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May 15, 2018

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

William F. Welch  
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 2017**





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## **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:<sup>1</sup>

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 fifty-three, 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 BHPL Board reports, the Prescription Monitoring report, the Drug Control Program report, and all Bureau expenditure reports are included herein.

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<sup>1</sup> 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

On August 15, 2016, the Division of Health Professions Licensure, formerly a division of the Massachusetts Department of Public Health's (DPH) Bureau of Health Care Safety and Quality, became the DPH Bureau of Health Professions Licensure (BHPL). The newly formed 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 2017 (FY17) regulatory, policy, licensure and enforcement activities.<sup>2</sup> 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. 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.

Under the leadership of BHPL Director, James G. Lavery, BHPL staff has worked diligently with the BHPL boards, PMP, and DCP during FY17 to complete a comprehensive review of the regulations enforced by BHPL, as mandated on April 1, 2015 by Executive Order 562. In FY17 the promulgation process was completed for many of these regulations, as the BHPL boards held public hearings and considered public comments prior to producing and approving final regulations and filing them with the Secretary of the Commonwealth of Massachusetts.

The Governor signed several pieces of legislation in the 189<sup>th</sup> legislative session that BHPL, through its Boards and programs have undertaken to implement, including Chapter 52 of the acts of 2016 – An act relative to substance use, treatment, education and prevention (The STEP Act). This report will discuss milestones of the ongoing implementation effort.

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<sup>2</sup> The *Bureau of Health Professions Licensure Annual Report* replaces 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 FY17***

In FY17, the Drug Formulary Commission, within DCP, completed the first year of drug evaluations and substitution analyses to create the first-in-the-nation statewide Formulary of Chemically Equivalent Substitutions for Opioids with Heightened Public Health Risk. The regulation (105 CMR 720.000), as amended and modernized to include the Formulary, was approved for promulgation on August 9, 2017.

FY17 marked DCP's initial implementation of the Drug Stewardship Program, through coordination with MassBIO and the Federal Food and Drug Administration, to communicate with every manufacturer of benzodiazepines and Schedule II and III opioids distributed in the commonwealth. Collection and approval of stewardship plans is ongoing to ensure appropriate coverage of take back programs throughout the commonwealth and provide for the safety and security of drugs that contribute to public health risk.

In FY17, the PMP rolled out the Massachusetts Prescription Awareness Tool (MassPAT) to support safe prescribing and dispensing of Schedules II – V controlled substances by allowing prescribers to view a patient's prescription history to improve the safety of drug therapy and coordinate care through communication with other providers, improving clinical outcomes and overall patient health. A massive communication and education effort resulted in prescribers and pharmacists being prepared for more frequent MassPAT checks and reporting requirements in FY18.

In the second quarter of 2017, prescribing trend information demonstrated that approximately 638,000 Schedule II opioid prescriptions were reported to the PMP, a nearly 24% decline from the first quarter of 2015, when 841,990 Schedule II opioid prescriptions were reported.

## **Introduction**

BHPL is comprised of the DCP, the PMP and 10 boards of health profession registration and certification: the Board of Certification of Community Health Workers, the Board of Registration in Dentistry, the Board of Registration of Genetic Counselors, the Board of Registration in Naturopathy, the Board of Registration in Nursing, the Board of Registration of Nursing Home Administrators, the Board of Registration of Perfusionists, the Board of Registration in Pharmacy, the Board of Registration of Physician Assistants, and the Board of Registration 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 PMP and the DCP, and in an open forum, we develop, implement, and enforce regulations and policies 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 DCP, PMP, and the 10 boards at BHPL work on behalf of the Commonwealth of Massachusetts.

# An Overview of the Bureau of Health Professions Licensure

## *Budget*

As of June 30, 2017, BHPL licensed, registered, certified, or authorized 277,956 health care professionals and businesses. The staffing level of BHPL was comprised of over 100 full-time equivalent active staff.

BHPL and its 10 boards of registration and certification are funded by a combination of three state appropriations and the Quality in Health Professions Trust Fund.<sup>3</sup>

- I. Appropriation account 4510-0721 supports the Board of Registration in Nursing.
- II. Appropriation account 4510-0722 supports the Board of Registration in Pharmacy.

The FY17 General Appropriation Act continued to support pharmacy inspections and investigations with a total of \$1.20M appropriated to BORP. This funding was used by BORP to hire additional staff to perform inspections and monitor sterile and non-sterile compounding pharmacies, including unannounced inspections of all pharmacies in the Commonwealth.

- III. Appropriation account 4510-0725 supports the remaining eight boards: Community Health Workers, Dentistry, Genetic Counselors, Naturopathy, Nursing Home Administrators, Perfusionists, Physician Assistants, and Respiratory Care.
- IV. The Quality in Health Professions Trust Fund, account 4510-0727, supports the operations of all 10 boards. 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.

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.<sup>4</sup>

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<sup>3</sup> See Appendix A: *BHPL FY17 Funding*.

<sup>4</sup> See Appendix B: *BHPL FY17 Expenditures*.

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

- a. FY17 Board Appropriations - \$2,420,800
- b. FY17 Expenditures - \$2,392,587.37<sup>5</sup>
- c. FY17 Uncommitted Balance - \$24,212.61

The following is a summary of the Trust account – 4510-0727:

- a. FY17 Trust Revenue - \$8,899,736
- b. FY17 Expenditures - \$11,282,466.13<sup>6</sup>
- c. FY17 Uncommitted Balance - \$0<sup>7</sup>

- V. Several appropriation accounts supported DCP and PMP in FY17<sup>8</sup>. Unlike the Board accounts, these are straight appropriation and retained revenue accounts with no carry forward of end of year balances. DCP registration fees are collected in excess of \$4,000,000, with just over \$1,000,000 retained for expenditures.<sup>9</sup>

The following is a summary of revenue and expenditure for the Drug Control Program – 4510-0616

- a. FY17 DCP Revenue Collections - \$4,574,550
- b. FY17 BHPL Retained Revenue - \$1,029,680
- c. FY17 Expenditures - \$700,550.57
- d. FY17 Uncommitted Balance - \$329,129.43

The following is a summary of revenue and expenditure for the Pharmaceutical and Medical Device Code of Conduct (PCOC) Program – 4510-0040

- a. FY17 DCP Revenue Collections - \$988,000
- b. FY17 BHPL Retained Revenue - \$73,061
- c. FY17 Expenditures - \$63,284.04
- d. FY17 Uncommitted Balance - \$9,776.96

Other than PCOC, which has its own line item, most DCP programs, including the Medication Administration Program and the Drug Stewardship Program, rely on the central DCP account, 4510-0616, for operational funding.

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<sup>5</sup> Original appropriation of \$2,420,800 was reduced by a 1% state account holdback.

<sup>6</sup> Detailed account in appendix B does not reflect expenditure of \$4,000 for ISA to treasurer's office.

<sup>7</sup> Sufficient trust roll-forward balances from FY16 used to fund expenses in FY17

<sup>8</sup> 4510-0616 (PMP), 4510-0040 (PCOC); 4510-0617 (DCP); 4510-0643 (PMP) and 4510-0644 (PMP)

<sup>9</sup> See Appendix C: *BHPL FY17 Expenditures*

## ***Compliance***

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 FY17, the Boards collectively resolved 746 formal complaints against health professional/facility licenses. Of the 746 formal complaints, 39%, or 294, were resolved by imposition of disciplinary action.

New to BHPL, the DCP's Enforcement Unit (EU) undertakes activities and initiatives to promote effective security and accountability measures to prevent theft, tampering, misuse and abuse of drugs. DCP investigators conducted inspections and investigations, collect evidence for analysis, develop regulations, policies and guidelines, and provide educational information and programs.

## **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 non-disciplinary 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, Stayed Suspension, or Reprimand. As of June 30, 2017, the Probation Department was monitoring 156 participants.

The Probation Department staff includes a Compliance Officer III, an Office Support Staff and a Probation Department Coordinator, hired in FY17. This new role allows for smoother and more enhanced operations to ensure more efficient and improved compliance monitoring.

The Probation Department has almost completed full development of the new database for probation monitoring. The new database is up and running on automated reports and compliance summaries, in addition to allowing the Probation Department to track licensee progress on a more detailed level.

## **The Massachusetts Professional Recovery System**

BHPL administers the Massachusetts Professional Recovery System (MPRS) for licensed health professionals (Dentists, Genetic Counselors, Nursing Home Administrators, Perfusionists, Pharmacists, Physician Assistants, and Respiratory Therapists). MPRS is a monitoring program that assists licensed health professionals who have problems with alcohol and/or other drugs to return to practice while protecting the public's health, safety, and welfare. An advisory panel of seven health care professionals with experience in substance use disorder treatment is available to consult with both participants and BHPL monitoring staff. The program takes five years to successfully complete. As of June 30, 2017, MPRS was monitoring the compliance of 10 participants (8 pharmacists, 1 dentist, and 1 physician assistant). During FY17, MPRS admitted 0 new participants, terminated 3 participants for unsuccessful completion of the program, and discharged 7 participants with successful completion of the program.

### **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 the use of, or dependence on, alcohol and/or other drugs, to return to nursing practice. The program takes five 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.

In FY17, the SARP staff conducted outreach activities at Southcoast Hospital in Fairhaven to educate healthcare providers on the prevalence of substance use disorders among nurses and the role of SARP.

As of June 30, 2017, SARP was monitoring the compliance of 166 participants. During FY17, SARP admitted 33 new participants, terminated 15 participants for unsuccessful completion of the program, and discharged 28 participants after successful completion of the program.

### **The Pharmacy Substance Use Disorder Program:**

During FY17, staff action policies, procedures and processes were developed with a goal to operationalize the Pharmacy Substance Use Disorder Program (PSUD) in FY18. PSUD was established by M.G.L. c. 112, § 24H in March, 2016. PSUD is a voluntary, non-disciplinary approach to substance use disorder recovery among licensed pharmacists, pharmacy technicians and pharmacy interns. Prior to enactment of M.G.L. c. 112, § 24H, the Board did not have the legal framework to offer a non-disciplinary, confidential rehabilitation program for licensees.

This new program will allow the Pharmacy Board to safely monitor pharmacists, pharmacy technicians and pharmacy interns with the goal of returning to safe pharmacy practice.

## ***Information Technology***

In FY17, the Information Technology (IT) department of BHPL 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 also vital to BHPL becoming more data focused.

IT added a new training module to the applicant checklist in MLO in order for staff of the Board of Registration in Dentistry to ensure applicants had completed the required pain management and opioid prescribing training as required by M.G.L. c. 94C, §18, as amended by St. 2016, c. 52. Also in response to the legislation, IT coordinated the emailing of over 155,000 BHPL licensees to serve as immediate notification of the changes in law mandated by St. 2016, c. 52.

In FY17, IT developed and installed several standing reports which serve as the foundation of the Bureau Dashboard. Working closely with the Quality Improvement Unit, IT will continue to develop standing reports in FY18 that will broaden the use of workplace management tools such as dashboards. The overall emphasis on these reports has led BHPL to focus on cleaning our data and improving the accuracy of our information.

In FY17, IT took the lead on the data conversion piece of the Massachusetts Controlled Substance Registration (MCSR) Automation project. IT has scrubbed the data, configured structure for the data transfer, and in FY18, will execute the conversion of controlled substance registrations to the BHPL online licensing platform. Additionally, IT created new MCSR license types in anticipation of the conversion. These include individual prescribers and facilities that hold a controlled substance registration.

## ***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 a member of the armed forces who is on active duty 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).

BHPL began receiving inquiries about the VALOR Act from service members, veterans and service member spouses in July 2013. From FY13 to FY16, BHPL has processed 80 applications for licensure by service members, veterans, or spouses, and logged the active duty status of 72 licensed service members.

In FY17, BHPL received a total of 24 licensure applications subject to the VALOR Act, comprised of 7 active duty, 17 spouses of active duty service members and 7 veterans.<sup>10</sup> The greatest concentration of applicants is military spouses applying for RN licensure.

In FY17, the active duty status of 4 licensed service members was logged. During FY17, 17 active duty service licenses were manually renewed. Appendix D shows the distribution of active service duty licensees, with the greatest concentration among Army dentists.<sup>11</sup> As in previous years, dentists remain the most highly represented licensee group across all active duty service licensees.

The BHPL [website](#) contains additional information and the necessary affidavit forms that VALOR Acts applicants must submit. Active military, military spouses, and veterans must identify themselves as such in order to obtain these benefits. BHPL has established a Bureau-wide staff action policy, which has been adopted by all BHPL boards, authorizing the processing of license applications and renewals under the VALOR Acts in an efficient and consistent manner.

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<sup>10</sup> See Appendix C: *FY17 VALOR Act Licensure Applications*.

<sup>11</sup> See Appendix D: *FY17 Active Service Duty Licensees*.

## **Quality Improvement**

In FY17, BHPL established a Quality Improvement (QI) Department, which was previously a strategic priority of the former Division of Health Professions Licensure in FY15. The QI Department 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. The QI Department is focused on making BHPL data more accurate and accessible. The QI Department works with BHPL IT to develop technological solutions that meet business requirements to increase workflow efficiency.

During FY17 the QI Unit, with the help of reports created by BHPL IT, designed and deployed the first BHPL Dashboard. The Dashboard is aimed at managers and provides an at-a-glance view of key performance indicators including, but not limited to: licensing volume and processing times, the status of pending complaints and open investigations, and the days to complete an inspection. These metrics give insight for management and allow for decision making rooted in data. In FY18, BHPL will continue to develop this tool and develop trainings for managers to learn to use the Dashboard in a way that facilitates their work.

The QI Department also develops BHPL policies and procedures and assesses compliance with those already in existence to ensure consistency across BHPL. As the QI Department continues to develop in FY18, it will shift focus to developing an internal auditing system for BHPL licensure and enforcement units, as well as the development of a formal Quality Improvement Plan for the BHPL.

## ***BHPL Initiatives***

**Regulation Review:** BHPL staff has worked diligently with the BHPL boards, PMP, and DCP during FY17 to complete a comprehensive review of the regulations enforced by BHPL, as mandated on April 1, 2015 by Executive Order 562. In FY17 the promulgation process was completed for many of these regulations, as the BHPL boards held public hearings and considered public comments prior to producing and approving final regulations and filing them with the Secretary of the Commonwealth of Massachusetts.

The following board regulations became effective in FY17:

245 CMR 2.00 – 6.00 – *Board of Registration in Nursing Home Administrators* – 12/30/16

270 CMR 2.00 – 5.00 – *Board of Registration in Genetic Counsellors* – 12/30/16

247 CMR 4.00 – *Board of Registration in Pharmacy* – 1/13/17

263 CMR 2.00 – 6.00 – *Board of Registration in Physician Assistants* – 3/24/17

The following DCP regulations became effective in FY17:

105 CMR 700 – *Implementation of M.G.L. c. 94C* – 5/7/17

105 CMR 721 – *Standards for prescription format and security in Massachusetts* – 5/7/17

105 CMR 722 – *Dispensing procedures for pharmacists* – 5/7/17

Rescission of 105 CMR 701 – *Regulations adopted jointly by DPH and the Board of Registration in Pharmacy for the Implementation of 94C* – became effective on 5/7/17

**Board Composition:** Under the leadership of Governor Charles Baker, in FY17, BHPL maintained focus on recruiting efforts to fill vacant board seats across all BHPL boards. By the end of FY17, 82% of all board seats were filled, up from 75.60% in FY15. A total of 17 new board members were appointed by Governor Baker during FY17.

