agents have limited access to MassPAT for drug-related investigations. Statutory changes contained in the 2018 CARE Act restricted direct access to MassPAT for local, state, and federal law enforcement. agencies with certain exceptions.

²¹ Pursuant to 105 CMR 700.012(C)(7), the Commissioner of Public Health designated Gabapentin as an "additional drug" for purposes of prescription monitoring, because it carries a *bona fide* potential for abuse.

PMP staff is tasked with promoting the utilization of MassPAT by all authorized users. This entails educational efforts to pass along best practices for incorporating MassPAT utilization into the provider's workflow. The PMP is committed to continuous improvement of MassPAT and to increasing utilization and compliance.

In addition, the PMP maintains a separate database that contains prescription records dating back to the program's inception in 1992. This database is updated daily via a download of all prescription records submitted to the Clearinghouse. This database and the daily download are monitored and maintained by EHS IT staff assigned to the PMP. This data is accessed through Structured Query Language (SQL), which allows an analysis of the data by Program and DPH epidemiologists to:

- Determine prescribing and dispensing trends;
- Develop predictive modeling of prescribing practices that lead to addiction;
- Provide pertinent information to health care providers, policymakers, and the public;
- Detect prescribing and dispensing practices of concern; and
- Gauge compliance to statutory requirements for data submission and MassPAT utilization.

The Prescription Monitoring Program Medical Review Group (MRG)

The MRG is authorized by statute (M.G.L. c. 94C, §24A) and was established in 1992 to review findings and make recommendations before actions are taken pursuant to 105 CMR 700.012(5)(a), which states "The Department shall review the prescription monitoring information collected pursuant to 105 CMR 700.012. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the Department shall notify the appropriate law enforcement or professional licensing, certification or regulatory agency or entity and provide prescription monitoring information required for an investigation."

Pursuant to regulation, members of the MRG must be licensed health care practitioners or pharmacists. Members of the MRG are appointed by the Commissioner and are considered Special State Employees as they have access to confidential information. The MRG is not subject to Open Meeting Law.

Although not required, each member has experience using MassPAT, is in active practice and good standing, and has experience in the prescribing or dispensing of controlled substances or in treating individuals who have a controlled substance addiction. To the extent feasible, at least one member should be licensed in the same discipline as the practitioner whose records are under review.

MRG Members:

Dr. Joseph S. Insler, MD, physician member Dr. Edward Michna, MD, physician member Dr. Mina Paul, DMD, dentist member Scott DeCesare, PharmD, R.Ph., pharmacist member Karen Horbowicz, PharmD, R.Ph., pharmacist member Emily Rowe, PharmD, R.Ph., pharmacist member Christopher Shaw, NP, advanced practice registered nurse member Dawn Williamson, NP, advanced practice registered nurse member Angelo Pucillo, PA, physician assistant member

FY19 MRG Meeting Dates:

September 27, 2018

II. Accomplishments of the PMP

MassPAT Enhancements: During FY19, the PMP concentrated on enhancements to MassPAT to improve user experience and value as a clinical tool, improvements to the statutorily required Prescriber Reports (M.G.L. c. 94C, § 24B), and the integration of the MassPAT data into provider's EHR systems and pharmacy software programs. In addition, the PMP continued its efforts to improve the timeliness and accuracy of the data collected in the PMP Clearinghouse.

Utilization: In FY19, MassPAT searches topped 7,410,000, an increase of over 1 million searches from FY18. Electronic Health Records (EHR) integrations contributed significantly to this increase.

Prescriber Reports: Mandated by M.G.L. c. 94C §24B, prescriber reports underwent a second overhaul in FY19. Based on an extensive survey, the PMP temporarily delayed the quarterly reports to incorporate suggested changes to the format and the metrics contained in the Prescriber Report. These changes include:

- Peer comparison measures that are based on per patient prescribing rather than average monthly totals;
- Stimulant prescription rates;
- A separate section of Medically Assisted Treatment (MAT) drug prescriptions has been developed to avoid confusion with other Opioids; and
- An improved visual display of data to provide a more user-friendly design.

