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Executive Office of Health and Human Services
Department of Public Health
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August 8, 2019

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

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

Dear Mr. Clerk,

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

Sincerely,

Monica Bharel, MD, MPH
Commissioner
Department of Public Health

Charles D. Baker
Governor

Karyn Polito
Lieutenant Governor

Marylou Sudders
Secretary

Monica Bharel, MD, MPH
Commissioner

Bureau of Health Professions

Licensure Annual Report

Fiscal Year 2018

Massachusetts Department of Public Health

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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:[1]

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

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

SECTION 43. The board of registration of dentistry, herein and in sections forty-three A to 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.

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

Executive Summary

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

BHPL is pleased to submit this report of fiscal year 2018 (FY18) regulatory, policy, licensure and enforcement activities.[2] This report summarizes and highlights statistics and accomplishments undertaken to fulfill the BHPL mandate to protect the public health, safety, and welfare in Massachusetts. The report reflects a commitment to establishing and improving practice standards for the health professions under the oversight of BHPL and providing transparency of drug control and prescription monitoring activities.

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

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

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

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

Significant Accomplishments of FY18

In FY18, DCP and the Board of Registration in Pharmacy implemented legislative provisions to significantly reduce barriers to obtaining and administering naloxone, the life saving opioid overdose reversal drug. In addition to implementation of legislative provisions calling for a statewide standing order for naloxone, allowing it to be purchased for any ultimate user, regulatory provisions were amended to allow purchase, distribution and trained administration of naloxone by more organization types and individuals.

In FY18, the Drug Stewardship Program (DSP) approved MED-Project's Drug Stewardship Plan (Plan), which will provide statewide collection and disposal of unwanted medications in partnership with 171 manufacturers of benzodiazepines and Schedule II and III opioids distributed in the commonwealth. This first-in-the-nation statewide Plan will ensure funding and support of drug take-back programs at law enforcement agencies throughout the commonwealth, provide resources and information for in-home disposal, contributing to the safety and security of drugs that contribute to public health risk.

In FY18, the Board of Registration in Pharmacy began accepting applications and issuing licenses for the newly established Pharmacy Technician in Training license. This new license type prevents an individual from working behind a pharmacy counter with access to controlled substances prior to receiving a license in the Commonwealth of Massachusetts.

During FY18, BHPL received and responded to 793 public record requests within the statutory 10-day response deadline or other timeframe agreed to by the requestor. BHPL led the total number of requests for bureaus and offices within DPH by approximately 100 requests in FY18.

Prescribing trend information demonstrated a 30% decline in Schedule II opioid prescriptions reported to the PMP from 841,990 in the first quarter of 2015 to approximately 568,000 in the second quarter of 2018.

In FY18, the Prescription Monitoring Program launched Electronic Health Record Integration pilots with several Health Care Entities: Partners Health, Walmart pharmacies and Boston Medical Center pharmacies. The Health Care Entities are utilizing Appriss Health's V5.1. Other Health Care Entities utilizing Epic software are anticipated to launch in FY19.

Introduction

BHPL is comprised of 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, DCP and the PMP, 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, the 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, 2018, BHPL licensed, registered, certified, or authorized 221,398 health care professionals and businesses. The staffing level of BHPL was comprised of 117 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.[3]

I. Appropriation account 4510-0721 supports[4] the Board of Registration in Nursing.[5]

II. Appropriation account 4510-0722 supports[6] the Board of Registration in Pharmacy.[7]

The FY18 General Appropriation Act continued to support pharmacy inspections and investigations with a total of $1.13M appropriated to the Board of Registration in Pharmacy. This funding was used by the Board of Registration in Pharmacy 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[8] the remaining eight boards: Community Health Workers, Dentistry, Genetic Counselors, Naturopathy, Nursing Home Administrators, Perfusionists, Physician Assistants, and Respiratory Care.[9]

IV. The Quality in Health Professions Trust Fund, account 4510-0727, supports[10] 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

[3] See Appendix A: *BHPL FY18 Board Funding.*
[4] See Appendix B: *BHPL FY18 Board of Registration in Nursing Expenditures Overview.*
[5] See Appendix C: *BHPL FY18 Board of Registration in Nursing Expenditures Detail.*
[6] See Appendix D: *BHPL FY18 Board of Registration in Pharmacy Expenditures Overview.*
[7] See Appendix E: *BHPL FY18 Board of Registration in Pharmacy Expenditures Detail.*
[8] See Appendix F: *BHPL FY18 Boards of Registration and Certification Expenditures Overview.*
[9] See Appendix G: *BHPL FY18 Boards of Registration and Certification Expenditures Detail.*
[10] See Appendix H: *BHPL FY18 Quality In Health Professions Trust Fund Expenditures Overview.*

permit streamlined and efficient operations for the issuance of licenses, registrations and certifications, the collection of revenue, the provision of information technology services, enforcement, investigations, legal services, and adjudicatory hearings, and budget and accounting functions. All funds expended from the trust fund are attributed to the shared administrative, licensing and enforcement activities of the 10 boards.[11]

The following is a summary of Board accounts 4510-0721, 4510-0722, and 4510-0725:
a. FY18 Board Appropriations - $2,135,175
b. FY18 Expenditures - $2,113,821.13

The following is a summary of the Trust account 4510-0727:
a. FY18 Trust Revenue - $11,117,044.50
b. FY18 Uncommitted Balance - $0

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

I. Retained revenue account 4510-0616 supports[12] DCP. In FY18, DCP was authorized to retain $1,029,680.00 of the revenue generated by Controlled Substance Registrations. Most Programs encompassed by DCP, including the Medication Administration Program (MAP) and DSP, rely on the central DCP account, 4510-0616, for operational funding.[13]

II. Account 4510-0617 supports[14] DCP through federal grant.[15]

III. Retained revenue account 4510-0040 supports[16] the Pharmaceutical and Medical Device Code of Conduct Program (PCOC). In FY18, PCOC was authorized to retain $73,061 of the revenue generated by PCOC.[17]

IV. Account 4510-0643 supports[18] the PMP through federal grant.[19]

[11] See Appendix I: *BHPL FY18 Quality In Health Professions Trust Fund Expenditures Detail.*
[12] See Appendix J: *BHPL FY18 Drug Control Program Expenditures Overview, 4510-0616.*
[13] See Appendix K: *BHPL FY18 Drug Control Program Expenditures Detail, 4510-0616.*
[14] See Appendix L: *BHPL FY18 Drug Control Program Expenditures Overview, 4510-0617.*
[15] See Appendix M: *BHPL FY18 Drug Control Program Expenditures Detail, 4510-0617.*
[16] See Appendix N: *BHPL FY18 PCOC Expenditures Overview*
[17] See Appendix O: *BHPL FY18 PCOC Expenditures Detail*
[18] See Appendix P: *BHPL FY18 PMP Expenditures Overview, 4510-0643*
[19] See Appendix Q: *BHPL FY18 PMP Expenditures Detail, 4510-0643.*

The following is a summary of DCP account 4510-0616:
a. FY18 DCP Revenue Collections - $4,670,825.00
b. FY18 BHPL Retained Revenue - $1,029,680.00
c. FY18 Expenditures - $975,731.87

The following is a summary of revenue and expenditure for PCOC – 4510-0040
a. FY18 DCP Revenue Collections - $956,000
b. FY18 BHPL Retained Revenue - $73,061.00
c. FY18 Expenditures - $26,753.72

Board 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 FY18, the BHPL Boards collectively resolved 572 formal complaints against health professional/facility licenses. Of the 572 formal complaints, 24%, or 139, were resolved by imposition of disciplinary action.