**Improving Transparency through Posting of Consent Agreements on Websites:** In FY17, BHPL made further strides towards the posting of recent consent agreements on Board websites, an undertaking that remains ongoing. The collection and preparation of Board of Pharmacy documents is 98% complete, and posting of the documents will remain ongoing into FY18.

**Online Licensure Renewals:** With the help of IT, BHPL's online licensure renewal improved from 90% in FY15 and 94% in FY16, to 96% in FY17.

### **Prescription Monitoring Program: Electronic Medical Record Integration**

FY17 was a major year for the PMP, which worked diligently toward integration of the Massachusetts Prescriber Awareness Tool (MassPAT) into healthcare entities' Electronic Medical Records (EMR) across Massachusetts. MassPAT integration will be the highest priority in FY18.

### **Controlled Substance Registration Automation**

In FY17, BHPL began the process of automating the MCSR process. DCP, QI, and IT worked together in FY17 to establish the framework for conversion to the current BHPL online platform, MyLicensingOffice and eGov.

# **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. Ten additional members are appointed by the Governor. The member makeup includes the following: four CHWs, one CHW training organization representative, one community-based CHW employer, one Massachusetts Association of Health Plans representative, one Massachusetts League of Community Health Centers representative, one Massachusetts Public Health Association representative, and one public member. Six members are required to be present to constitute a quorum.

### **CHW Board Members**

Jean Zotter, Commissioner of DPH Designee, Chair

Henrique O. Schmidt, CHW member, Secretary

Sheila Och, CHW member

Maritza Smidy, CHW member

Catherine Bourassa, Community-based CHW employer member

Patricia Edraos, Massachusetts League of Community Health Centers representative

Joanne Calista, CHW training organization representative

Margaret Hogarty, Massachusetts Public Health Association representative

Steve Bucchianeri, Pharm. D., Massachusetts Association of Health Plans representative

Denise Lau, Public member

### **FY17 CHW Board Meetings**

July 11, 2016

August 22, 2016

September 13, 2016

October 11, 2016

November 8, 2016

December 13, 2016

January 10, 2017

February 14, 2017

April 11, 2017

May 9, 2017

June 27, 2017

## **II. Accomplishments of the CHW Board**

**Draft Regulations:** During FY17, the Board voted to adopt the edits approved by administrative review in alignment with the strategic priority of promulgating new regulations on March 23, 2017. The CHW Board held three public hearing sessions to engage the CHW community. The public hearings were held in Boston on June 9, 2017 and Worcester and Westfield on June 19, 2017. On November 14, 2017, public hearing comments were reviewed by the Board. Final edits were proposed and passed with a unanimous vote.

**Process Training Program Applications:** In FY17, the CHW Board worked on developing the Training Program Application Criteria. The criteria will be the standard by which the CHW Board will review and approve training program applications. The CHW Board is in process of finalizing the Training Program application for implementation once the regulations are promulgated.

**Good Moral Character Policy:** In fulfillment of the FY16 strategic priority of developing a Good Moral Character policy, the CHW Board voted on October 11, 2016 to approve the Suitability for Certification policy. The policy is finalized and will become effective once the regulations are promulgated.

**Process Certification Applications:** In alignment with the strategic priority of processing certification applications from FY 16, in FY17, the CHW Board drafted the Individual Certification application; application checklist, and Frequently Asked Questions (FAQs). The CHW Board engaged stakeholders such as MACHW to conduct focus groups across the commonwealth to determine the ability of CHW's to complete the application. Feedback from the focus groups was shared with the CHW Board at the April 11, 2017 meeting.

**Stakeholder Engagement:** In FY17, the CHW Board hosted several guest speakers who spoke to the CHW Board about technical, legal, and field related topics. Featured guests included Commissioner of the Massachusetts Department of Public Health Monica Bharel, MD, MPH, Victor Ortiz, Director, Office of Problem Gambling Services at the Massachusetts Department of Public Health, Jacquelyn Toledo, Director of Leadership Development from the Massachusetts Association of Community Health Workers (MACHW), Clinton Dick, Executive Director of the Office of Private Occupational School Education from the Division of Professional Licensure and Alec Harris from Legal Services Center of Harvard Law School. CHW Board staff also participated in the 8<sup>th</sup> Annual Community Health Worker Conference.

**Board Composition:** CHW Board staff continued to focus on CHW Board seats during FY17. During FY17, one new CHW Board member was appointed.

## **III. License and Licensee Statistics**

Due to the recent establishment of the CHW Board, no applications for certification were processed in FY17.

#### **IV. Compliance: Disciplinary Statistics**

Due to its recent establishment, the CHW Board took no disciplinary action in FY17.

# **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 (six dentists, two dental hygienists, one dental assistant and two public members) and two non-voting dental assistant advisors. By statute, five voting members must be present to constitute a quorum.

### **Dentistry Board Members**

Dr. Stephen DuLong, faculty dentist member, Chair

Ailish M. Wilkie, CPHQ, public member, Secretary

Dr. Keith Batchelder, dentist member

Dr. David Samuels, dentist member

Dr. John Hsu, dentist member

Dr. Paul Levy, dentist member

Dr. Patricia Wu, dentist member

Dr. Cynthia M. Stevens, dentist member

Lois Sobel, RDH, dental hygienist member

Jacyn Stultz, RDH, MS, dental hygienist member

Kathleen Held, dental assistant member

Ward J. Cromer, PhD, public member

### **FY16 Dentistry Board Meetings**

July 6, 2016

September 7, 2016

October 5, 2016

November 2, 2016

December 7, 2016

January 18, 2017

February 1, 2017

March 1, 2017

April 5, 2017

May 3, 2017

June 7, 2017

## **II. Accomplishments of the Dentistry Board**

**Registration of Dental Assistants:** The Dentistry Board began accepting initial licensure applications, as required by M.G.L. c. 112, §51½, in October 2014. As of June 30, 2017, the Dentistry Board has issued 9,549 licenses to Dental Assistants. The Dentistry Board continues to receive new Dental Assistant licensure applications daily.

**Complaint Committee:** In April 2016, the Dentistry Board held its first Complaint Committee (CC) to review pending investigations against licensees, as permitted by 234 CMR 9.02(2). The goal of the CC is to undertake a preliminary review of allegations filed against licensees and opened as staff assignments for a determination whether sufficient evidence exists to proceed with formal complaints. The CC is composed of three Dentistry Board members, two of which must be licensed dentists. The CC must either agree by unanimous decision or refer the matter to the full Dentistry Board for its consideration at the next scheduled Dentistry Board meeting. The CC's membership is rotating, and is scheduled to meet every month after regularly scheduled Board meetings. Expedited review of allegations against licensees is expected to result in a quicker resolution of allegations and better focused investigations. In FY17, the CC eliminated the backlog of matters awaiting preliminary review, resulting in a streamlined, more efficient process and increased licensee and complainant satisfaction.

**Community Outreach:** Several Dentistry Board members and staff participated in the Yankee Dental Congress in January 2017, hosting a one-hour continuing education course on current Dentistry Board licensure requirements, regulations and policies. In FY17, Dentistry Board staff also presented an ethics course to the current dental hygiene and dental assisting students at the MCPHS/Forsyth School of Dental Hygiene in September 2016 and February 2017, Mt. Ida College in March 2017, and Quinsigamond Community College in April 2017. Board staff also participated in the vocational/technical educators' conference in June 2017 and the mobile resource day hosted by the Henry Schein Co. in Waltham, Massachusetts in July 2017.

## **III. Regulations and Policies**

**Regulatory Review Workgroup:** The Dentistry Board convened a workgroup in FY15, comprised of Dentistry Board members, Dentistry Board staff, oral surgeons, pediatric dentists, orthodontists and dental assistants to undertake a section-by-section, line-by-line review of the Dentistry Board's August 2010 amendments to 234 CMR. The workgroup met on the following occasions during FY17:

July 20, 2016  
August 17, 2016  
September 27, 2016  
October 18, 2016  
December 21, 2016  
February 22, 2017  
March 22, 2017  
April 26, 2017

May 17, 2017

The workgroup completed its review of the Dentistry Board’s regulations pertaining to anesthesia and sedation, 234 CMR 6.00. The Dentistry Board adopted the workgroup’s recommendations and submitted them for further review prior to a public hearing.

The workgroup also began reviewing 234 CMR 5.00, pertaining to requirements for the practice of dentistry, dental hygiene and dental assisting. The workgroup tackled the requirements for the practice of public health dental hygiene first and invited members of the dental hygiene community to participate in its review, including the DPH Office of Oral Health, the ForsythKids project, the Forsyth Institute and public health dental hygiene practitioners.

**IV. License and Licensee Statistics**

Biennial licensure,	7,222	Dentists
Biennial	6,925	Dental Hygienists
Biennial	7,397	Dental Assistants
Biennial	3,144	Dental Hygienists - Anesthesiology Permits
Annual	179	Limited and Faculty License
Biennial	573	Facility Permits
Biennial	218	General Anesthesia Permits
Biennial	574	Nitrous Oxide Permits
Biennial	313	Conscious Sedation Permits
Biennial	40	Portable Dental Operation and Mobile Dental Facility Permits
<b>TOTAL</b>	<b>26,585</b>	

**V. Compliance: Disciplinary Statistics**

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
196	240	69	130	34	26%

# **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 five members, including four GCs and one public member. Three members are required to be present to constitute a quorum.

### **GC Board Members**

Gretchen Schneider, MS, LGC, GC member, Chair  
Kayla Sheets, MS, LGC, GC member, Vice-Chair  
Shelley Rose McCormick, MS, LGC, GC member  
Lauren Lichten, MS, LGC, GC member  
Jillian Fleming, Public member

### **FY17 GC Board Meetings**

July 07, 2016  
October 6, 2016  
January 5, 2017

## **II. Accomplishments of the GC Board**

**Promulgate Amended Regulations:** In alignment with the strategic priority of promulgating amended regulations in FY17, pursuant to Executive Order 562, the GC Board approved the regulation revisions for 270 CMR 2.00 through 5.00. Following administrative review and approval, a public hearing occurred on August 23, 2016. The comment period was closed on

August 26, 2016, and the GC Board approved the final revisions at the October 6, 2016 meeting. The revised regulations became effective December 30, 2016.

**Application Processing Efficiency:** In FY17, the GC Board developed a partnership with the American Board of Genetic Counseling Inc. (ABGC), the credentialing organization for the profession that administers the certification examination. As a result, ABGC now reports exam results directly to the GC Board. ABCG also worked with GC Board staff to enhance the reporting criteria so that the GC Board is aware of pass and fail scores.

**Board Composition:** GC Board staff continued to focus on GC Board seats during FY17. During FY17, one new GC Board member was appointed.

**Staff Action Policies:**

1. Routine Responses Policy, adopted July 7, 2016  
This policy facilitates staff responses to routine correspondence and requests for extensions on behalf of the Board.
2. Applicants who do not hold a Social Security Number Policy, adopted July 7, 2016  
This policy is for instances where an initial applicant for a limited license under M.G.L. c. 112, §§252-258, does not possess a social security number and may not be entitled to one, or alternatively, may obtain one after securing a limited license.
3. Department of Revenue Suspensions Policy, adopted January 5, 2017  
This policy implements state laws relating to coordination with the Child Support Enforcement division of the Department of Revenue.

**Board Meeting Efficiency:** The GC Board will work to adopt remote participation at Board Meetings. Per Open Meeting Law (M.G.L. c. 30A, §§18-25) a public body may use remote participation in the administration of Board meetings providing that the process is adopted by the Board and the minimum requirements are met. As the statutory requirement for the GC Board is only two meetings annually, the Board will be able to facilitate meetings once a quorum is established in person by allowing additional members who cannot attend in person participate remotely.

**III. License and Licensee Statistics**

Biennial licensure	<b>269</b>	<b>Genetic Counselors</b>
	<b>2</b>	<b>Provisional Genetic Counselors</b>
<b>TOTAL</b>	<b>271</b>	

**IV. Compliance: Disciplinary Statistics**

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
0	1	2	1	1	100%

# **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 in FY17 and became effective in early FY18, 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 five members, including two naturopathic doctors, one physician, one clinical pharmacologist and one public member. A majority of appointed members are required to be present to constitute a quorum.

### **Naturopathy Board Members:**

Due to its recent establishment, Naturopathy Board members were not appointed in FY17.

### **FY17 Board Meetings:**

Due to its recent establishment, the Naturopathy Board held no Board meetings in FY17.

## **II. Accomplishments of the Naturopathy Board**

Due to its recent establishment, the Naturopathy Board had no accomplishments for FY17.

## **III. License and Licensee Statistics**

Due to its recent establishment, the Naturopathy Board did not process any applications for licensure in FY17.

## **IV. Compliance: Disciplinary Statistics**

Due to its recent establishment, the Naturopathy Board took no disciplinary action in FY17.



# **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 Nursing Board is made up of 17 members including nine registered nurses, four licensed practical nurses, one physician, one pharmacist, and two consumers. Nine members are required to be present to constitute a quorum.

### **Nursing Board Members**

Katherine Gehly, MSN, CNP, RN, Associate Degree Educator Member, Chairperson  
Barbara Levin, RN, BSN, ONC, CMSRN, LNCC, Direct Care Member, Vice Chairperson  
Donna Zucker, Ph.D, RN, Bachelor's Degree Educator Member  
L. Kelly, DNP, CNP, Advanced Practice Direct Care Member  
Lori Keough, PhD, CNP, Advanced Practice Direct Care Member  
Colleen LaBelle, BSN, RN, Direct Care Member  
Patricia Noonan MS, RN, Practical Nursing Education Member  
Ann-Marie Peckham, RN, MSN/MBA, RN, Hospital Administration Member  
Joan Killion, LPN, LPN Acute Care Member  
Gail Dufault, LPN, LPN Community Health Member  
Jackie Fantes, MD, FAAFP, Physician Member  
Catherine L. Simonian, RPh, PharmD, Pharmacist Member  
Sara Abbott, Public Member  
Deborah Drew, Public Member

### **FY17 Nursing Board Meetings**

July 13, 2016

August 10, 2016

September 14, 2016

October 19, 2016

November 9, 2016

December 14, 2016

January 11, 2017 (cancelled for lack of quorum)

January 19, 2017 (rescheduled meeting)

February 8, 2017

March 8, 2017

April 12, 2017  
May 10, 2017  
June 14, 2017

## II. Accomplishments of the Nursing Board

**Complaint Committee:** The Nursing Board established a Complaint Committee (CC) in March 2016 to facilitate the timely review of, and action on, allegations of licensee misconduct. The CC is composed, at a minimum, of the Nursing Board Chair, the Executive Director and the Supervisor of Investigators. The CC meets twice per month and reports its recommendations to the full Nursing Board prior to its next scheduled meeting. As of June 30, 2017, the CC recommended action to the Nursing Board on 314 cases. Minutes of the complaints and staff assignments reviewed by the CC are provided to the Nursing Board, prior to its next scheduled meeting, to review in conjunction with the Investigation Reports, then complaints and staff assignments are presented to the Nursing Board at its next scheduled meeting for action on the CC recommendations for resolution.