The metrics continue to include:

- The prescribers most frequently prescribed Schedule II-V medications;
- Strength of dosage measured in Morphine Milligram Equivalent (MME);
- Duration of the opioid therapy;
- Benzodiazepine prescription rates;
- Number of patients receiving prescription from >5 prescribers;
- Number of patients having prescriptions filled at >5 pharmacies;
- Number of patients on overlapping opioids and benzodiazepines; and
- PMP utilization.

Accompanying the Prescriber Report, and available for download in MassPAT, is a Metrics Explanation PDF, designed to help the practitioner understand each data field on the report. PMP staff also put together an FAQ for anticipated questions that was posted on the PMP website and available by link in the MassPAT Announcements section.

Frequency

Survey responses continued to support quarterly reports rather than the annual statutorily required frequency, to keep their prescribing practices in the forefront and promote greater opportunity for reflection and change. The PMP will continue to produce quarterly prescriber reports, each time looking back over the previous six months.

The Delivery Method

A considerable effort was made to ensure that the initial prescriber report was received by each practitioner. Every registered Health Care Entity (HCE) was notified repeatedly, urging each to take the necessary steps to allow PMP encrypted emails to pass through firewalls and filtering systems. Despite this effort, many practitioners noted that they did not receive their report. PMP staff worked with vendor, Appriss Health, to have the reports embedded in the MassPAT dashboard, available for download by each practitioner. The current Prescriber Report and the 3 previous reports are now available in MassPAT for download.

Electronic Heath Records (EHR) Integration: Integrating MassPAT data within an EHR provides a streamlined clinical workflow for providers. The integration eliminates the need for providers to pull-up the MassPAT browser, successfully log-in, and enter their patient's name and date of birth. Instead, the EHR automatically initiates a patient query, validates the provider's credentials in MassPAT and returns the patient's prescription record directly within the provider's EHR.

By the close of FY19, over 150 provider organizations, accounting for more than half of the prescribers registered in the Commonwealth, have one-click access to a patient's PMP report directly from the patient's EHR. A study of Partners Health prescribers indicated a 34% increase in PMP utilization in the 6 months after integration when comparted to the 6 months prior to integration.

Pharmacy Data Submission Compliance: The timeliness and quality of data is the foundation of an effective PMP. Program staff developed a pharmacy compliance weekly report and workflow to address delinquent pharmacies and pharmacies whose files were routinely rejected for data submission errors. In FY19, through continued aggressive outreach, the rate of delinquency, the number of rejected files, and the length of time to correct and resubmit rejected files all decreased to all-time lows.

Interstate Data Sharing: The PMP continues to expand and improve interstate data sharing. Currently, the PMP has entered into data sharing agreements with 32 states and the District of Columbia, including all New England states and New York.²² The established data sharing agreements allow providers in Massachusetts to query a partner state through MassPATto ensure that they are able to see a complete picture of their patient's prescription history.

²² See Appendix S: Interstate Data Sharing.

III. Prescribing Trends

Prescriptions: The number of prescriptions for opioids continued to fall. Prescriptions for Schedule II opioids fell by 9% in FY19 compared to FY18. Overall there has been a 38.8% decline in Schedule II opioid prescriptions since the first quarter of 2015.

Patients: Just over 236,000 individuals in Massachusetts received prescriptions for Schedule II opioids in the second quarter of 2019. This is a small decrease from the previous quarter and greater than a 39.5% decrease from 390,532 in the first quarter of 2015.²³

²³ See Appendix T: Individuals Receiving Schedule II Opioid Prescriptions and MassPAT Search Activity Trends: Q1 2015 - Q2 2019.

Conclusion

The foregoing accomplishments and statistics are highlights from FY19. BHPL, including its 10 boards, the DCP and PMP have maintained a continued commitment to establishing and improving practice standards for the health professions under BHPL oversight, and makes strides every day to fulfill the mandate to protect the public health, safety, and welfare in Massachusetts. The review of existing regulations, continued emphasis on board composition and outreach efforts, and integration of the DCP and PMP within BHPL reinforce the overall goal of BHPL to improve public health and safety.

Contact Us/Feedback

Your feedback is important to us. Please take our survey and share any questions or comments.