Probation Department

The Probation Department at BHPL monitors licensees whose practice is subject to conditions or who must fulfill requirements, either as part of a formal disciplinary probation or as a 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, 2018, the Probation Department was monitoring 137 participants.

In FY18, the Probation Department completed development of a new database for probation monitoring. The new database is capable of running 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 administered the Massachusetts Professional Recovery System (MPRS) for licensed health professionals (Dentists, Genetic Counselors, Nursing Home Administrators, Perfusionists, Pharmacists, Physician Assistants, and Respiratory Therapists). MPRS was a monitoring program that assisted licensed health professionals who had problems with alcohol and/or other drugs to return to practice while protecting the public's health, safety, and welfare. An advisory panel of 7 health care professionals with experience in substance use disorder treatment was available to consult with both participants and BHPL monitoring staff. The program took 5 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 FY18, MPRS did not admit any new participants or terminate any participants for unsuccessful completion of the program. Two participants were discharged with successful completion of the program. On November 2, 2017, MPRS was closed. At that time, MPRS was monitoring the compliance of 8 participants (7 pharmacists and 1 physician assistant). The 8 remaining participants transferred over to the new the Pharmacy Substance Use Disorder Program after approval from their respective licensing Boards.

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 5 years to successfully complete. SARP is designed to protect the public health, safety, and welfare by establishing adequate safeguards to maintain professional standards of nursing practice, while monitoring and supporting the ongoing recovery of participants and their return to safe nursing practice.

In FY18, the SARP staff conducted outreach activities at Endicott College and Salem State University to educate nursing students and faculty on the prevalence of substance use disorders among nurses and the role of SARP.

As of June 30, 2018, SARP was monitoring the compliance of 153 participants. During FY18, SARP admitted 22 new participants, terminated 14 participants for unsuccessful completion of the program, and discharged 21 participants after successful completion of the program.

The Pharmacy Substance Use Disorder Program

During FY18, the Pharmacy Substance Use Disorder Program (PSUD) began full operations. PSUD was established in 2016 by M.G.L. c. 112, §24H. PSUD is a voluntary, non-disciplinary approach to substance use disorder recovery among licensed pharmacists, pharmacy technicians and pharmacy interns. This new program allows the Board of Registration in Pharmacy to safely monitor pharmacists, pharmacy technicians and pharmacy interns with the goal of returning to safe pharmacy practice.

In FY18, the Rehabilitation Evaluation Committee (REC), consisting of 7 members recruited and appointed by the Board of Pharmacy, was initiated. In November 2017, PSUD began admissions. Education and community outreach programs were presented to 8 pharmacy groups including all 3 colleges of pharmacy in Massachusetts. Education was also published in the National Association of Boards of Pharmacy (NABP) newsletter.

In FY18, PSUD responded to 20 inquiries, received 16 applications for admission and enrolled 13 licensees.

Information Technology

In FY18, the Information Technology Department of BHPL (ITD) made multiple modifications and improvements to MyLicense Office (MLO), the licensure database utilized by BHPL, to improve efficiency in various licensure processes. These modifications and improvements are vital to BHPL becoming more data focused.

In FY18, ITD continued the data conversion piece of the Massachusetts Controlled Substance Registration (MCSR) Automation project. ITD staff scrubbed data, configured structure for the data transfer, and in FY19, will execute the conversion of controlled substance registrations to the BHPL online licensing platform.

During FY18, ITD created the new license type and corresponding online application for the Pharmacy Technician in Training license for the Board of Registration in Pharmacy. ITD staff also worked to develop the initial Community Health Worker certification for the Board of Certification of Community Health Workers. This new certification will be completed in FY19.

Lastly, in FY18, ITD staff began preparation for a new cloud environment and new application system updates for MLO that will be deployed in FY19.

Quality Improvement

Formed in FY17, the Quality Improvement Department (QID) of BHPL consists of dedicated staff that analyzes BHPL data to make informed decisions and recommendations for improvements of BHPL operations, and oversees all BHPL improvement initiatives. QID staff is focused on making BHPL data more accurate and accessible. The QID works with BHPL ITD to develop technological solutions that meet business requirements to increase workflow efficiency.

In FY18, the QID worked with the Executive Office of Technology Services and Security, and the BHPL Programs to transition the BHPL and BHPL Program webpages to the new Mass.gov website. Most of the new webpages have been operational for the second half of FY18. In FY19, the webpages will undergo a second round of review based on user feedback and comments.

The QID monitors BHPL staff training and makes recommendations for future trainings to BHPL leadership. In FY18, the QID sought specialized trainings for BHPL staff, working with the DPH Commissioner's Office to provide critical Customer Service Training for administrative staff. Five BHPL staff successfully completed DPH Lean Six Sigma Green Belt training, and 10 BHPL staff successfully completed DPH Lean Six Sigma White Belt training.

The QID is also responsible for oversight of BHPL public record requests. BHPL received and responded to 793 public record requests within the statutory 10-day response deadline or other timeframe agreed to by the requestor, during FY18. BHPL led the total number of requests for bureaus and offices within DPH by approximately 100 requests in FY18.

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

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

I. Each of the BHPL boards will accept relevant education, training, and service completed by a license applicant as a member of the armed forces or the military reserves toward the qualifications required for licensure pursuant to M.G.L. c. 112, §1B(b);

II. The license of an active duty service member remains valid until he or she is released from active duty, and for 90 days thereafter pursuant to M.G.L. c. 112, §1B(c);

III. BHPL expedites the licensure process for military spouses who are licensed in other states and have left employment there to accompany a spouse relocated to the Commonwealth due to a military transfer pursuant to M.G.L. c. 112, §1B(d); and

IV. BHPL waives the Commonwealth's portion of the initial application and licensure fees for all licenses issued pursuant to the VALOR Act pursuant to M.G.L. c. 112, §1B(g).