**Quality Improvements:** In FY17, licensure audits conducted by BHPL identified, and allowed Nursing Board staff to address, vulnerabilities that existed in the Nursing Board licensure process, resulting in the development of new operational policies for license application processing, the implementation of new license verification requirements, and the addition of new standards for the verification of graduation from an approved nursing education program.

In FY17, the Nursing Board staff implemented an online nursing license application.

**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, 2017, there were 73 Nursing Board-approved registered nurse and practical nurse education programs:

- 26 practical nurse programs:
  - Pre-requisite approval: Salter College
  - Initial approval status: None
  - Approval with warning status
    - Diman Regional School of Practical Nursing (2/8/17 Board action)
    - Quincy College (6/14/17 Board action)
    - Roxbury Community College (2/8/17 Board action)
  - Full approval: all other practical nurse programs (22)
- 20 registered nurse associate degree programs with full approval;
  - Pre-requisite approval status: None
  - Initial approval status: None
  - Approval with warning status:
    - Bunker Hill Community College (6/14/17 Board action)
    - Laboure College (11/9/16 Board action)

- Quincy College (6/14/17 Board action)
  - Roxbury Community College (2/8/17 Board action)
- Full approval status: all other associate degree programs (16)
- 20 registered nurse baccalaureate degree programs with full approval;
  - Pre-requisite approval status: None
  - Initial approval status: None
  - Full approval status: all other baccalaureate degree (pre-licensure only) programs
- 1 registered nurse hospital-based diploma program with full approval; and
- 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 October 2016 and March 2017, introducing 28 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*, and the regulatory requirements for Massachusetts nurse licensure by examination.

**Nursing Faculty Workshop:** The Nursing Board hosted 28 nursing faculty at a Faculty Workshop: *Faculty Role in Maintaining Program Compliance with Nursing Education Regulation with Discussion of Pending Regulatory Changes* in April 2017.

### III. Regulations and Policies

**Regulation Review:** In June 2016, the Executive Office of Health and Human Services and the Executive Office of Administration and Finance approved proposed revisions to Nursing Board regulations (244 CMR 3.00 through 9.00) and the creation of a new section 10.00, containing a single set of definitions applicable to all of the Nursing Board regulation chapters. The Nursing Board had approved the revisions, under Executive Order 562, at its December 2015 meeting. In FY17, the Nursing Board published the revisions for comment, and it will act on administrative recommendations for further changes in FY18.

**Issued Revised Advisory Rulings:** 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 FY17, the Nursing Board updated the following Advisory Rulings in accordance with its systematic review schedule:

- AR 9101: Administration of Sedation/Analgesia
- AR 9901: RN as First Assistants at Surgery
- AR 9902: Advanced Practice Registered Nurse as First Assistants at Surgical Procedures
- AR 0901: Pain Management
- AR 1001: Management of Patients Receiving Analgesia by Catheter Technique
- AR 1301 Cosmetic and Dermatologic Procedures

**Policy Review:** In FY17, the Nursing Board updated the following policies in accordance with its systematic review schedule:

- Administrative Policy 08-01: Delegation of Signature Authority

Education Policy 06-01: Board-designated Tests of English Proficiency and Required Minimum Cut Scores  
 SARP Policy 99-03: SARP Participant Body Fluid Monitoring Policy  
 SARP Policy 99-04: SARP Medical Waiver  
 SARP Policy 99-06: Board Staff Action to Implement Substance Abuse Rehabilitation Committee Recommendations  
 SARP Policy 06-001: Management of SARP Participants' Relapse in Substance Use Recovery  
 SARP Policy 07-001: SARP Bridge Agreements  
 SARP Policy 07-002: Termination or Withdrawal from the SARP Admission Process  
 Standard Conduct Policy 01-01: Determination of Compliance with the Standard of Conduct at 244 CMR 9.03(15) Prohibiting Patient Abandonment

In FY2017, the Nursing Board adopted the following policies and made provisions to the SARP Participant's Consent Agreement for SARP Participation: Licensure Policy 16-03: *Reinstatement Eligibility Criteria for Nurses Prescribed buprenorphine/naloxone Combination*. The Nursing Board adopted this policy on September 14, 2016 to establish criteria for licensure reinstatement of certain nurses. Edits to the policy were approved by the Nursing Board on October 19, 2016.

SARP Policy 17-01: *Board Delegation of Authority to Activate the License Suspension*. The Nursing Board adopted this policy to expedite action on a nursing license where certain substantiated conduct of a SARP participant poses a serious risk to public health, safety and welfare, and facilitate timely actions on certain substantiated violations of a CASP. This policy was adopted April 8, 2017.

The Nursing Board staff updated the Consent Agreement for SARP Participation (CASP) to include provisions for non-disciplinary restrictions/non-disciplinary conditions to be noted on license status for SARP participants during various stages of participation in the SARP and for toxicology monitoring.

#### IV. License and Licensee Statistics

Biennial licensure	129,323	Registered Nurses (RN)
	452	RN Nurse Midwives
	8,109	RN Nurse Practitioners
	505	RN Psychiatric Clinical Nurse Specialists
	54	RN Clinical Nurse Specialists
	1,187	RN Nurse Anesthetists
	19,613	Licensed Practical Nurses (LPN)
<b>TOTAL</b>	<b>159,324</b>	

#### V. Compliance: Disciplinary Statistics

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Closed</u>	<u>Number of Formal Complaints Closed with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
226	265	244	378	170	45%

# **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 four NHAs, one NHA employed by a non-proprietary nursing home, one educator, one physician, one registered nurse, one hospital administrator, and two public members. Eight members are required to be present to constitute a quorum.

### **NHA Board Members**

Nancy Lordan, NHA member, Chair

William Graves, BS, NHA member, Vice-Chair

Roxanne Webster, RN, registered nurse member, Secretary

Mary McKenna, Executive Office of Elder Affairs representative

Mary Ellen Coyne, MassHealth Office of Long Term Services & Supports

Sherman Lohnes, Commissioner of DPH, Designee

Mary Katherine Moscato, MBA, hospital administration member

James Divver, NHA member

Michael Baldassarre, FACHCA, NHA member

Patrick J Stapleton, MS, non-proprietary NHA member

Jeanette Sheehan, MS, RN, CS, public member

Dan Gebremedhin, M.D., M.B.A. physician

### **FY17 NHA Board Meetings**

July 15, 2016

August 19, 2016

September 16, 2016

October 21, 2016

November 18, 2016

December 16, 2016

January 20, 2017

February 17, 2017

March 17, 2017

May 19, 2017

June 16, 2017

## II. Accomplishments of the NHA Board

**Amended Regulations Promulgated:** In FY17, the NHA Board approved regulation revisions for 245 CMR 2.00 through 6.00. A public hearing occurred on August 19, 2016 and the period for public comment was closed on August 26, 2016. The NHA Board quickly approved the final revisions on September 16, 2016. The final regulations were filed and promulgated with an effective date of December 30, 2016.

**Continuing Education:** On May 19, 2017, the NHA Board voted to accept continuing education (CE) hours for vendors and courses approved by the National Associations of Boards of Examiners of Long Term Care Administrators (NAB). This policy provides licensees with an efficient means of determining whether CE courses and programs meet the CE requirements set forth at 263 CMR 4.03(2). As a result, the NHA Board discontinued the review and approval of CE programs and courses for CE vendors.

**Board Composition:** NHA Board staff continued to focus on NHA Board seats during FY17. During FY17, one new NHA Board member was appointed, and two members were re-appointed.

### Staff Action Policies:

1. Determination of Preceptor Qualifications – adopted March 17, 2017  
The NHA Board adopted this policy to authorize NHA Board staff to determine whether a NHA who applies to act as a preceptor for an Administrator in Training (AIT) meets the regulatory qualifications as specified in 245 CMR 3.02(1)(b) on the Board's behalf.
2. Determination of Eligibility for NHA Licensure – adopted August 18, 2017  
The NHA Board adopted this policy to process license applications in an efficient and timely manner and to authorize NHA Board staff to determine whether an applicant for NHA licensure meets the criteria set forth in M.G.L. c. 112, §§108, 110-113 and the NHA Board's regulations at 245 CMR 3.00 through 3.07.
3. Staff Action on Nursing Home Survey Reports – adopted November 18, 2016  
The NHA Board adopted this policy to provide the Executive Director or his/her designee with authority, in certain circumstances, to timely resolve investigations against individual nursing home administrators following nursing home survey findings that indicate deficiencies in the management of nursing homes.
4. Approved Status –NAB Standard – adopted April 21, 2017  
The NHA Board adopted this policy to provide guidance to the NHA Board's licensees on how to comply with NHA Board regulations at 245 CMR 4.00. Pursuant to 245 CMR 4.02, every NHA shall complete a minimum of 20 contact hours of continuing education per annual license renewal period.
5. Department of Revenue Suspensions Policy, adopted January 20, 2017

This policy implements state laws relating to coordination with the Child Support Enforcement division of the Department of Revenue.

6. NAB Examination Application Alert – adopted June 1, 2017.

The NHA Board Alert was shared with industry partners to notify NHAs that NAB was restructuring its examinations on July 5, 2017. Candidates must pass a 100- item Core of Knowledge exam and a 50- item line of service exam, and apply for examination eligibility through a new system, accessible through the NAB website.

**III. License and Licensee Statistics**

Annual licensure	880	Nursing Home Administrators
	66	Administrators in Training (Internship)
<b>TOTAL</b>	<b>946</b>	

**IV. Compliance: Disciplinary Statistics**

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
<b>26</b>	<b>34</b>	<b>10</b>	<b>4</b>	<b>4</b>	<b>100%</b>

# **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 insuring 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 seven members including four perfusionists, one anesthesiologist, one cardiovascular surgeon, and one public member. By statute, four members are required to be present to constitute a quorum.

### **Perfusionist Board Members**

Kevin Lilly, CCP, Perfusionist member, Chair  
Kyle Spear, CCP, Perfusionist member, Vice-Chair  
Michelle Tozer, CCP, Perfusionist member, Secretary  
Sary Aranki, M.D., Cardiovascular surgeon member

### **FY17 Perfusionist Board Meetings**

November 23, 2016

March 17, 2017

June 6, 2017

## II. Accomplishments of the Perfusionist Board

**Amended Regulations Promulgated:** In FY17, the Board completed the promulgation process for amendments to 267 CMR 2.00 through 5.00. On January 13, 2017, a public hearing was held, and the period for public comment closed on January 20, 2017. At the June 6, 2017 meeting, the Board voted to approve regulations as revised based on public comment. The regulations were subsequently filed and promulgated with an effective date of July 28, 2017.

**Board Composition:** Perfusionist Board staff continued to focus on Perfusionist Board seats during FY17. During FY17, one new Perfusionist Board member was appointed, and two members were re-appointed.

### Staff Action Policies:

1. Perfusionist Board Staff Disposition of Selected Staff Assignments and Complaints – adopted November 23, 2016.

The Perfusionist Board adopted this policy to authorize and allow for the timely review and disposition of staff assignments and complaints pertaining to an individual Perfusionist’s continuing education deficiencies for license renewal.

2. Routine Responses – adopted November 23, 2016

This policy facilitates staff responses to routine correspondence and requests for extensions, on behalf of the Perfusionist Board.

## III. License and Licensee Statistics

Biennial licensure, except Provisional Licenses, which are annual.	104	Full Licenses
	0	Provisional Licenses
TOTAL	104	

## IV. Compliance: Disciplinary Statistics

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
0	1	0	0	0	0%

# **The Board of Registration in Pharmacy**

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

Summary FY 2017 [7/1/16 to 6/30/17]

## **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 eight pharmacists, one pharmacy technician, one nurse, one physician, and two public members. By statute, seven members are required to be present to constitute a quorum.

### **Pharmacy Board Members**

Timothy Fensky, RPh, FACA, sterile compounding pharmacist member, President

Michael Godek, RPh, pharmacist member, President-elect

Susan Cornacchio, JD, RN, public member, Secretary

Patrick Gannon, RPh, hospital pharmacist member

Andrew Stein, Pharm D, RPh, independent pharmacist member

Phillippe Bouvier, RPh, independent pharmacist member

Garrett Cavanaugh, RPh, chain pharmacist member

William Cox, CPhT, pharmacy technician member

Dr. Ali Raja, MD, MBA, MPH, physician member

Karen Conley, DNP, RN, AOCN, NEA-BC, nurse member

Richard Tinsley, MBA, MEd, public member

Stephanie Hernandez, PharmD, RPh, long term care member

Kim Tanzer, Pharm D, RPh, academic member

### **FY17 Pharmacy Board Meetings**

August 2, 2016

August 30, 2016

October 6, 2016

November 1, 2016

December 6, 2016

January 5, 2017  
February 2, 2017  
March 2, 2017,  
April 6, 2017  
May 4, 2017  
June 15, 2017  
June 29, 2017

### **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 FY17, the expert members weighed in on important pharmacy topics, including how to respond to above action level environmental monitoring results, pharmacy technician “technology-check-tech” responsibilities, and telepharmacy. The Advisory Committee will continue to advise the Pharmacy Board in FY18, including making recommendations after the public hearing on revisions to the draft 247 CMR section 17.00, on sterile compounding, developing a procedure for failed HEPA filters in ISO-classified environments, and guidance for providing information to consumers for compounded products.

The Advisory Committee is made up of 8 members, including the Commissioner of Public Health or their designee, one expert in USP Chapter 71, one expert in USP Chapter 795, one expert in USP Chapter 797, one expert in Pharmacoeconomics, one expert in Clinical Pharmacology, one Microbiologists, and one 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, five 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  
Anthony M. Cundell, PhD, 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  
Eric S. Kastango, MBA, RPh, FASHP, 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  
Open, cGMP member

## **FY17 Advisory Committee Meetings**

October 14, 2016

### **II. Accomplishments of the Pharmacy Board**

**Naloxone Standing Orders:** Pursuant to M.G.L. 94C, §19B (b) pharmacists in Massachusetts may dispense naloxone rescue kits, by standing order, to any person. The rescue kits can allow a patient, family or bystander to administer a potentially life-saving dose of naloxone to someone who is believed to be suffering from an overdose of an opiate drug, after notifying 911. The Pharmacy Board has continued to encourage pharmacies to submit a standing order for naloxone. In FY17, the standing orders total rose to 854 pharmacies, which is approximately 70% of all retail pharmacies in Massachusetts. A list of specific pharmacies that have standing orders on file with the Pharmacy Board is available [on the Board's website](#).

**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. In order to provide continuing education credit for lectures provided by small groups of presenters such as pharmacy residents and interns, the Pharmacy Board approved 156 such programs in FY17.

**Pharmacy Technician Training Programs:** In order to standardize the training programs and exams across Massachusetts, the Pharmacy Board approved Policy 2017-01, establishing specific criteria for pharmacy technician training programs and exams to receive Pharmacy Board approval.

**Pharmacy Compliance Inspections:** During FY17, 12 pharmacy investigators, on behalf of the Pharmacy Board, conducted a total of 1,789 pharmacy inspections in the following categories:

- 1,616 retail compliance inspections,
- 57 non-sterile compounding inspections,
- 41 sterile compounding inspections,
- 62 site visits,
- 10 wholesale distributor inspections, and
- 3 nuclear pharmacy inspections.