The Bureau of Health Professions Licensure 239 Causeway Street, Suite 500 Boston, MA 02114 800-414-0168 www.mass.gov/orgs/bureau-of-health-professions-licensure

Appendix A: BHPL FY19 Board Funding



*Community Health Workers, Dentistry, Genetic Counselors, Naturopathy, Nursing Home Administrators, Perfusionists, Physician Assistants and Respiratory Care. **Unexpended collected trust revenue can be carried forward at the end of each fiscal year. Due to license renewal cycles set by statute, HPL collects more trust revenue during even fiscal years than the odd fiscal years and sufficient trust roll forward balances from the even fiscal years are needed to fund expenses in the odd fiscal years.

Appendix B: BHPL FY19 Board of Registration in Nursing Expenditures Overview



Appendix C: BHPL FY19 Board of Registration in Nursing Expenditures Detail

See attached Excel spreadsheet for detailed expenditures.

Appendix D: BHPL FY19 Board of Registration in Pharmacy Expenditures Overview



Appendix E: BHPL FY19 Board of Registration in Pharmacy Expenditures Detail

See attached Excel spreadsheet for detailed expenditures.
Appendix F: BHPL FY19 Boards of Registration and Certification Expenditures Overview



Appendix G: BHPL FY19 Boards of Registration and Certification Expenditures Detail

Appendix H: BHPL FY19 Quality In Health Professions Trust Fund Expenditures Overview



Appendix I: BHPL FY19 Quality In Health Professions Trust Fund Expenditures Detail

Appendix J: BHPL FY19 Drug Control Program Expenditures Overview



Appendix K: BHPL FY19 Drug Control Program Expenditures Detail

Appendix L: BHPL FY19 PCOC Expenditures Overview



Appendix M: BHPL FY19 PCOC Expenditures Detail

Appendix N: BHPL FY19 PMP Expenditures Overview



Appendix O: BHPL FY19 PMP Expenditures Detail

Appendix P: FY19 VALOR Act Licensure Applications





Appendix R: FY19 Drug Control Program Enforcement Unit Disciplinary Statistics

Drug Incident Intake	Drug Incident Field Interaction ²⁴	1070
	Tampering Investigations	36
	Desk Audits ²⁵	246
	Investigations On-Site	143
	Field Interaction Report (FIR) ²⁶	68
Registration Activity	New Registrations	647
	Registration Desk Audits	557
	Registration On-Site Inspections	90
Routine Audits & Re-Inspections	Site Visits and Complaint Investigations	6
Criminal Investigations	Practitioners Diverting or Tampering	36
Embargo ²⁷		0

²⁴ Field interaction may involve, but is not limited to, telephone calls to health care facilities, employment agencies, requesting documentation, review of documentation and/or interaction with regulatory or law enforcement agencies.

²⁵ Desk Audits may consist of obtaining additional documentation, statements and for troubleshooting problems with a goal geared toward providing immediate assistance to the health care facility to reduce and prevent additional diversion. 20% of Intake activity results in desk audits.

²⁶ FIRs are DCP generated intelligence reports involving a drug diversion incident. These reports do not always warrant the threshold for referral to a regulatory or law enforcement agency.

²⁷ See M.G.L. c. 94, §189A "...Whenever the commissioner of public health or his duly authorized agent, finds or has probable cause to believe based upon inspection or chemical, bacteriological or physical examination, that any drug, cosmetic or device is adulterated or misbranded, ... such article suspected of being adulterated or misbranded shall be detained or embargoed...warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by said commissioner, his agent, or the court..."



Appendix S: Interstate Data Sharing

Appendix T: Individuals Receiving Schedule II Opioid Prescriptions and MassPAT Search Activity Trends: Q1 2015 – Q2 2019²⁸



----- Individuals Receiving Schedule II Opioid Prescriptions ----- Number of Searches by Prescribers and Pharmacists

²⁸ PMP data are subject to updates. The MA PMP database is continuously updated to allow for prescription record correction data submitted by pharmacies. The data for the quarterly trends were extracted on 7/12/2018.

³⁵ Search activity includes prescribers, delegates, and pharmacists registered in MassPAT (and in the previous Online system) and licensed users of EHR Integration

³⁶ Pharmacies are required to report daily.

³⁷ STEP bill signed into law (7-day supply requirements go into effect).

³⁸MA prescribers required to look up patient when prescribing a Schedule II or III opioid medication.