BHPL began receiving VALOR Act inquiries from service members, veterans and service member spouses in July 2013. From FY13 to FY17, BHPL staff processed 121 applications for licensure by service members, veterans, or spouses, and logged the active duty status of 79 licensed service members.

In FY18, BHPL received 39 licensure applications subject to the VALOR Acts, comprised of 16 active duty service members, 14 spouses of active duty service members and nine veterans.[20] The greatest concentration of applicants is military spouses applying for RN licensure.

In FY18, the active duty status of 18 licensed service members was logged and 8 active duty service licenses were manually renewed. The total number of active duty status licensees currently stands at 42. Appendix T shows the distribution of active service duty licensees, with the greatest concentration among Army dentists.[21] 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 forms that VALOR Acts applicants must submit. Active military, military spouses, and veterans must identify themselves as such in order to obtain these benefits. A Bureau-wide staff action policy adopted by all BHPL boards, authorizes the processing of license applications and renewals under the VALOR Acts in an efficient and consistent manner.

[20] See Appendix S: *FY18 VALOR Act Licensure Applications.*
[21] See Appendix T: *FY18 Active Service Duty Licensees.*

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: 4 CHWs, 1 CHW training organization representative, 1 community-based CHW employer, 1 Massachusetts Association of Health Plans representative, 1 Massachusetts League of Community Health Centers representative, 1 Massachusetts Public Health Association representative, and 1 public member. 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
Shawn Matthews, CHW member
Catherine Bourassa, Community-based CHW employer member
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

FY18 CHW Board Meetings

July 11, 2017
August 22, 2017
September 18, 2017
October 11, 2017
November 14, 2017
January 9, 2018
February 13, 2018
April 10, 2018
May 8, 2018
June 12, 2018

II. Accomplishments of the CHW Board

Draft Regulations: During FY18, the regulations for the CHW Board at 272 CMR Sections 2.00, 3.00, 4.00, 5.00, 7.00, 8.00, and 9.00 were promulgated. 272 CMR 6.00 was reserved for future development.

Training Program Applications: In FY18, the CHW Board finalized the Training Program Application Criteria. The criteria will be the standard by which the Board will review and approve training program applications. The criteria provided sub-regulatory guidance to training programs on 272 CMR 5.00.

Process Certification Applications: In FY18, the CHW Board finalized the Individual Certification application; application checklist, and Frequently Asked Questions (FAQs). the Board continued to work toward finalizing a user-friendly certification application for implementation, which will ensure that all forms and applications created will be fillable PDFs for easy completion.

Stakeholder Engagement: The Board Chair and Executive Director presented at the 9th Annual Community Health Worker/Patient Navigator Conference on May 3, 2018.

Board Composition: CHW Board staff continued to focus on filling CHW Board seats during FY18. In FY18, 1 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 FY18.

IV. Compliance: Disciplinary Statistics

Due to its recent establishment, the CHW Board took no disciplinary action in FY18.

The Board of Registration in Dentistry

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

I. Administration

About the Board

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

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

Dentistry Board Members

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

FY18 Dentistry Board Meetings

July 5, 2017
September 6, 2017
October 4, 2017
November 1, 2017
December 6, 2017
January 17, 2018
February 7, 2018
March 7, 2018
April 4, 2018
May 2, 2018
June 6, 2018

II. Accomplishments of the Dentistry Board

Complaint Committee: In FY18, the Dentistry Board's Complaint Committee continued to meet each month after scheduled monthly Board meetings as part of its ongoing effort to make a preliminary determination that sufficient evidence had been gathered to warrant the filing of formal complaints against licensees. The backlog of matters awaiting this preliminary review was successfully eliminated, leading the Board members to agree that future Complaint Committee meetings should be scheduled for every other month instead of every month.

Community Outreach: Dentistry Board members and staff participated in the Yankee Dental Congress in January 2018, hosting a one-hour continuing education course on current Dentistry Board licensure requirements, regulations and policies. In July 2017, Executive Director Barbara A. Young participated in the first annual Mobile Dental Resource Day in Waltham, MA and offered a presentation on the Board's current regulations regarding mobile and portable dentistry. In FY18, Executive Director Barbara A. Young also presented an ethics course to the current dental, dental hygiene and/or dental assisting students at the MCPHS/Forsyth School of Dental Hygiene in November 2017 and March 2018, Quinsigamond Community College in April 2018 and the Boston University School of Dental Medicine in May 2018.

Board Composition: Dentistry Board staff continued to maintain representative board membership during FY18.

III. Regulations and Policies

Safe and Effective Opioid Prescribing/Pain Mgmt. Mandatory Education: At its April 4, 2018 meeting, the Dentistry Board approved the following 2 continuing education courses on safe and effective opioid prescribing and pain management, proposed to meet the educational objectives of MGL c. 94C, §18(e):

- Dr. Richard Harold of the Massachusetts Dental Society proposed a course entitled, "Pharmacological Management of Acute Dental Pain and the Opioid Epidemic", which offers 2 contact hours; and
- Dr. Howard Pactovis of Dynamic Dental Safety, Inc. proposed a course entitled, "Opioid Safety and Pain Management in the Dental Office, which offers 2 contact hours.

Regulatory Review Workgroup: The Dentistry Board Regulatory Review Workgroup continued its comprehensive review of the Board's regulations at 234 CMR. All proposed changes to the Board's regulations will be submitted to the Board for its consideration and future promulgation. The Workgroup met on the following dates during FY18:

July 19, 2017
September 27, 2017
October 18, 2017
December 27, 2017
February 21, 2018
March 28, 2018
April 25, 2018
May 23, 2018

Malpractice Settlements: The Dentistry Board adopted a policy at its July 5, 2017 meeting that investigations would be opened upon notice from the National Practitioners Data Bank that a malpractice settlement of $25,000 or greater was reached against a named licensee.

Clinical Competency Examinations: The Dentistry Board adopted a policy at its July 5, 2017 meeting and further refined the policy on May 2, 2018, establishing that applicants for initial dental licensure who submit scores on the WREB (Western Regional Examination Board) clinical competency exam must include passing scores on the now optional prosthodontic and periodontic sections of the WREB and 2 restorative procedures in the operative section of the WREB.

Applications for Anesthesia/Sedation Facility Permits: The Dentistry Board adopted a policy at its Sept. 6, 2017 meeting to allow time for additional required submissions by stating that incomplete applications for anesthesia/sedation facility permits will be kept open for 3 months after the date the application was received, rather than 1 year, to avoid a delay in processing these applications and to assure the Board that current and accurate information had been provided by the applicant.

Continuing Education Requirements: The Dentistry Board adopted a policy at its March 7, 2018 meeting permitting licensed dentists who participate in a post-graduate specialty program to use the successful completion of that specialty training as the equivalent of the successful completion of 40 CEUs required for licensure renewal.