Pharmacy investigators also worked to incorporate educational guidance into inspections and site visits. The Pharmacy Board looks forward to maintaining inspection totals and a strong field presence in FY18 with a full roster of pharmacy investigators.

**Nuclear Pharmacy Inspections:** During FY17, the Pharmacy Board utilized a contracted expert from the National Association of Boards of Pharmacy (NABP) to conduct inspections of the three nuclear pharmacies in Massachusetts. The three inspections were completed in March 2017 and several of the pharmacy investigators shadowed the NABP inspector in order to gain knowledge in the highly specialized pharmacy practice area. The Pharmacy Board intends to use

the contracted experts going forward, until pharmacy investigators have been adequately trained to conduct these specialized inspections.

**Staff Training:** During FY17, one pharmacy investigator attended NABP sponsored sterile compounding training. One pharmacy investigator attended a Pharmaceutical Drug Diversion Training sponsored by the Federal Bureau of Investigations. Staff and investigator training continues to be a priority for the Pharmacy Board, with several trainings scheduled for FY18.

**Educational Outreach:** Pharmacy Board staff continued to make outreach a large focus of FY17, engaging the professional community with proposed new standards and providing guidelines following statutory changes. Outreach also included participation in the following pharmacy continuing education programs, which attracted a wide range of licensees in a variety of pharmacy practice settings:

- Safe Prescriber Working Group in conjunction with law enforcement;
- MassHealth Provider Training Series;
- PharmEd Conference Series;
- Northeastern University lecture series: “Compounding: Implementing Best Practices for Sterile and Non-Sterile Compounding 2017”;
- Board of Pharmacy Regulatory Update at the Massachusetts Pharmacists Association;
- Board of Pharmacy Regulatory Update at the Massachusetts Health Council;
- Roundtable discussion with several institutional pharmacy directors regarding 247 CMR 17.00;
- Board of Pharmacy Regulatory Update at the Council of Boston Teaching Hospitals;
- Board of Pharmacy Regulatory Update at Massachusetts College of Pharmacy and Health Sciences - Reed 2017;
- Board of Pharmacy Regulatory Update at the Cape Cod Outreach Continuing Pharmacy/Nursing Education Program; and
- Board of Pharmacy Regulatory Update at the 6th Annual Alumni, Friends and Preceptor Anniversary at Northeastern University.

### 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 St. 2014, c.159. 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 line-by-line review of each change during the open session of Pharmacy Board meetings in FY15, FY16, and FY17.

The *highlights* of the Pharmacy Board’s activities in FY17 related to amending regulations and promulgating new regulations include the following:

247 CMR 3.00: Personal Registration	<ul style="list-style-type: none"> <li>● Final Draft Adopted by Board: 08/02/16</li> <li>● Public Hearing: 09/19/16</li> <li>● Board Review and Vote on Public Comment: 01/05/17</li> </ul>
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	<ul style="list-style-type: none"> <li>• Promulgated: 08/11/17</li> </ul>
247 CMR 5.00: Orally & Electronically Transmitted Prescriptions	<ul style="list-style-type: none"> <li>• Final Draft Adopted by Board: 11/01/16</li> <li>• Public Hearing: 06/29/17</li> </ul>
247 CMR 6.00: Licensure of Pharmacies	<ul style="list-style-type: none"> <li>• Final Draft Adopted by Board: 04/05/17</li> <li>• Public Hearing: 06/29/17</li> </ul>
247 CMR 8.00: Pharmacy Interns and Technicians	<ul style="list-style-type: none"> <li>• Final Draft Adopted by Board: 08/02/16</li> <li>• Public Hearing: 09/19/16</li> <li>• Board Review and Vote on Public Comment: 03/02/17</li> </ul>
247 CMR 9.00: Professional Practice Standards	<ul style="list-style-type: none"> <li>• Final Draft Adopted by Board: 11/01/16</li> <li>• Public Hearing: 06/29/17</li> </ul>
247 CMR 10.00: Disciplinary Proceedings	<ul style="list-style-type: none"> <li>• Final Draft Adopted by Board: 08/02/16</li> <li>• Public Hearing: 09/19/16</li> <li>• Board Review and Vote on Public Comment: 01/05/17</li> </ul>
247 CMR 12.00: Restricted Pharmacy	<ul style="list-style-type: none"> <li>• Final Draft Adopted by Board: 11/01/16</li> <li>• Public Hearing: 06/29/17</li> </ul>
247 CMR 14.00: Petition for Waiver	<ul style="list-style-type: none"> <li>• Final Draft Adopted by Board: 08/02/16</li> <li>• Public Hearing: 11/30/16</li> <li>• Board Review and Vote on Public Comment: 03/02/17</li> <li>• Promulgated: 09/22/17</li> </ul>
247 CMR 15.00: Continuous Quality Improvement Program	<ul style="list-style-type: none"> <li>• Final Draft Adopted by Board: 11/01/16</li> <li>• Public Hearing: 06/29/17</li> </ul>
247 CMR 16.00: Collaborative Drug Therapy Management	<ul style="list-style-type: none"> <li>• Final Draft Adopted by Board: 08/02/16</li> <li>• Public Hearing: 09/19/16</li> <li>• Board Review and Vote on Public Comment: 03/02/17</li> </ul>
247 CMR 17.00: Sterile Compounding	<ul style="list-style-type: none"> <li>• Public Hearing: 11/13/17</li> </ul>
247 CMR 18.00: Non-Sterile Compounding	<ul style="list-style-type: none"> <li>• Public Hearing: 07/18/16</li> <li>• Board Review and Vote on Public Comment: 11/01/16</li> </ul>
247 CMR 20.00: Reporting	<ul style="list-style-type: none"> <li>• Final Draft Adopted by Board: 11/01/16</li> <li>• Public Hearing: 06/29/17</li> </ul>

The *highlights* of the Pharmacy Board’s activities in FY17 related to approval of new and updated advisories include the following:

**Advisory on Staff Ratios:** This Advisory was updated by the Pharmacy Board to include provisions for higher pharmacist-to-intern ratios in non-dispensing academic settings.

**Advisory on New Managers of Record:** This Advisory was approved by the Pharmacy Board for pharmacists who are new to the Manager of Record position. It provides a listing of responsibilities, with their citations, that rest with the manager. It also serves as a reminder to those managers who are already managing a pharmacy in this position.

**Advisory on Levels of Non-Sterile Compounding:** The Pharmacy Board approved this advisory to clarify the categories of non-sterile compounding. It provides definitions and examples for the three levels: simple, moderate and complex non-sterile compounding. This advisory is important because the Pharmacy Board will be issuing separate licenses for those pharmacies that engage in complex non-sterile compounding after new regulations are promulgated.

**Advisory for Opioid Training for CDTM Pharmacists:** Pharmacists involved in collaborative drug therapy management (CDTM) have the ability to prescribe controlled substances under the supervision of a physician. As a result, CDTM pharmacists need to obtain training pursuant to M.G.L. c. 94C, § 18(e). This Advisory was approved by the Pharmacy Board to provide guidance as to the expectations and available venues through which CDTM pharmacists can meet this requirement.

**Advisory on Pharmacy Requirement to Maintain a Defective Drug Preparation Log:** The Pharmacy Board adopted this advisory to educate pharmacists on the requirement to maintain a defective drug preparation log for compounded preparations. It also provides specific reporting requirements surrounding defective drug preparations pursuant to M.G.L. c. 112, § 39D (e).

**Recommended Pharmacy Response to Above Action Level Environmental Monitoring Results:** Based on recommendations from the Advisory Committee's Sub-Committee on Abnormal Results, guidance was developed regarding proper response and successful remediation of above action level environmental monitoring (EM) results in a sterile compounding environment.

**Remediation Considerations for Handling Above Action Level Environmental Monitoring (EM) Results:** This document provides an in-depth approach to the assessment and analysis of above action level contamination in a sterile compounding environment. It incorporates current USP <797> standards along with FDA aseptic processing standards for documentation and follow-up. Assessment of the situation at hand along with investigatory techniques can help a pharmacy identify a root cause and develop a corrective action preventative action plan.

**Sale of Hypodermic Syringes and Needles:** Many pharmacies only sell packages of syringes and needles that contain at least 10 units. This advisory was updated to advise licensees that it is strongly recommended to stock single unit-of-use syringes for customers who ask for them.

**Multistate Pharmacy Jurisprudence Examination (MPJE®):** Study materials for students to prepare for the state law portion of the licensing exam for pharmacists were updated to reflect new regulations. The extensive pool of exam questions was also reviewed and updated.

**Compounding of Commercially Available Drug Products:** A memo was issued to remind pharmacies that they may not compound any drug that is essentially a copy of a commercially available drug product in accordance with the federal Food, Drug, and Cosmetic Act.

**Policy 2011-01: Proper Storage of Refrigerated and Frozen Medications:** This policy was updated to provide guidance on how to handle pharmaceuticals that have been exposed to temperature excursions in a refrigerator or freezer.

**Policy 13-01: Staff Action to Approve Minor Repairs to Compounding Pharmacies:** This policy was edited to provide pharmacy board staff the ability to approve an application for remodeling, change in the configuration, or change in square footage of an existing compounding pharmacy.

**Policy 2015-02: Guidelines for Pharmacist Continuing Education Requirements:** The pharmacy board edited this policy to include new continuing education requirements found in recently promulgated regulations.

**Policy 16-02: Requirements and Procedures for Reporting Theft of Loss of Controlled Substances:** This policy was edited to advise licensees on the reporting procedure for suspected losses. It allows time for licensees to conduct a full investigation to determine if an actual physical loss of drug has occurred.

**Policy 16-04: Staff Action to Handle Above Action Level Results:** The Board of Registration in Pharmacy has adopted this policy to authorize Board staff to effectively manage above action level results from environmental monitoring (EM) reported by licensees involved in sterile compounding.

**Policy 2016-03: An Introduction and Guide to the Practice and Implementation of Lean Concepts in a Pharmacy Setting:** The pharmacy board adopted this policy as guidance for pharmacies in the implementation of lean concepts training as required by M.G.L. c. 112, §§ 39G (a) (6), 39H (a) (6), and 39I (a) (7). Sterile compounding, complex non-sterile compounding, and institutional sterile compounding pharmacies must ensure their employees are trained in lean concepts.

**Policy 2017-02: Pharmacy Technician Licensure by Reciprocity:** Under 247 CMR 8.00, a pharmacy technician currently licensed and in good standing in another state, may be licensed by the Pharmacy Board provided the requirements for licensure in the original state are substantially equivalent to the requirements of the Board. This policy itemizes equivalency criteria.

**Licensure Policy 17-02: Staff Action Approval of Pharmacy Technician Training Programs and Examinations:** The Pharmacy Board adopted this policy to authorize Board Staff to review and approve pharmacy technician training programs and examinations in accordance with 247 CMR 8.02 and Policy 2017-02.

**Policy 2017-04: Retail Pharmacy Participation in Research Studies:** This policy prescribes the procedures and requirements in order for a licensed retail pharmacy to participate in research studies involving controlled substances.

**Joint Policy 2017-08: Pharmacist Administration of Vaccines:** As a result of the changes made to 105 CMR 700.004 (B)(6) permitting qualified pharmacists and pharmacy interns to administer certain vaccines to individuals 9 years of age and older, the Board of Pharmacy, Drug Control Program, and Immunization Program have updated this policy.

#### IV. License and Licensee Statistics

Biennial licensure,	12,591	Pharmacists
except Wholesale	64	Nuclear Pharmacists
Distributors, which are	10,146	Pharmacy Technicians

annual	4,213	Pharmacy Interns
	1,072	Retail Pharmacies
	1,088	Retail Pharmacy Controlled Substance Permits
	34	Certificate of Fitness Permits
	4	Nuclear Pharmacies
	41	Wholesale Distributors
	41	Wholesale Distributors Controlled Substance Permits
	1	Resident Outsourcing Facilities
	33	Non-Resident Outsourcing Facilities
	1	Provisional Outsourcing Facility
	2	Outsourcing Controlled Substance
TOTAL	29,331	

**V. Compliance: Disciplinary Statistics**

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
215	234	306	215	74	34%

# **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 nine members: four PAs, one PA educator, two public members, and two physicians, one of which is a member of the Massachusetts Medical Society. By statute, five 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

Paul Crehan, PA-C., PA member

W. Brian Gorsuch, Ph.D, MS, PA-C, MPAS, PA member

Alithia Carol Broderick, PA-C, PA member

Dr. Richard Baum, MD, Massachusetts Medical Society representative member

Dr. Robert Baginski, MD, physician member

Laura Hilf, RN, MS, public member

### **FY17 PA Board Meetings**

August 11, 2016

September 8, 2016

November 10, 2016

December 8, 2016

January 12, 2017

March 9, 2017

April 13, 2017

May 11, 2017

June 8, 2017

## II. Accomplishments of the Board

**Domestic Violence Training:** In alignment with the strategic priority of establishing regulations in compliance with M.G.L. c. 112, §264, the amended regulations for the PA Board (263 CMR 3.08) were updated to reflect the Domestic Violence Training requirement for licensure at renewal.

**Promulgate Amended Regulations:** In FY17, the PA Board approved the regulation revisions for 263 CMR 2.00 through 6.00. A public hearing was held on November 29, 2016 and the period for public comment was closed on December 6, 2016. The PA Board approved the revisions to the amended regulations on the PA Board voted to approve the regulations January 12, 2017. The regulations were filed and promulgated with an effective date of March 24, 2017.

**Educational Outreach:** In FY 17, PA Board staff in partnership with 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:

- Northeastern University on August 6, 2016 and April 4, 2017
- BayPath University on March 24, 2017
- Boston University on July 28, 2017

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

In addition, PA Board staff attended a PA Assembly to mark the inauguration the new PA program at Westfield State University on March 16, 2017.

**Reporting Board Discipline:** In FY17, the PA Board joined the Federation of State Medical Boards (FSMB). The FSMB represents 70 state medical and osteopathic regulatory boards within the United States and supports its member boards as they fulfill their mandate of protecting public health, safety and welfare through the proper licensing, disciplining, and regulation of physicians and other health care professionals. The PA Board now reports discipline to FSMB.

**Board Composition:** PA Board staff continued to focus on PA Board seats during FY17. During FY17, one new PA Board member was appointed, and two members were re-appointed.

**Board Operations:** In addition, the Board staff completed the following in FY17:

Completed a Six Sigma analysis of the licensing process resulting in the following:

- Updated licensing application and processes
- Launched a pilot with Northeastern University on the collection of transcripts from the primary source verifier.

### Staff Action Policies

1. Routine Responses, adopted August 11, 2016

- This policy facilitates staff responses to routine correspondence and requests for extensions, on behalf of the Board.
1. Department of Revenue Suspensions Policy, adopted August 11, 2016
    - This policy implements state laws relating to coordination with the Child Support Enforcement division of the Department of Revenue.
  2. Investigations of Unauthorized Prescriptive Practice, adopted August 11, 2016
    - The PA Board adopted this policy to authorize and allow for the timely review and disposition of staff assignments (pre-complaints) and complaints pertaining to unauthorized prescriptive practice by physician assistants.
  3. Authority to Evaluate Individual License Applications, adopted March 9, 2017
    - The PA Board adopted this policy to authorize Board staff to evaluate the Good Moral Character of a specific subset of applicants who meet certain criteria.
  4. Referrals to the Office of the Attorney General, adopted May 11, 2017
    - This policy facilitated referrals to the Office of the Attorney General concerning unlicensed practice, practice after revocation or suspension, practice under a false name, false use of credentials, or potential Medicaid fraud.
  5. Policy on the Management of Pain, adopted March 9, 2017
    - To insure patient access to appropriate, legitimate and effective pain management.

The PA Board posted seven alerts to its web page and shared with industry partners.

1. Continuing Education: Domestic and Sexual Violence, adopted on November 10, 2016  
Due to changes in the law, effective July 1, 2015, PAs must obtain continuing medical education (CME) and training in domestic violence and in sexual violence.
2. Death Certificate Advisory, adopted November 10, 2016  
Effective July 1, 2016, section 48 of chapter 133 § 48 of the Acts of 2016 amended M.G.L. c., 46 §9 to authorize PAs to sign death certificates.
3. New Disability Placard Application, adopted on January 12, 2017  
Due to a form changes, notifications to all medical providers were issued relative to the new forms and a webpage for access to additional information on the changes to the forms.
4. Mandatory Continuing Education: Controlled Substances, adopted on December 8, 2016  
Due to changes in the law, PAs are required to obtain continuing medical education (CME) in six particular subject matters as a condition of licensure. For those PAs who prescribe controlled substances, pursuant to M.G.L. c. 94C, §18, PAs must complete CMEs on topics related to pain management and opioid prescribing practices.
5. Schedule II Opioids: Prescription Form Requirements and Patient Requests for Partial Fill, adopted on January 12, 2017  
Prescribers, including PAs, were informed about a recent change in state law relating to patient requests for partial fill of Schedule II opioids, and provided guidance on compliance with these statutory changes.
6. Immunization Administration by Medical Assistants, adopted on January 12, 2017

Primary care providers (PCP), including PAs, were informed that M.G.L. c. 112, § 265, as amended by Chapter 234 of the Acts of 2016, allows a PCP acting within his or her designated scope of practice to delegate the administration of an immunization of a patient to a CMA who meets specified qualifications.

7. Voluntary Non-Opioid Directive Form, adopted on March 9, 2017

PAs received guidance regarding Voluntary Non-Opioid Directives, established in Chapter 52 of the Acts of 2016, to allow patients to better inform providers of their preference not to take opioids.

**III. License and Licensee Statistics**

Biennial licensure	3,323	Full Licenses
	0	Temporary Certifications
<b>TOTAL</b>	<b>3,323</b>	

**IV. Compliance: Disciplinary Statistics**

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
<b>15</b>	<b>16</b>	<b>3</b>	<b>5</b>	<b>3</b>	<b>60%</b>

# **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 seven members, including two respiratory therapists, one nurse, two physicians, and two consumers of respiratory care services. Four members are required to be present to constitute a quorum.

### **RC Board Members**

Paul Nuccio, MS, RRT, FAARC, Board Chair, Respiratory Therapist Member

Jordan Rettig, MD., Vice Chair, Physician Member

Essam Ansari, M.D., Physician Member

Martha DeSilva, Secretary, Respiratory Therapist Member

Molly Caravallo, R.N., Nurse Member

### **FY17 RC Board Meetings**

November 15, 2016

December 20, 2016

March 21, 2017

April 18, 2017

May 16, 2017

June 20, 2017

## **II. Accomplishments of the Board**

**Regulation Review:** In alignment with the FY16 strategic priority of promulgating amended regulations, the RC Board approved revisions for 261 CMR 2.00 through 6.00 and submitted for administrative review and approval. The public hearing was held on January 17, 2017. The comment period was closed on January 24, 2017. Revisions based on public comment are undergoing administrative review.

**Board Composition:** RC Board staff continued to focus on RC Board seats during FY17. During FY17, three new RC Board members were appointed, and one member was re-appointed.

### **Staff Action Policies**

1. Authority to Evaluate Individual License Applications, adopted November 16, 2016

This policy is to authorize RC Board staff to evaluate the Good Moral Character of a specific subset of applicants who meet certain criteria.

2. RC Board Staff Disposition of Selected Complaints, adopted March 21, 2017

This policy is to authorize and allow for the timely review and disposition of staff assignments and complaints pertaining to unlicensed practice by respiratory therapists.

3. Authority to Evaluate Individual License Applications (Amended), adopted March 21, 2017

The RC Board adopts this policy to authorize RC Board staff to evaluate the Good Moral Character of a specific subset of applicants who meet certain criteria.

4. Referral to the Office of the Attorney General, adopted May 16, 2017

This policy facilitates referrals to the Office of the Attorney General concerning unlicensed practice, practice after revocation or suspension, practice under a false name, false use of credentials, or potential Medicaid fraud.

The RC Board posted two alerts to the Board's web page and shared with industry partners.

1. CE Hours Compliance, adopted on August 16, 2016

This Alert reminds Respiratory Therapists of the RC Board's authority under M.G.L. c. 112, §§23S and 23Z to determine eligibility for license renewal. The RC Board conducted a random audit to verify that licensees are in fact complying with the RC Board's regulations.

2. Advisory on Continuing Education Requirements, adopted on June 20, 2017

The RC Board announced an increase in the number of continuing education (CE) contact hours required for license renewal from 15 CE hours to 30 CE hours, per license renewal period, effective in 2018, as specified at 261 CMR 5.02. The renewal period runs from June 1 of even numbered years through May 31 of the next even-numbered year.

**III. License and Licensee Statistics**

Biennial licensure	3088	Full Licenses
	40	Limited Permits (no renewals)
<b>TOTAL</b>	<b>3,128</b>	

**IV. Compliance: Disciplinary Statistics**

<b><u>Number of Staff Assignment Investigations Opened</u></b>	<b><u>Number of Staff Assignment Investigations Closed</u></b>	<b><u>Number of Formal Complaints Opened</u></b>	<b><u>Number of Formal Complaints Resolved</u></b>	<b><u>Number of Formal Complaints Resolved with Discipline Imposed</u></b>	<b><u>% of Formal Complaints Resolved w/Discipline Imposed</u></b>
<b>1</b>	<b>8</b>	<b>5</b>	<b>13</b>	<b>8</b>	<b>62%</b>

# **The Drug Control Program**

M.G.L. c. 94c

## **About the Program**

The Drug Control Program (DCP) transitioned to BHPL over the course of FY17. DCP is responsible for the oversight of the following program areas: The Drug Formulary Commission, the Massachusetts Controlled Substance Registration, the Medication Administration Program, the Drug Stewardship Program, and the Pharmaceutical Code of Conduct.

DCP has statutory responsibility to set standards for the control of prescribing, dispensing and administration of pharmaceuticals by health care providers as well as 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.

## ***The Drug Formulary Commission***

M.G.L. c. 17, § 13

### **I. Administration**

#### **About the Program**

The Drug Formulary Commission (DFC) is charged to prepare 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. Staff of the DCP plan meeting agendas and develop materials in consultation with a pharmacist from UMass Medical School.

#### **Commission Members:**

James Lavery, Director, Bureau of Health Professions Licensure, DPH Commissioner’s designee  
Dr. Paul Jeffrey, Director of Pharmacy, MassHealth

Tracey McMillan, Bureau of Managed Care, Division of Insurance

Dr. Joanne Doyle Petrongolo, Ambulatory Care Pharmacist for the Integrated Care Management Program at Massachusetts General Hospital

Dr. Jeffrey Supko, Associate Professor of Medicine, Harvard Medical School; Director, Cancer Pharmacology Core, Dana-Farber/Harvard Cancer Center, Massachusetts General Hospital

Dr. Theoharis Theoharides, Director, Molecular Immunopharmacology and Drug Discovery Laboratory, Tufts University  
Dr. Virginia Lemay, Clinical Assistant Professor, University of Rhode Island and Community Pharmacist, Rite Aid Pharmacy  
Stephen Feldman, RPh, Former Director of the Psychotropic Drug Intervention Program at Beacon Health Strategies; Founder, CEO and President of the ICPS Group  
Dr. Daniel Carr, Professor of Public Health and Community Medicine, Anesthesiology and Medicine; Director, Pain Research, Education and Policy Program, Tufts University School of Medicine  
Cheryl Campbell, Corporate and IP Attorney at McCarter & English LLP  
Dr. Alexander Walker, Chief Transitions Officer; Chairman of the Department of Emergency Medicine and Urgent Care Services, Hallmark Health Systems  
Dr. Douglas Brandoff, Co-Director, Palliative Care Clinic, and Physician Leader, Dana-Farber Cancer Institute  
Dr. Kenneth Freedman, Chief Medical Officer, Lemuel Shattuck Hospital; Clinical Professor of Medicine, Tufts University  
Dr. Shihab U. Ahmed, Course Director for Harvard Medical Student's Clerkship at the MGH Center for Pain Medicine, Department of Anesthesia, Critical Care and Pain Medicine  
Logan Leslie, Harvard Law and Business School Student; Veteran  
Cindy Steinberg, National Director of Policy and Advocacy, U.S. Pain Foundation

#### **FY17 Commission Meetings:**

July 14, 2016  
September 15, 2016  
December 15, 2016  
March 20, 2017  
May 18, 2017

## **II. Accomplishments of the Commission**

**Non-Opioids for Pain Management:** On July 14, 2016, the DFC completed development and approved the first 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.

**Interchangeable Abuse Deterrent Drug Products:** On May 18, 2017, the DFC completed the review of each drug product, currently available in the United States, with FDA approved abuse deterrent labelling or with a manufacturer's claim of abuse deterrent property (ADP). They were evaluated using a DFC-developed, standardized monograph, which resulted in the approval of 10 drug products for placement on the Formulary as Interchangeable Abuse Deterrent (IAD) drug products: Oxycontin<sup>®</sup>, Embeda<sup>®</sup>, Hysingla ER<sup>®</sup>, Oxaydo<sup>®</sup>, Nucynta ER<sup>®</sup>, Xtampza ER<sup>®</sup>, Troxyca ER<sup>®</sup>, Arymo ER<sup>®</sup> and Morphabond ER<sup>®</sup>. Three drug products were reviewed and denied IAD placement on the Formulary: Opana ER<sup>®</sup>, Zohydro ER<sup>®</sup> and Targniq<sup>®</sup>.

**Evaluation of Chemical Equivalence:** Also on May 18, 2017, the DFC completed an analysis of the 10 IADs established against the 28 HPHR opioids established during FY16, to determine

whether any IAD is a chemically equivalent substitution for a HPHR opioid. The analysis was conducted with consideration for the accessibility, cost drug efficacy and ADP efficacy, as required by statute.

The DFC voted in favor of substituting Embeda<sup>®</sup>, Morphabond ER<sup>®</sup> and Arymo ER<sup>®</sup> for five HPHR opioids each: Morphine Extended-Release, 24-hour capsule, Kadian<sup>®</sup>, Morphine Extended-Release, 12 or 24-hour capsule (the generic for Kadian<sup>®</sup>), MS Contin<sup>®</sup>, and Morphine Extended-Release tablet (the generic for MS Contin<sup>®</sup>). Additionally, the DFC voted in favor of substituting Hysingla<sup>®</sup> for Zohydro ER<sup>®</sup>.

Resolution of this final step completed the final draft of the Formulary, which is the first draft Formulary in the nation.

## ***Massachusetts Controlled Substance Registration***

M.G.L. c. 94C

### **I. Administration**

#### **About the Department**

The Massachusetts Controlled Substance Registration (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.

### **II. Accomplishments of the Department**

**Department Relocation:** In January 2017, the MCSR Department moved from 99 Chauncey Street to join the majority of BHPL at 239 Causeway Street.

**Review of Application Processing Standards:** After the MCSR Department relocated, Quality Improvement staff worked with Department staff to overhaul application processing standards, resulting in the following changes:

- Practitioner applicants who live outside Massachusetts will no longer be denied an MCSR if they are duly licensed in Massachusetts;
- Applications that do not include Social Security number, or a signed and notarized No SSN Affidavit, will be rejected as incomplete applications;
- Applications that are not signed original documents will be rejected;
- Information on file with the MCSR Department will no longer be changed until the Department is in receipt of a completed Amended Information Application;
- Applications that are returned will include a cover sheet indicating the specific reason the application was rejected; and
- Applications that are returned by the MCSR Department to the applicant will be considered denied if a corrected application is not returned to the MCSR Department within 21 business days.

**MCSR Data Cleansing:** In preparation of the upcoming conversion of existing MCSR data to the BHPL licensing database, MyLicense Office (MLO), staff from IT and QI worked with MCSR Department staff to fix errors in MCSR provider records.

**III. License and Licensee Statistics**

Annual licensure, except Physicians, which are every three years	11,810	Physician Assistants and Advanced Practice Registered Nurses
	1,170	Optometrists
	71	Pharmacists
	38,642	Practitioners (Physicians, Podiatrists and Dentists)
	995	Research studies
	2,369	Veterinarians
	576	Ambulances
	871	Clinics
	25	Analytical Labs
	134	Drug distributors
	34	Drug manufacturers
	54	Drug distributors and manufacturers
	150	Hospitals
<b>TOTAL</b>	<b>56,901</b>	

## ***Drug Control Program 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 drugs by conducting inspections and investigations; collecting evidence for analysis; developing regulations, 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, lack of appropriate pain medications and possible abuse.

#### **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 distribution 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 abusing and diverting controlled substances from a place of employment due to a substance abuse impairment issue. Drug tampering involves substitution of a patient's or resident's controlled substance medications using a placebo, saline or other ineffective medication, usually by a health care professional, as a means of drug diversion. Tampering cases are the most time critical and complex investigations, because patients may be in danger of being harmed by the adulterated product. The EU has a unique responsibility to identify the tampering substance, remove the evidence to the State Police Laboratory or Federal Laboratory for analysis, identify a suspect while investigators work closely with law enforcement (local, state and federal) to prosecute the 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 diversion. 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, 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.

See **Appendix F** for detailed disciplinary statistics.

## ***The Medication Administration Program (MAP)***

105 CMR 700.003(F)

### **I. Administration**

#### **About the Program**

The Medication Administration Program (MAP) was promulgated in 1993, in response to a 1988 report of the state auditor. That report recommended replacement of the previous unregulated practice of medication administration by unlicensed staff working in Department of Mental Health (DMH) and Department of Developmental Services<sup>12</sup> (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 Massachusetts Controlled Substances Registrations 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 met in December 2016 and annually to ensure effective policy communication.

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<sup>12</sup> Formerly Department of Mental Retardation

## II. Accomplishments of the Medication Administration Program

### Curriculum

A new Curriculum *Responsibilities in Action-Understanding the Connections* was developed and piloted for MAP Certification Training. The previous curriculum and trainings will be phased out, and the new curriculum will be in place at MAP Registered sites by June 30, 2019.

### Medication Database

An updated database, *MedSoft Version 7*, was developed and provided as an on-line download for MAP Service Providers. MedSoft Version 7 allows MAP staff to print Health Care Provider orders (based on data entered from original orders) with corresponding medication administration records. The use of the database system is not required by any of the Departments, but is a convenient option for users, who are responsible for compliance with the MAP guidelines and requirements.

## 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 changes until the next iteration of the MAP Policy Manual.

## IV. Medication Administration Program: Massachusetts Controlled Substance Registration Statistics

The MAP requires that all medication storage sites be registered with the Drug Control Program. The MAP Massachusetts Controlled Substances Registration (MCSR) is valid for a year. MAP Certified staff can only administer medications in sites that have a valid MAP MCSR.