IV. License and Licensee Statistics

Biennial licensure,	6,740	Dentists
Biennial	7,226	Dental Hygienists
Biennial	8,575	Dental Assistants
Biennial	3,433	Dental Hygienists - Anesthesiology Permits
Annual	450	Limited and Faculty License
Biennial	682	Facility Permits
Biennial	244	General Anesthesia Permits
Biennial	721	Nitrous Oxide Permits
Biennial	312	Conscious Sedation Permits
Biennial	45	Portable Dental Operation and Mobile Dental Facility Permits
TOTAL	28,428	

V. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	**Number of Staff Assignment Investigations Closed**	**Number of Formal Complaints Opened**	**Number of Formal Complaints Resolved**	**Number of Formal Complaints Resolved with Discipline Imposed**	**% of Formal Complaints Resolved w/Discipline Imposed**
191	246	139	84	32	38%

The Board of Registration of Genetic Counselors

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

I. Administration

About the Board

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

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

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

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

GC Board Members

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

FY18 GC Board Meetings

December 4, 2017
April 5, 2018

II. Accomplishments of the GC Board

Application Processing Efficiency: In FY18, the application process was reviewed by the GC Board to eliminate the need for applicants to request verification to be mailed to the GC Board, as the American Board of Genetic Counseling Inc. (ABGC) now directly provides exam results to the GC Board and they are the primary source for exam results.

Board Composition: GC Board staff continued to focus on GC Board seats during FY18. During FY18, Board staff has submitted 1 new candidate for appointment, and 1 current member for reappointment.

III. Policies

Staff Action Policy 17 – 03: Petitions for Retirement Status was adopted December 4, 2017._This policy authorizes the Executive Director or his/her designee to place a licensee on a Retired status upon request of the licensee.

Remote Participation: At its April 5, 2018 meeting, the GC Board adopted a Remote Participation policy. Per M.G.L. c. 30A, §§18-25, a public body may use remote participation in the administration of meetings provided that the process is adopted by the Board and the minimum requirements are met.

IV. License and Licensee Statistics

Biennial licensure	319	Genetic Counselors
	6	Provisional Genetic Counselors
TOTAL	325	

V. Compliance: Disciplinary Statistics

The GC Board took no disciplinary action in FY18.

The Board of Registration in Naturopathy

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

I. Administration

About the Board

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

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

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

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

FY18 Board Meetings:
October 24, 2017
November 28, 2017
January 23, 2018
February 27, 2018
March 27, 2018
April 24, 2018
May 22, 2018
June 26, 2018

II. Accomplishments of the Naturopathy Board

Regulations: In FY18, the Naturopathy Board began to discuss and draft regulations. The finalized draft regulations, once agreed upon by the Naturopathy Board, will be submitted for administrative review, opened for public comment, and promulgated in FY19.

III. License and Licensee Statistics

Due to its recent establishment, the Naturopathy Board did not process any applications for licensure in FY18.

IV. Compliance: Disciplinary Statistics

Due to its recent establishment, the Naturopathy Board took no disciplinary action in FY18.

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 9 registered nurses, 4 licensed practical nurses, 1 physician, 1 pharmacist, and 2 consumers. By statute, nine members are required to be present to constitute a quorum.

Nursing Board Members

Barbara Levin, RN, BSN, ONC, CMSRN, LNCC, Direct Care Member, Chairperson
Lori Keough, PhD, CNP, Advanced Practice Direct Care Member, Vice Chairperson
Eleonor Pusey-Reid, DNP, Bachelor's Degree Educator Member
Linda Kelly, DNP, CNP, Advanced Practice Direct Care Member
Colleen LaBelle, BSN, RN, Direct Care Member
Anthony Alley, MSN, RN, NE-BC, RN, Service Administrator
Joan Killion, LPN, LPN, Acute Care Member
Gail Dufault, LPN, LPN, Community Health Member
Nicole Murphy, LPN, Long term Care Member
Jackie Fantes, MD, FAAFP, Physician Member
Kelly Barnes, JD, RPH, Pharmacist Member
Deborah Drew, Consumer Member

FY18 Nursing Board Meetings

July 12, 2017
August 9, 2017
September 13, 2017
October 11, 2017
November 8, 2017
December 13, 2017
January 10, 2018
February 14, 2018
March 14, 2018
April 11, 2018
May 9, 2018
June 13, 2018

II. Accomplishments of the Nursing Board

Paperless Licensure: In FY18, the Nursing Board stopped issuing paper licenses and began sending license renewal notices to licensees via email. This paperless initiative began with the Registered Nurse renewal cycle that opened in November 2017.

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, 2018, there were 69 Nursing Board-approved registered nurse and practical nurse education programs:

- 23 practical nurse programs:
  - Pre-requisite approval: None
  - Initial approval status: None
  - Approval with warning status:
    - Roxbury Community College (2/8/17 Board action)
  - Withdrawal of approval:
    - Quincy College, (May 9, 2018 Board action)
  - Full approval: all other practical nurse programs (21)
- 19 registered nurse associate degree programs:
  - Pre-requisite approval status: None
  - Initial approval status: None
  - Approval with warning status:
    - Roxbury Community College (2/8/17 Board action)
  - Withdrawal of approval:
    - Quincy College (May 9, 2018 Board action)
  - Full approval status: all other associate degree programs (17)
- 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 August 2017 and February 2018, introducing 31 new nurse administrators and administrative staff to the Nursing Board's regulations at 244 CMR 6.00, *Approval of Nursing Education Programs and the General Conduct Thereof*, including the regulatory requirements for Massachusetts nurse licensure by examination.

Nursing Faculty Workshop: The Nursing Board hosted 105 nursing faculty at a Faculty Workshop: *Faculty Role in Maintaining Program Compliance with Nursing Education Regulation with Discussion of Pending Regulatory Changes* in September and October of 2017.

III. Regulations and Policies

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 FY18, the Nursing Board updated the following Advisory Rulings in accordance with its systematic review schedule:

AR 10:02 Massachusetts Advance Practice Registered Nurse Prescriptive Authority in Veteran Health Administration or Other Qualified Federal Entities in Jurisdictions Other than Massachusetts
AR 14:01 Enhancing the Disclosure of Unanticipated Outcomes
AR 93:05 Foot Care
AR 93:24 Accepting, Verifying, Transcribing and Implementing Prescriber Orders
AR 08:01 Cardiopulmonary Resuscitation in Long-term Care Facilities

During FY18, the Nursing Board also adopted
AR 18:01 Licensure Eligibility to Practice.