Department	Number of Service Providers	Number of Sites given MCSR
Department of Developmental Services	117	2733
Department of Mental Health	46	150
Caring Together DMH/DDS	47	492
<b>TOTAL</b>	<b>210</b>	<b>3,375</b>

## VI. Hotline Medication Occurrences Reports

DPH MAP Registered sites are required to make a report, directly to Department of Public Health within 24 hours of discovery, on any Medication Occurrence followed by a medical intervention (e.g., lab work, tests, health care provider visit, clinic visit, ER visit, hospitalization, etc.), illness, injury or death.

### **Hotline Statistics**

In FY17, there were 110 Medication Occurrence ‘hotlines’ reported to the DPH-DCP.

## ***The Drug Stewardship Program (DSP)***

105 CMR 702.000 (draft)

### **I. Administration**

#### **About the Program**

The Drug Stewardship Program (DSP) began implementation very 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)*, which took effect on March 14, 2016. 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 collaborative 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 received only one Plan submission from a manufacturing collaborative, called MED-Project. The collaborative is comprised of over 94 member manufacturers who buy into the Plan manager, MED-Project. The Plan is currently under review and has not been approved as of publication.

### **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 to leverage the fast pace of this temporary mandate.

#### **IV. Participation Statistics**

The DSP has received one Plan submission (approval pending), consisting of 94 manufacturers (as of 6/30/17), 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 Pharmaceutical and Medical Device Manufacturer Code of Conduct (PCOC)***

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 the Department of Public Health (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 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 PCOC each year and pay an initial registration or renewal fee by check. PCOC receives and processes applications.

An IT solution is anticipated to automate this process.

##### **Annual Disclosure Reports**

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, PCOC operates under state regulation (105 CMR 970.000). After promulgating the regulations, the Federal Drug Administration 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. <https://openpaymentsdata.cms.gov/>. The Federal rules preempt 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 Law reports must be published by PCOC within 90 days of receipt from DEA.

### **IV. Registration Statistics**

PCOC staff received 29 initial registrations since July 1, 2017 and 348 registration renewals in the same time period, for a total of 377 registered drug and device manufacturers. A total of 17,411 payments were reported to 11,261 recipients. These figures do not include preempted Federal Sunshine Act payments.

### **V. Compliance: Disciplinary Statistics**

DPH Office of General Counsel received two voluntary disclosures of PCOC violations this year. Both were referred to the Attorney General for further action, which has not been finalized at time of publication.

### ***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 the Department of Public Health’s (Department) Drug Control Program (DCP) and the Board of Registration in Pharmacy (BORP) 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 substance 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<sup>13</sup>, 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 pharmacist access to necessary patient information for timely intervention of at-risk patients.

During FY 2017, the Department concentrated its efforts on the implementation of the Massachusetts Prescription Awareness Tool (MassPAT). Following an extensive process of gathering information from stakeholders regarding the preferred features of an online PMP, the Department selected Appriss Health as the vendor to build and maintain MassPAT to Massachusetts specifications. MassPAT went live on August 22, 2016. In FY17, the PMP also worked on initiatives to improve the timeliness of the data collected in the PMP Clearinghouse, including outreach efforts to pharmacies in order to achieve compliance of the 24 hour/next business day reporting of PMP data.

This prescription data is accessed through 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.

MassPAT is also made available to Law Enforcement and Regulatory agents who complete a day-long training in the use of MassPAT, and substance abuse. Utilization of MassPAT by law enforcement and regulatory agents requires an open and ongoing drug related investigation. The PMP provides monthly training opportunities in various locations throughout the state to promote effective use of MassPAT by these agents.

PMP staff is tasked with promoting the utilization of MassPAT by all authorized users. This entails educational efforts to pass along best practices, as well as identifying and implementing

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<sup>13</sup> 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.

policies and technological changes to improve the system’s ease of use. 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 is monitored and maintained by EOHHS 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. Although not required, each current member has experience using the PMP, is in active practice and good standing, and has experience in the prescribing or dispensing of controlled substance medications 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.

Below is a list of current MRG members. The program goal is to appoint two members per license discipline, including doctors, pharmacists, dentists, podiatrists, physician assistants and advance practice registered nurses. Members 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.

<b>License Discipline</b>	<b>Current Member</b>
Physician	Douglas Brandoff, MD
Physician	Alfred DeMaria, MD
Physician	Edward Michna, MD
Pharmacist	Scott DeCesare, PharmD
Pharmacist	Karen Horbowicz, PharmD
Pharmacist	Emily Rowe, PharmD
Nurse Practitioner	Christopher Shaw, NP
Nurse Practitioner	Dawn Williamson, NP

Physician Assistant	Angelo Pucillo, PA
Dentist	Mina Paul, DMD
Podiatrist	Open

**FY17 MRG Meeting Dates**

July 21, 2016

September 29, 2016

October 27, 2016

December 8, 2016

January 26, 2017

March 23, 2017

April 27, 2017

May 25, 2017

## **PMP Addendum: December 16, 2015 to June 30, 2016**

As noted in the introduction, the *Bureau of Health Professions Licensure Annual Report*, and its appendices, replaces three separate annual legislative reports 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”. While the *Bureau of Health Professions Licensure Annual Report* is based on information from the previous fiscal year, FY17, prior PMP Annual Reports, were based on information from the previous calendar year. In order to accomplish this report consolidation, the CY16 PMP Annual Report was not issued, and only the last two quarters of CY16 are included in FY17. To ensure a complete picture of the PMP, this addendum provides information from the first two quarters of CY16.

Several important activities and events took place during the six month period between the last mandated legislative report, covering the period of November 2, 2014 to December 15, 2015, and the *Bureau of Health Professions Licensure Annual Report* for FY17.

### The New and Improved PMP

In December 2015, the Commonwealth entered into a contract with Appriss, Inc., an established online PMP software vendor, to provide a new system for the MA Online PMP. The primary components of the new PMP include the following:

#### *The PMP Clearinghouse*

Appriss provided a new data submission tool, the PMP Clearinghouse, for pharmacies or their vendors to submit prescription records to the PMP as required by statute every 24 hours or the next business day.

In February 2016, the program held its first of four monthly information sessions with pharmacy stakeholders to outline the process of transitioning from the current data submission vendor, Atlantic Associates, Inc., to Appriss’s PMP Clearinghouse. The sessions communicated the requirements that pharmacies:

- Submit all outstanding data corrections to Atlantic Associates by May 31, 2016;
- Create an account with PMP Clearinghouse; and
- Determine the submission method among the following options:
  - Automatic Upload
  - Secure File Transfer Protocol (sFTP)
  - Manual File Upload
  - Universal Claim Form (UCF)

On May 31, 2016, pharmacies ceased to submit data to Atlantic Associates, Inc., and instead began submitting data to Appriss’ PMP Clearinghouse.

### The Massachusetts Prescription Awareness Tool (MassPAT)

MassPAT, the online PMP for prescribers and pharmacists, includes the following features:

- An improved user-friendly interface and faster access to reports;

- Interoperability with other states' online PMP systems, permitting prescribers to check whether their patients are receiving prescriptions in other states;
- Integration to link with the Commonwealth health providers' electronic medical record systems to ensure safe prescribing; and
- Efficient onboarding for users including prescribers, delegates, residents and interns, and pharmacies and dispensers.

A “go live” date of August 22, 2016 was chosen for MassPAT, which required a carefully coordinated communications campaign to prepare prescribers, pharmacists, and delegates for online registration that would commence on July 14, 2016. Multiple meetings with stakeholders were held to help craft the message and settle on modes of delivering these messages.

#### Changes to the PMP SQL Data Base

Based on stakeholder feedback MassPAT would contain 12 months of a patient's prescription history for drugs in Schedule II-V. However, MA PMP maintains a database of prescription records dating back to the inception of the program in 1992. This allows PMP and Department epidemiologists to view trends over time, and to be able to provide data covering periods greater than 12 months to statutorily authorized parties. The contract with Appriss requires a daily export of prescription data to the program, which then must be loaded to the SQL database. This required an extensive recoding to prepare for the reception of this data from Appriss beginning on June 1, 2016.

#### Multiple Provider Alerts

During this period of preparation for the new and improved PMP, the program was tasked with maintaining the old system and providing services to registered users. The program issued patient alerts on a monthly basis to prescribers who prescribed a Schedule II or III opioid to an individual who had received 10 or more prescriptions from 6 or more prescribers involving 4 or more pharmacies in the specified 90 day period. These alerts were issued on monthly basis from January 2016 to June 2016 to both prescribers who were registered with the PMP and those who were not.

## **II. Accomplishments of the PMP**

### **MassPAT Go Live**

On June 11, 2015 the Governor's Opioid Working Group made the recommendation to improve the PMP: "The Commonwealth's prescription monitoring program (PMP) is an essential tool to identify sources of prescription drug diversion. By improving the ease of use of the PMP and enhancing its capabilities, it will no longer be an underutilized resource." Following an extensive process of gathering information from stakeholders regarding the preferred features of an online PMP, the Department selected Appriss Health as the vendor to build and maintain MassPAT to Massachusetts specifications. MassPAT, went live on August 22, 2016.

### **Registrations**

In FY17, MassPAT registrations soared to 54,861, including delegates and 27,750 registered physicians. By the close of FY17, 95% of prescribers of at least one Schedule II or III opioid were registered with MassPAT.

### **Searches**

In FY17, MassPAT searches topped 5 million, and the weekly average number of patient searches reached 125,000.

### **Law Enforcement Trainings**

Six trainings were offered to Law Enforcement and Regulatory agents in FY17, certifying approximately 155 agents for access to MassPAT. Trainings were conducted by:

- Thomas Shannon – Det. Lt. (Retired), former commanding officer of MSP Diversion Investigative Unit, and
- Susan Waddell – Special Agent in Charge (retired) – U.S. Department of Health and Human Services- Office of Inspector General, New England Region.

This PMP training is designed for those law enforcement officers and prosecutors assigned to cases involving prescription drug abuse or diversion. The group sought to address other issues that are often found in drug abuse cases, and help the officers understand some of the underlying factors commonly encountered with this problem, including:

- A pain management professional's perspective on the use and abuse of prescription drugs, treatment challenges and their approach to their patients.
- An overview of drug diversion investigative techniques, applicable state and federal criminal statutes related to diversion, health care insurance fraud, abuse of public health care programs and prescription related crimes.
- An overview of state substance abuse services available to individuals throughout the Commonwealth and the role of law enforcement in referrals.
- The application and use of the online MassPAT data in the investigative process and the fundamental instruction of registering for and accessing the system.
- A review of the statutory requirements of M.G.L. c. 94C, §24A and federal HIPAA requirements for law enforcement.

Training sessions are scheduled for a four-hour block which includes two breaks and question and answer periods. Discussion and feedback is always encouraged by all presenters. Handouts

include copies of each PowerPoint slide presentation, resource cards provided by BSAS with listings of local services, and the NADDI trifold drug charts to identify pills. These charts are published by DEA and made available to government agencies upon request at no charge.

### **Outreach, Education, and Video Tutorials**

During FY17, 14 live presentations and webinars were delivered to various stakeholder groups, including physicians, medical residents, pharmacists, and dentists. To facilitate the registration and effective utilization of MassPAT a series of video tutorials and slide decks were created and posted on the PMP website. These included tutorials aimed at delegates who routinely performed “bulk” searches of more than one patient for their supervising prescriber.

### **Prescriber Reports**

The PMP is required by statute to annually provide information to individual prescribers on how they are prescribing Schedule II and III opioids in comparison to other prescribers within their specialty. The first such report to prescribers was issued on March 1, 2017. This confidential notification is not available for distribution by the Department and is only shared with the individual provider. Using data reported into the PMP, the Department calculated the mean and median prescribing quantity and volume (solid dosage units) of all prescribers who prescribed at least one Schedule II or III opioid in Calendar Year (CY) 2016 by specialty category. Specialty information was obtained from the information self-reported into MassPAT by prescribers.

Approximately 27,900 prescribers of at least one Schedule II or III opioid in CY 2016 received a 2017 Provider Trend Notification. Approximately 24,745 prescribers were registered in MassPAT and were sent their password-protected 2017 Prescriber Report by email. Approximately 3,155 prescribers were not registered in MassPAT and received their Report by mail. Residents were excluded from the distribution as they prescribe against their facility’s DEA #, and the Notification was based on the number of prescriptions filled per individual DEA # in CY 2016.

The Department will continue to enhance the Provider Trend Notification to share data with prescribers to help them safely care for their patients and bring collective awareness to what opioids are being prescribed.

### **Steps Toward EMR 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.

The PMP enlisted four Health Care Entities (HCEs) to serve as integration pilots, Partners Health, Atrius Health, the Cambridge Health Alliance and UMass Memorial Medical Center. The PMP integration plan was to provide four options for integration – three Application Program Interfaces (APIs) that would utilize the PMP Gateway for transmission of data (Appriss’s custom V5, ASAP, and NCPDP), and the Mass HIway (HIE). Each would have its own strengths and weaknesses for HCEs to weigh.

PMP data contains both personally identifiable data (PII) and protected health information (PHI). To protect patient’s rights, the highest standard of data security must be applied to PMP data. In Massachusetts, there are laws in place to ensure PMP data security. To ensure that patient data is protected, the EHR integration requires that HCEs comply with Massachusetts’ security measures.

In FY17, EOHHS IT staff and contractors began the process of conducting security tests on the four options through which PMP data would travel into a HCE’s EMR system. By the close of FY17, EOHHS IT had cleared the Mass HIway (HIE) and the ASAP API that would be used to transmit PMP data through Appriss’s PMP Gateway. The two remaining APIs, Appriss’s V5 and NCPDP had not passed the security review, and significant work continued to bring the remaining APIs up to Massachusetts security standards.

### **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.

### **Medical Residents Become Primary Account Holders**

Initially, medical residents were granted delegate accounts requiring supervision. This policy proved less than optimal based on input from supervisors who stated their inability to monitor the prescribing practices of numerous residents. Based on this feedback a programmatic decision was made to grant residents primary accounts in MassPAT. In this way, the PMP staff could monitor resident activity and each resident could view their own prescription history independently. The migration to primary accounts began in June of 2017 and will be completed in early FY18.

### **Interstate Data Sharing**

In FY17, the PMP entered into data sharing agreements with 31 states and the District of Columbia, including those listed below:

New Hampshire	Minnesota	West Virginia	Mississippi
Rhode Island	South Dakota	Louisiana	D.C.
Connecticut	Alabama	Arkansas	Nevada
Vermont	Colorado	New Mexico	Georgia
New York	Texas	Oklahoma	Indiana
Virginia	Idaho	Maine	New Jersey
South Carolina	Pennsylvania	North Dakota	Illinois
Arizona	Kansas	Ohio	Alaska

The established data sharing agreements allow providers in Massachusetts to query a partner state through MassPAT. With all New England states and New York connected to share prescription data, providers can see a complete picture of their patient’s prescription history. Through FY18, the PMP will work towards connecting with all 50 states.