Policy Review: In FY18, the Nursing Board updated the following policies in accordance with its systematic review schedule:

Licensure Policy 17-03 Board Delegation to Board Staff to Make Final Determination of Good Moral Character Compliance
Licensure Policy 99-04 Staff Action in the Determination of Good Moral Character Compliance for Initial Nurse Licensure by Examination or by Reciprocity, or for Advanced Practice Authorization by the Board
SARP Policy 05-001 SARP Eligibility Criteria and Admission Process
SARP Policy 07-001 SARP Bridge Agreement
SARP Policy 05-002 Staff Action Policy for Admission to SARP
SARP Policy 13-01 SARP Eligibility Criteria for Nurses Prescribed a Buprenorphine/Naloxone Combination

During FY18, the Nursing Board also adopted
Education Policy 18-01: Board Delegation Authority to Approve Qualified Nursing Program Administrator.

IV. License and Licensee Statistics

Biennial licensure	117,936	Registered Nurses (RN)
	504	RN Nurse Midwives
	9,601	RN Nurse Practitioners
	663	RN Psychiatric Clinical Nurse Specialists
	67	RN Clinical Nurse Specialists
	1,277	RN Nurse Anesthetists
	21,028	Licensed Practical Nurses (LPN)
TOTAL	151,076	

V. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	**Number of Staff Assignment Investigations Closed**	**Number of Formal Complaints Opened**	**Number of Formal Complaints Closed**	**Number of Formal Complaints Closed with Discipline Imposed**	**% of Formal Complaints Resolved w/Discipline Imposed**
111	**118**	**316**	**242**	**143**	**59%**

The Board of Registration of Nursing Home Administrators

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

I. Administration

About the Board

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

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

NHA Board Members

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

FY18 NHA Board Meetings

July 21, 2017
August 18, 2017
September 15, 2017
October 20, 2017
November 17, 2017
January 19, 2018
February 16, 2018
April 20, 2018
May 18, 2018
June 15, 2018

II. Accomplishments of the NHA Board

Board Composition: NHA Board staff continued to focus on filling NHA Board seats in FY18. During FY18, 1 new NHA Board member was appointed, and Board staff submitted 3 current members for re-appointment.

III. Policies

Staff Action Policy 17 – 03: Petitions for Retirement Status was adopted September 15, 2017. This policy authorizes the Executive Director or his/her designee to place a licensee on a Retired status upon request of the licensee.

Sanction Hearing Policy: At its September 15, 2017 meeting, the NHA Board adopted a Sanction Hearing policy, requiring the full Board to preside over sanction hearings rather than an administrative hearings officer, who currently presides over these hearings. This policy seeks to shorten the time between a sanction hearings and the issuance of a Tentative Decision and Final Decision and Order.

Staff Authority to Renew Expired Licenses: The NHA Board adopted this staff action policy on November 17, 2017 to describe the criteria by which Board staff may renew an individual's license consistent with 245 CMR 3.06 (1) and (2).

Staff Action on Nursing Home Survey Reports: The NHA Board adopted revisions to this existing policy on April 20, 2018 to provide greater specificity in allowing the Executive Director or designee to resolve investigations in a timely manner.

IV. License and Licensee Statistics

Annual licensure	890	Nursing Home Administrators
	83	Administrators in Training (Internship)
TOTAL	973	

V. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	**Number of Staff Assignment Investigations Closed**	**Number of Formal Complaints Opened**	**Number of Formal Complaints Resolved**	**Number of Formal Complaints Resolved with Discipline Imposed**	**% of Formal Complaints Resolved w/Discipline Imposed**
21	**27**	**6**	**4**	**2**	**50%**

The Board of Registration of Perfusionists

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

I. Administration

About the Board

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

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

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

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

Perfusionist Board Members

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

FY18 Perfusionist Board Meetings

December 5, 2017

II. Accomplishments of the Perfusionist Board

Board Composition: Perfusionist Board staff continued to focus on Perfusionist Board seats in FY18. During FY18, 1 new Perfusionist Board member was appointed, 1 current Board member was submitted for reappointment, and 2 candidates were submitted for appointment.

III. Policies:

Staff Action Policy 17-01: Collection of Social Security Numbers and Department of Revenue Suspensions: This policy was adopted by the Perfusionist Board on December 5, 2017, allowing licensees' social security numbers to be shared with the Department of Revenue to uphold their statutory authority to instruct the Board to revoke licenses for failure to pay child support or taxes.

Referrals to the Office of the Attorney General: The Perfusionist Board adopted this policy on December 5, 2017, allowing Board staff to refer cases to the Office of the Attorney General when appropriate.

IV. License and Licensee Statistics

Biennial licensure, except Provisional Licenses, which are annual.	117	Full Licenses
	4	Provisional Licenses
TOTAL	121	

V. Compliance: Disciplinary Statistics

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

The Board of Registration in Pharmacy

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

I. Administration

About the Board

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

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

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

Pharmacy Board Members

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

FY17 Pharmacy Board Meetings

August 3, 2017
September 7, 2017
October 5, 2017
November 2, 2017
December 7, 2017
January 22, 2018 (Rescheduled from January 4, 2018 for weather)
February 1, 2018

March 1, 2018
April 5, 2018
May 3, 2018
June 7, 2018
June 28, 2018

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 FY18, the expert members weighed in on important pharmacy topics, including an Advisory on Pharmacy Response to failed HEPA filters and ISO-Classified Environments adopted 2/1/18; Draft Policy 2018-xx Emerging Models of Pharmacy Practice Including Central Fill, Central Processing, and Telepharmacy (Shared Pharmacy Services); and guidance for providing counseling/printed material/drug information for compounded products. The Advisory Committee will continue to advise the Pharmacy Board in FY19, with expert advice and input prior to the Board voting on promulgation of 247 CMR 17.00 Sterile Compounding.

The Advisory Committee is made up of 8 members, including the Commissioner of Public Health or their designee, 1 expert in USP Chapter 71, 1 expert in USP Chapter 795, 1 expert in USP Chapter 797, 1 expert in Pharmacoeconomics, 1 expert in Clinical Pharmacology, 1 Microbiologists, and 1 expert in cGMP for aseptic processing. At the request of the board, the commissioner may appoint additional members knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine or related specialties. By statute, 5 members are required to be present to constitute a quorum.

Advisory Committee Members

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

FY18 Advisory Committee Meetings
November 16, 2017
May 17, 2018

II. Accomplishments of the Pharmacy Board

Licensure of Pharmacy Technicians in Training: Following the promulgation of 247 CMR 8.00, the Pharmacy Board began accepting applications and issuing licenses for the newly established Pharmacy Technician in Training license. A Pharmacy Technician in Training is an individual training to become a Pharmacy Technician through on the job training. Since the implementation of this new license type, no individual in the Commonwealth of Massachusetts may work behind a pharmacy counter with access to controlled substances prior to receiving a Pharmacy Board license.