### **Gabapentin Added as a Drug of Interest**

Section 69 of Chapter 52 of the Acts of 2016 required DPH to promulgate regulations to classify Gabapentin and its chemical equivalents as additional drugs for the purposes of section 24A. Regulation changes to 105 CMR 700.000 (Implementation of M.G.L. c. 94C), promulgated on May 5, 2017, include criteria for the classification of additional drugs. For the purposes of reporting to the PMP, Gabapentin, including its chemical equivalents, has been classified as an additional drug according to the criteria enumerated in 105 CMR 700.012(C)(7).

The program conducted webinars for stakeholders and sent emails to pharmacies, data submitters and prescribers in preparation for the change. August 1, 2017 was selected as the start date; however, pharmacies were granted a grace period of 1 year to submit customer ID information with the prescription files to allow their pharmacy software vendors to adjust.

### **Prescribing Trends**

#### *Prescriptions*

In 2017Q2 there were approximately 638,000 Schedule II opioid prescriptions reported to the PMP, a nearly 24% decline from 2015Q1 (n = 841,990 Schedule II opioid prescriptions). See Appendix G for details.

#### *Patients*

See Appendix H for details.

### **MPE Trend**

One of the most important contributions of the PMP has been the rapid reduction in individuals with activity of concern, a 27% drop from Q4 of 2015 to Q4 of 2016. See Appendix I for details.

### **Conclusion**

The foregoing accomplishments and statistics are highlights from FY17. BHPL and its 10 boards 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 DCP and PMP within BHPL reinforce the overall goal of BHPL to improve public health and safety.

## **Contact Us/Feedback**

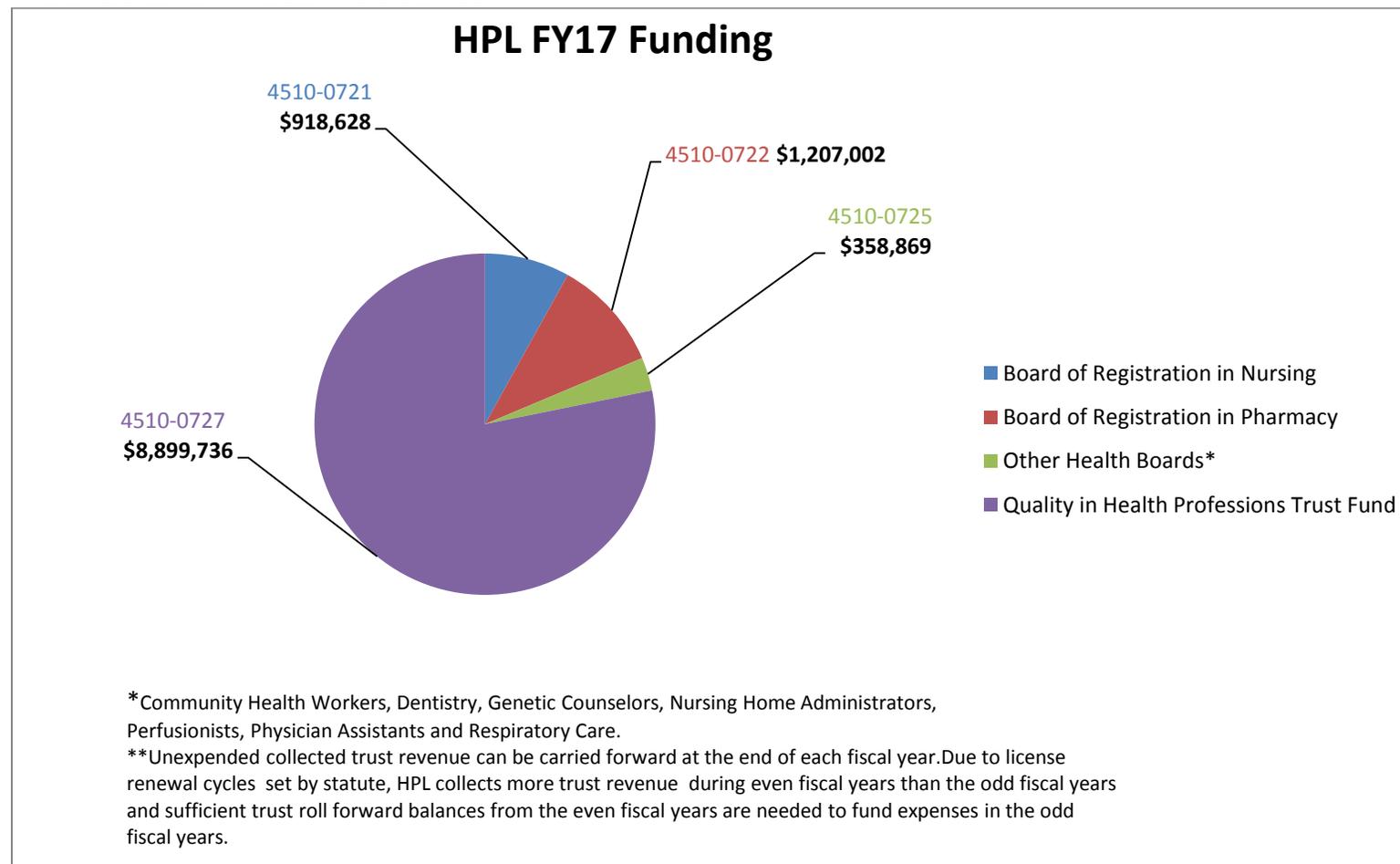
Your feedback is important to us. Please [take our survey](#) and share any questions or comments.

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](http://www.mass.gov/orgs/bureau-of-health-professions-licensure)

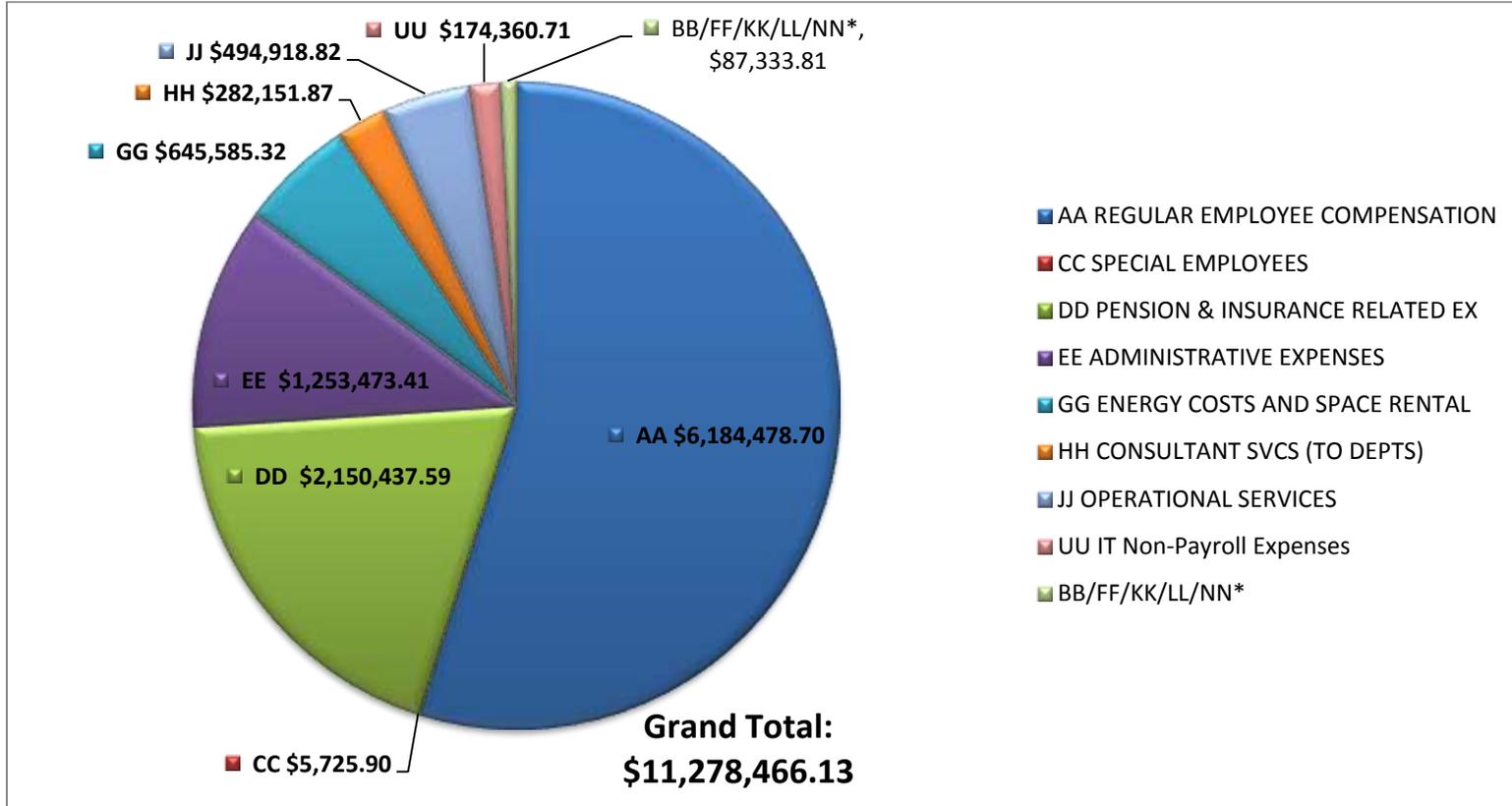
## Appendix A: BHPL FY17 Funding

### Boards and Trust Accounts



# Appendix B: BHPL FY17 Expenditures

## Trust Account

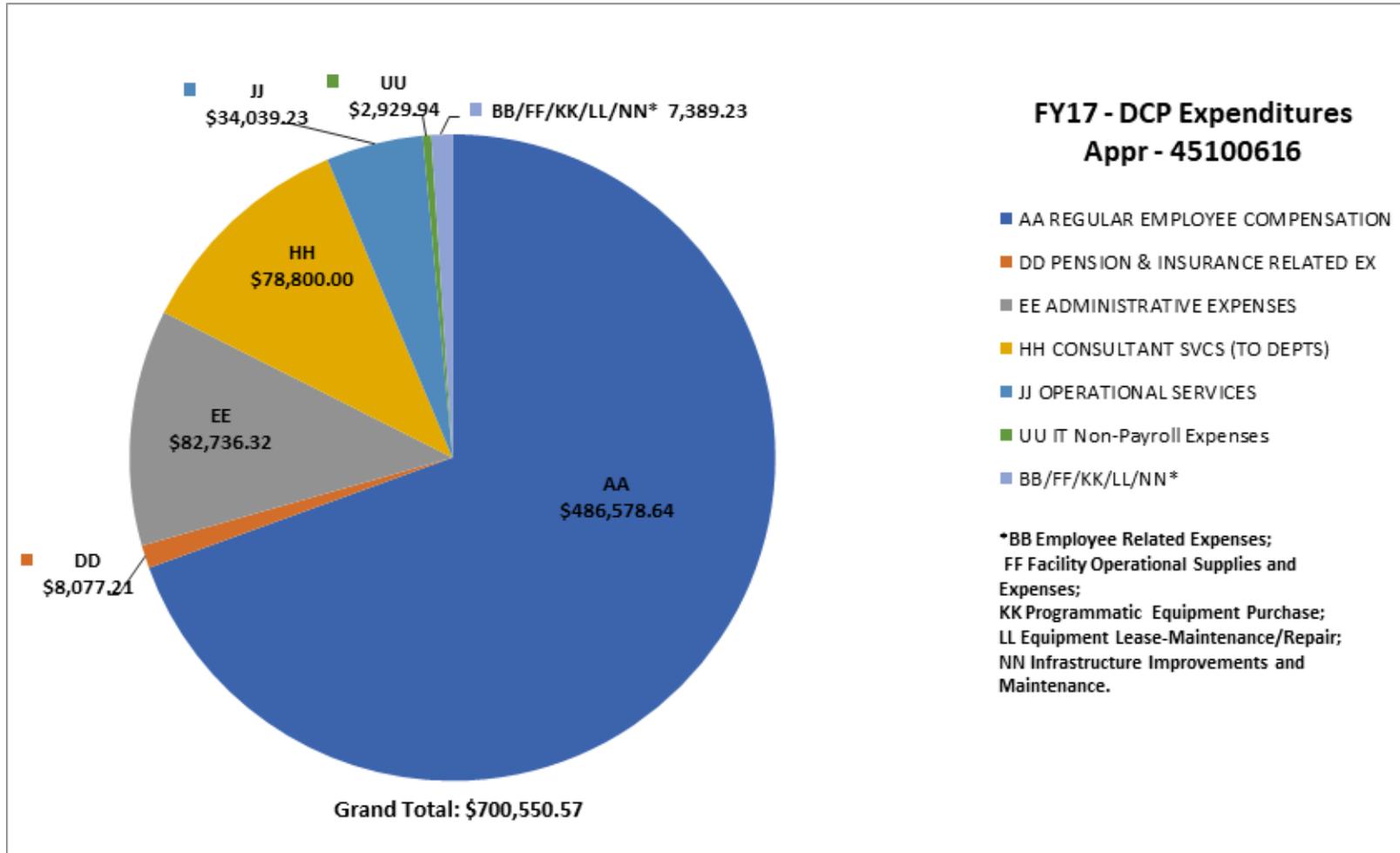


See attached excel spreadsheet for detailed expenditures

\*BB Employee Related Expenses; FF Facility Operational Supplies and Expenses; KK Programmatic Equipment Purchase; LL Equipment Lease-Maintenance/Repair; NN Infrastructure Improvements and Maintenance