Naloxone Standing Orders: In the fall of 2017, the Pharmacy Board, in collaboration with the Department of Public Health's Bureau of Substance Addiction Services, determined that all areas of Massachusetts experience high incidences of opioid-related overdoses or deaths compared to the national average. With this determination, all pharmacies are now required to stock naloxone in accordance with M.G.L. c. 94C section 19C. The Pharmacy Board inspectors ensure compliance during routine pharmacy inspections.

Pharmacy Board Newsletter: In FY18, the Board of Pharmacy began an educational quarterly newsletter in conjunction with the National Association of Boards of Pharmacy (NABP). The newsletter consists of regulatory updates as well as guidance regarding common pharmacy practice issues.

Pharmacy Board-Approved Continuing Education Programs: The approval of continuing education programs by the Pharmacy Board staff is a valuable service provided to the pharmacy community at no charge. To provide continuing education credit for lectures provided by small groups of presenters such as pharmacy residents and interns, the Pharmacy Board approved 150 such programs in FY18.

Pharmacy Technician Training Programs: Pursuant to Policy 2017-01, which establishes standards for pharmacy technician training programs and exams, the Pharmacy Board approved 10 pharmacy technician training programs.

Pharmacy Compliance Inspections: During FY18, 12 pharmacy investigators, on behalf of the Pharmacy Board, conducted a total of 2,323 pharmacy inspections in the following categories:

- 1,931 retail compliance inspections;
- 58 non-sterile compounding inspections;
- 37 sterile compounding inspections;
- 248 site visits;
- 43 wholesale distributor inspections; and
- 6 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 FY19 with a full roster of pharmacy investigators.

Nuclear Pharmacy Inspections: During FY18, the Pharmacy Board utilized a contracted expert from the NABP to conduct inspections of the 6 nuclear pharmacies in Massachusetts. 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 FY18, the Director of Pharmacy Investigations and two Pharmacy Investigators attended NABP sponsored sterile compounding training. Staff and investigator training continues to be a priority for the Pharmacy Board, with several trainings scheduled for FY19.

Educational Outreach: Pharmacy Board staff continued to make outreach a large focus of FY18, 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:

- Multi-dose packaging regulation review for Long Term Care Facilities for the American Society of Consulting Pharmacists;
- Pharmacy Substance Use Disorder Series for Massachusetts College of Pharmacy and Health Sciences University, Northeastern University, and Western New England University Pharmacy inspection process overview at Massachusetts College of Pharmacy and Health Sciences – Worcester;
- PharmEd Conference Series;
- Northeastern University lecture series: "Compounding: Implementing Best Practices for Sterile and Non-Sterile Compounding 2018";
- Board of Pharmacy Regulatory Update Series for MassHealth and Conduent;
- Board of Pharmacy Regulatory Update at the Massachusetts Health Council;
- Board of Pharmacy Regulatory Update at Massachusetts College of Pharmacy and Health Sciences - Reed 2018;
- Board of Pharmacy Regulatory Update at the 7th Annual Alumni, Friends and Preceptor Anniversary at Northeastern University.

Stakeholder Meetings: In FY18, Pharmacy Board staff held several meetings with stakeholders to discuss issues such as renovation/expansion of sterile compounding pharmacies and innovative pharmacy practices. In FY18, the Board participated in 52 such meetings with pharmacists, hospitals, retail pharmacies, technology companies, and other healthcare organizations.

III. Regulations and Policies

Proposed Amendments and Additions to 247 CMR: Following the 2012 multi-state meningitis outbreak that was attributed to products from a Massachusetts-based pharmacy, sweeping pharmacy practice reform was mandated by 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 detailed review of each change during the open session of Pharmacy Board meetings in FY15, FY16, FY17, and FY18.

The *highlights* of the Pharmacy Board's activities in FY18 related to amending regulations and promulgating new regulations include the following:

247 CMR 3.00: Personal Registration	• Final Draft Adopted by Board: 08/02/16 • Public Hearing: 09/19/16 • Board Review and Vote on Public Comment: 01/05/17 • Promulgated: 08/11/17
247 CMR 5.00: Orally & Electronically Transmitted Prescriptions	• Final Draft Adopted by Board: 11/01/16 • Public Hearing: 06/29/17
247 CMR 6.00: Licensure of Pharmacies	• Final Draft Adopted by Board: 04/05/17 • Public Hearing: 06/29/17
247 CMR 8.00: Pharmacy Interns and Technicians	• Final Draft Adopted by Board: 08/02/16 • Public Hearing: 09/19/16 • Board Review and Vote on Public Comment: 03/02/17 • Promulgated: 04/06/18
247 CMR 9.00: Professional Practice Standards	• Final Draft Adopted by Board: 11/01/16 • Public Hearing: 06/29/17
247 CMR 10.00: Disciplinary Proceedings	• Final Draft Adopted by Board: 08/02/16 • Public Hearing: 09/19/16 • Board Review and Vote on Public Comment: 01/05/17
247 CMR 12.00: Restricted Pharmacy	• Final Draft Adopted by Board: 11/01/16 • Public Hearing: 06/29/17
247 CMR 14.00: Petition for Waiver	• Final Draft Adopted by Board: 08/02/16 • Public Hearing: 11/30/16 • Board Review and Vote on Public Comment: 03/02/17 • Promulgated: 09/22/17
247 CMR 15.00: Continuous Quality Improvement Program	• Final Draft Adopted by Board: 11/01/16 • Public Hearing: 06/29/17

247 CMR 16.00: Collaborative Drug Therapy Management	• Final Draft Adopted by Board: 08/02/16 • Public Hearing: 09/19/16 • Board Review and Vote on Public Comment: 03/02/17 • Promulgated: 12/15/17
247 CMR 17:00: Sterile Compounding	• Public Hearing: 11/13/17
247 CMR 18.00: Non-Sterile Compounding	• Public Hearing: 07/18/16 • Board Review and Vote on Public Comment: 11/01/16
247 CMR 20.00: Reporting	• Final Draft Adopted by Board: 11/01/16 • Public Hearing: 06/29/17

Advisory on Best Practice Recommendations for Prescription Delivery: With the increasing number of pharmacies offering delivery of prescription medications, the Pharmacy Board developed this guidance document centering on patient safety and confidentiality as well as drug security throughout the steps of the delivery process.

Advisory on Controlled Substance Inventory Management: In an effort to provide additional guidance on drug control within the pharmacy setting, the Pharmacy Board created this advisory to help with the timely detection of discrepancies or losses, reduce the likelihood of theft, as well as increase personal accountability, patient safety, and enhance medication delivery systems.

Advisory on Failed HEPA-filters in ISO-classified Environments: As this topic is not addressed in the sterile compounding chapter of the United States Pharmacopoeia (USP), the Pharmacy Board felt that guidance and remediation steps in the event of a High Efficiency Particulate Air (HEPA) filter failure in an ISO classified environment was needed.

Advisory on Conducting Repairs/Service to Sterile Compounding/Complex Non-Sterile Facilities: As some minor repairs and equipment maintenance may be performed without Board approval, the Board developed this advisory to provide guidance as to what projects would be included as requiring Board approval. This advisory offers advice on how to protect the sterile environment and compounded products during the work.

Policy 2018-01: Permitted Prescription Changes: In response to new requirements, DCP and the Pharmacy Board collaborated to issue this policy clarifying the amendments and additions pharmacists may make to prescriptions after consultation with prescribers or their agents.

Policy 2018-02: Continuing Education (CE) Credits for Post-Graduate Pharmacy Academic Classes: The Pharmacy Board developed this policy to allow pharmacists acquiring post-graduate education in the field of pharmacy to receive CE credit if the classes meet certain requirements.

Policy 2018-03: Pharmacist Continuing Education Requirements: Updated this policy to include general language revisions as well as a "grace" period to obtain the mandatory continuing education for those pharmacists who received state licensure late in the calendar year.

Policy 13-01: Staff Action Expanded to Approve Technician Trainee licenses: This policy was updated to provide pharmacy board staff the ability to approve license requests for technician trainees based on specific criteria.

Policy 14-01: Staff Action to Identify Individual Licensure Applications requiring Good Moral Character evaluation: This policy sets criteria for determining which license applicants must appear for a good moral character evaluation and which may be licensed without such appearance. The policy was updated to address pharmacy technicians in training applications.

Policy 14-02: Board Delegated Review: The Board of Pharmacy updated this policy allowing Board staff, with 1 Board member, to resolve Staff Assignments relating to pharmacist continuing education deficiencies.

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

IV. License and Licensee Statistics

Biennial licensure, except Wholesale Distributors, which are annual	13,299	Pharmacists
	67	Nuclear Pharmacists
	10,941	Pharmacy Technicians
	2,177	Pharmacy Technicians in Training
	4,840	Pharmacy Interns
	1,142	Retail Pharmacies
	1,168	Retail Pharmacy Controlled Substance Permits
	41	Certificate of Fitness Permits
	6	Nuclear Pharmacies
	42	Wholesale Distributors
	42	Wholesale Distributors Controlled Substance Permits
	2	Resident Outsourcing Facilities
	45	Non-Resident Outsourcing Facilities
	1	Provisional Outsourcing Facility
	3	Outsourcing Controlled Substance
TOTAL	33,816	

V. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	Number of Staff Assignment Investigations Closed	Number of Formal Complaints Opened	Number of Formal Complaints Resolved	Number of Formal Complaints Resolved with Discipline Imposed	% of Formal Complaints Resolved w/Discipline Imposed
151	**207**	**127**	**237**	**82**	**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 9 members: 4 PAs, 1 PA educator, 2 public members, and 2 physicians, 1 of which is a member of the Massachusetts Medical Society. By statute, 5 members are required to be present to constitute a quorum.

PA Board Members

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

FY18 PA Board Meetings

July 13, 2017
September 14, 2017
October 12, 2017
December 14, 2017
February 8, 2018
April 12, 2018
June 14, 2018

II. Accomplishments of the Board

Board Composition: PA Board staff continued to focus on PA Board seats during FY18. During FY18, 1 new PA Board member was appointed. In addition, Board staff submitted 3 current members for reappointment.

Educational Outreach: In FY18, PA Board staff and PA Board Chair, Dipu Patel-Junankar, presented an overview of the PA Board to the graduating classes of PA students at the following Massachusetts colleges and universities:

- Tufts University on September 1, 2017
- Northeastern University on April 13, 2018
- BayPath University on April 26, 2018
- Boston University on June 29, 2018

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

On February 8, 2018, the PA Board conducted an interactive mock Board meeting for students in the Northeastern University PA program. The mock meeting included role-playing by students, Board members, and Board staff, using fictitious cases based on common issues that come before the Board.

III. Policies

Staff Action Policy 17 – 03: Petitions for Retirement Status was adopted September 14, 2017. This policy authorizes the Executive Director or his/her designee to place a licensee on a Retired status upon request of the licensee.

Remote Participation: At its February 8, 2018 meeting, the PA Board adopted a Remote Participation policy. Per M.G.L. c. 30A, §§18-25, a public body may use remote participation in the administration of meetings provided that the process is adopted by the Board and the minimum requirements are met.

Sanction Hearing Policy: At its September 15, 2017 meeting, the PA Board adopted a Sanction Hearing policy. The policy requires the full Board to preside over sanction hearings rather than an administrative hearings officer, who currently presides over these hearings. This policy seeks to shorten the time between a sanction hearing and the issuance of a Tentative Decision and Final Decision and Order.

Website Alerts: In FY18, the PA Board posted 2 Alerts to its web page:

1. Scope of Pain: Information about websites where pharmacology CMEs may be attained.
2. MassHealth Order and Refer Enrollment Process: Physician Assistants must enroll with MassHealth as an Ordering, Referring and Prescribing non-billing provider (*if not already enrolled with MassHealth as an approved, billing provider*) before seeking to renew his or her Physician Assistant license.

IV. License and Licensee Statistics

Biennial licensure	3,816	Full Licenses
	0	Temporary Certifications
TOTAL	3,816	

V. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	Number of Staff Assignment Investigations Closed	Number of Formal Complaints Opened	Number of Formal Complaints Resolved	Number of Formal Complaints Resolved with Discipline Imposed	% of Formal Complaints Resolved w/Discipline Imposed
6	**10**	**12**	**2**	**2**	**100%**

The Board of Respiratory Care

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

I. Administration

About the Board

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

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

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

RC Board Members

Paul Nuccio, MS, RRT, FAARC, Respiratory Therapist Member, Chair
Jordan Rettig, MD, Physician Member, Vice-Chair
Martha DeSilva, Respiratory Therapist Member, Secretary
Essam Ansari, MD, Physician Member
Molly Caravallo, RN, Nurse Member

FY18 RC Board Meetings

July 18, 2017
September 19, 2017
Ocotober 17, 2017
April 17, 2018

II. Accomplishments of the Board

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

Board Composition: RC Board staff continued to focus on RC Board seats in FY18. During FY18, 2 current members were submitted for reappointment.

III. Policies

Sanction Hearing Policy: At its October 17, 2017 meeting, the RC Board adopted a Sanction Hearing policy, requiring the full Board to preside over sanction hearings rather than the currently require administrative hearings officer. This policy seeks to shorten the time between a sanction hearings and the issuance of a Tentative Decision and Final Decision and Order.