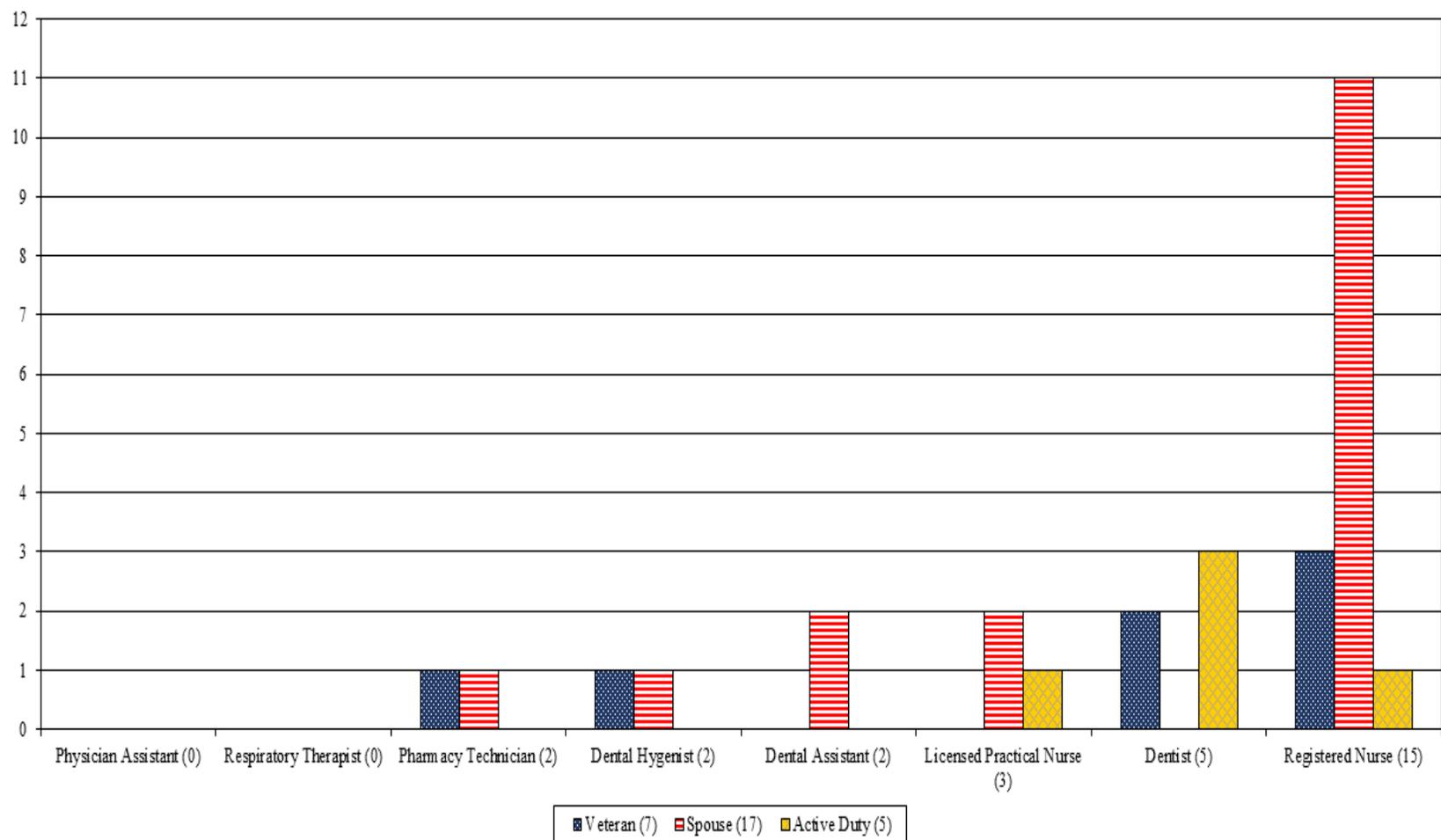
# Appendix C: BHPL FY17 Expenditures

## Other BHPL Accounts

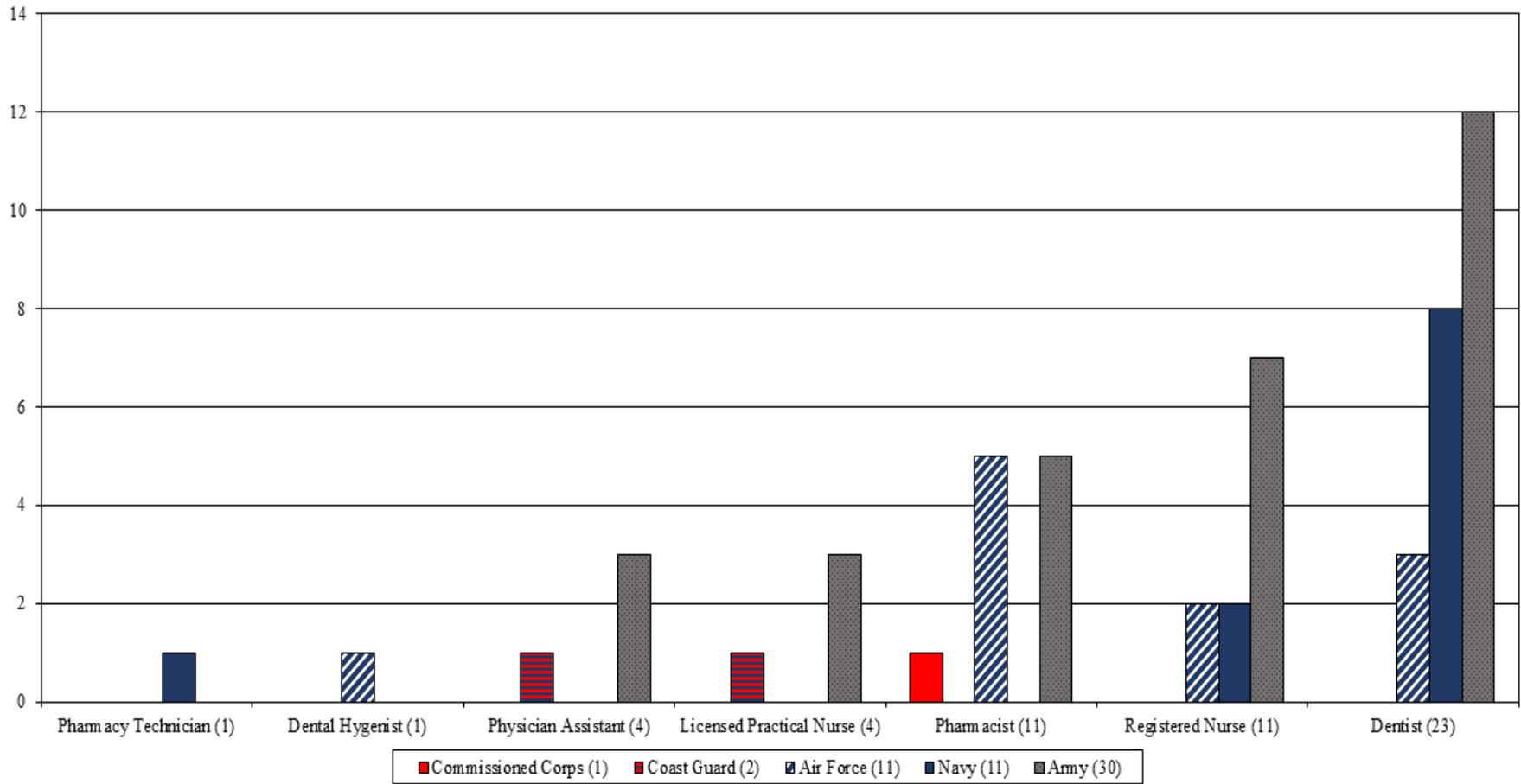


See attached excel spreadsheet for detailed expenditures

## Appendix D: *FY17 VALOR Act Licensure Applications*



## Appendix E: *FY17 Active Service Duty Licensees*



## Appendix F: Drug Control Program – Enforcement Unit: Disciplinary Statistics

DCP Field Activity Items		FY17
Drug Incident Intake	Drug Incident Field Interaction <sup>14</sup>	694
	Tampering Investigations	39
	Desk Audits <sup>15</sup>	188
	Investigations On-Site	286
	Field Interaction Report (FIR) <sup>16</sup>	84
Registration Activity	New Registrations	270
	Registration Desk Audits	125
	Registration On-Site Inspections	80
Routine Audits & Re-inspections	Site Visits and Complaint Investigations	12
Criminal Investigations	Health care practitioners diverting or tampering with drugs.	18
Embargo <sup>17</sup>		0

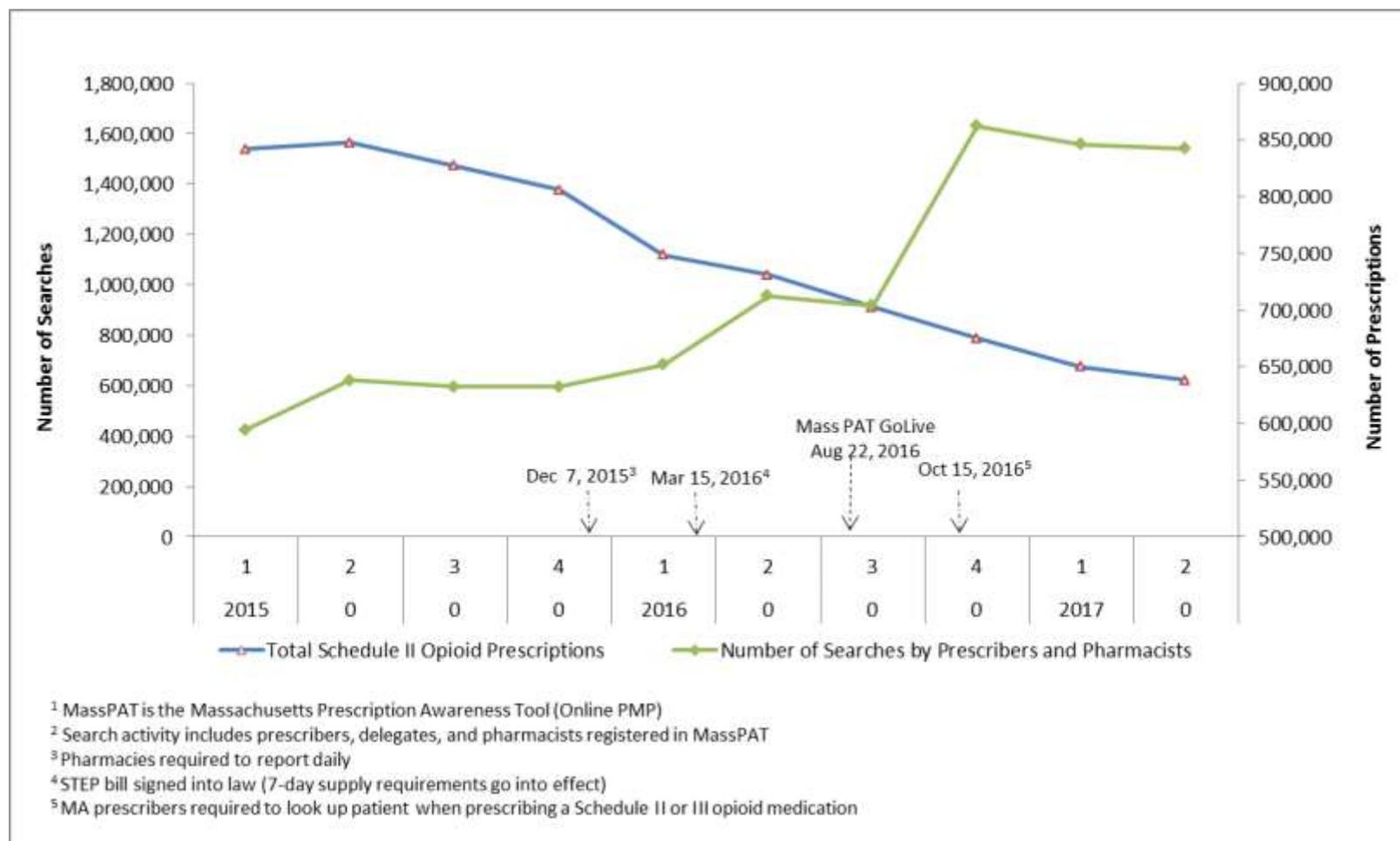
<sup>14</sup> Field interaction may involve, but is not limited to, telephone calls to health care facilities, employment agencies, requesting documentation, review of documentation and/or interaction with regulatory or law enforcement agencies.

<sup>15</sup> Investigative Desk Audits may consist of obtaining additional documentation, statement's 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.

<sup>16</sup> FIR reports are DCP generated intelligence reports involving a drug diversion incident. These reports do not always warrant the threshold referral to a regulatory or law enforcement agency.

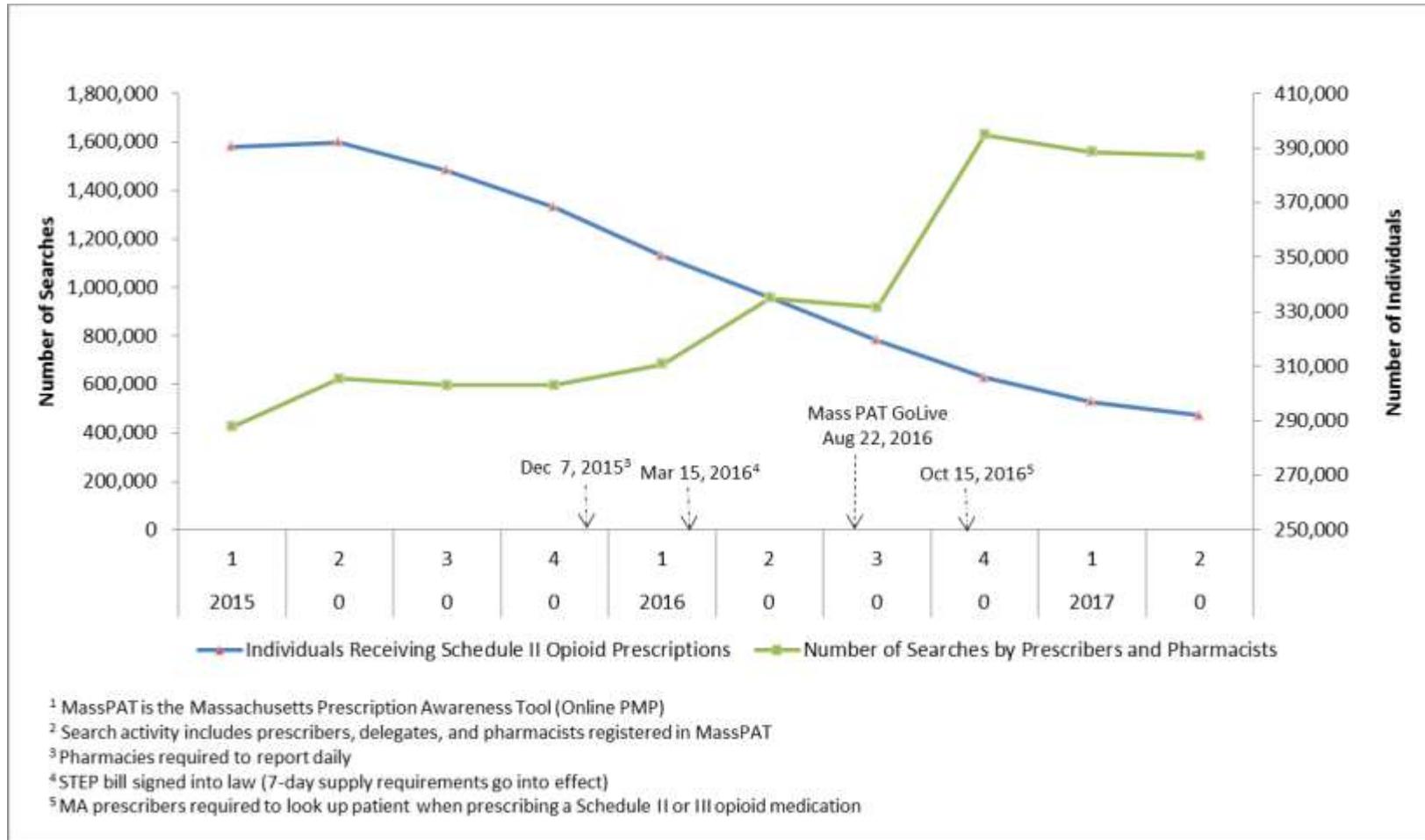
<sup>17</sup> See M.G.L. c. 94, § 189A "...Whenever the commissioner of public health or his duly authorized agent, finds or has probable cause to believe based upon inspection or chemical, bacteriological or physical examination, that any drug, cosmetic or device is adulterated or misbranded, ... such 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 G: MassPAT Search Activity Trends MA: Q1 2015 - Q2 2017 Schedule II Opioid Prescriptions



Note: 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 7/11/2017.

## Appendix H: Individuals Receiving Schedule II Opioid Prescriptions and MassPAT<sup>1</sup> Search Activity<sup>2</sup> Trends



Note: 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 7/11/2017.

## Appendix I: Rate of Individuals with Activity of Concern in MA (CY 2013–2016)