Staff Action Policy 15-01: The RC Board amended this policy on October 17, 2017, giving RC Board staff broader authority to dispose of specified Staff Assignments and Complaints.

Staff Action Policy 17-01: Collection of Social Security Numbers and Department of Revenue Suspensions: This policy was adopted by the RC Board on April 17, 2018. The policy allows licensees' social security numbers to be shared with the Department of Revenue to uphold their statutory authority to instruct the RC Board to revoke licenses for failure to pay child support or taxes.

Website Alerts: In FY18, the RC Board posted 2 Alerts to its web page:

1. **An Act Relative to Respiratory Therapy:** M.G.L. c. 112, §23V, enacted on July 18, 2017, authorizes employees of durable medical equipment companies, who have completed a minimum of 500 hours of positive airway pressure equipment and supply-related training under the supervision of a respiratory therapist licensed in the Commonwealth, to perform the delivery, initial setup and maintenance of positive airway pressure equipment and supplies for home care patients.

2. **Alert on the Insertion and Maintenance of Arterial Lines and Vascular Catheters:** This alert notifies licensees and the general public that the RC Board voted to adopt the American Association for Respiratory Care's position on the insertion and maintenance of arterial lines by respiratory therapists and the insertion and maintenance of vascular access catheters by respiratory therapists.

III. License and Licensee Statistics

Biennial licensure	2,801	Full Licenses
	44	Limited Permits (no renewals)
TOTAL	2,845	

IV. Compliance: Disciplinary Statistics

Number of Staff Assignment Investigations Opened	Number of Staff Assignment Investigations Closed	Number of Formal Complaints Opened	Number of Formal Complaints Resolved	Number of Formal Complaints Resolved with Discipline Imposed	% of Formal Complaints Resolved w/Discipline Imposed
3	**1**	**2**	**3**	**3**	**100%**

The Drug Control Program

M.G.L. c. 94c

About the Program

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

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

Massachusetts Controlled Substances Registration

M.G.L. c. 94C

I. Administration

About the Department

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

II. Accomplishments of the Department

MCSR Data Cleansing: In FY18, staff continued to prepare for the conversion of MCSR data to the BHPL licensing database, MLO in FY19. Staff from ITD and QID worked with MCSR staff to fix errors in provider records.

III. Registration Statistics

Annual licensure, except Physicians, which are every three years		Advanced Practice Registered Nurses
		Optometrists
	61	Pharmacists
	3,188	Physician Assistants
	29,621	Practitioners (Physicians, Podiatrists and Dentists)
	2,128	Veterinarians
	952	Research studies
	23	Analytical Labs
	551	Ambulances
	805	Clinics
	132	Drug distributors
	82	Drug manufacturers
	49	Drug distributors and manufacturers
	145	Hospitals
	234	Municipalities
	28	Non-Municipal Public Agency
TOTAL	45,292	

DCP Enforcement Unit

I. Administration

About the Unit

The Enforcement Unit (EU) of DCP promotes effective security and accountability to prevent theft, tampering, misuse and abuse of 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 use disorder. 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, and 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 change, or change in controlled substance storage and accountability. During complaint investigations, routine audits of narcotic security and accountability may be conducted to improve drug security and accountability.[22]

[22] See Appendix R: *Drug Control Program Enforcement Unit Disciplinary Statistics*.

The Medication Administration Program
105 CMR 700.003(F)

I. Administration

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

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

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

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

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

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

II. Accomplishments of the MAP

Curriculum: A new Curriculum *Responsibilities in Action-Understanding the Connections* was developed in FY18 and will be in place at MAP Registered sites by June 30, 2019, as the previous curriculum and trainings will be phased out.

III. Regulations and Policies

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

Amendments to MAP regulations in 105 CMR 700.003(F), relative to requirements for stable populations and dedicated staff work, will take effect in FY19.

IV. MAP: MCSR Statistics

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

Department	Number of Service Providers	Number of Sites issued MCSR
DDS	164	2726
DMH	45	555
Caring Together DMH/DCF	43	141
Youth Therapeutic Day Services	5	10
TOTAL	257	3,432

VI. Hotline Medication Occurrences Reports

MAP Registered sites are required to report any Medication Occurrence directly to DCP within 24 hours of discovery, followed by a medical intervention (e.g., lab work, tests, health care provider visit, clinic visit, ER visit, hospitalization, etc.), illness, injury or death. In FY18, there were 134 Medication Occurrence 'hotlines' reported to DCP.

The Drug Stewardship Program

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

I. Administration

About the Program

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

II. Accomplishments

Stakeholder Engagement and Communication: DSP worked closely with pharmaceutical manufacturer associations and stewardship collaboratives to develop guidance and compliance checklists. DSP, through relationships with the Federal Food and Drug Association, developed complete lists of covered manufacturers to ensure communication, which described 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 one Plan submission from a manufacturing collaborative, called MED-Project. The collaborative is comprised of over 150 member manufacturers who buy into the Plan manager, MED-Project. DSP and MED-Project have collaborated to ensure this sole statewide Plan provides a comprehensive and effective method of ensuring the safety and security of unwanted medications.

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

medicines once they are no longer needed for the purpose for which they were prescribed, and options to dispose of unwanted drugs conveniently and safely. MED-Project's Plan is expected to receive final approval in early FY19 and immediately begin operation.

III. Regulations and Policies

The STEP Act created 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.

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

IV. Participation Statistics

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

VI. Compliance

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

The Drug Formulary Commission

M.G.L. c. 17, §13

I. Administration

About the Program

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

Members of the DFC are appointed by the Governor and include practicing physicians and pharmacists, pharmaceutical researchers, addiction specialists and patient advocates. DFC currently has 3 vacancies. DCP staff plan meeting agendas and develop materials in consultation with a consultant pharmacist from the University of Massachusetts Medical School.

Commission Members:

James Lavery, BHPL Director, DPH Commissioner's designee
Dr. Paul Jeffrey, Director of Pharmacy, MassHealth designee
Tracey McMillan, Bureau of Managed Care, Division of Insurance designee
Dr. Joanne Doyle Petrongolo, Clinical Chemist member
Dr. Jeffrey Supko, Pharmaceutical Chemist member
Dr. Theoharis Theoharides, Clinical Pharmacologist member
Dr. Virginia Lemay, Retail Pharmacist member
Dr. Daniel Carr, Pharmaceutical Manufacturing member
Cheryl Campbell, Biologics Manufacturing member
Dr. Alexander Walker, Practicing Physician member
Dr. Shihab U. Ahmed, Practicing Physician (pain management) member
Logan Leslie, Public member
Cindy Steinberg, Public (elderly representative) member

FY18 Commission Meetings:

August 17, 2017
October 19, 2017
December 14, 2017
February 5, 2018
March 15, 2018
May 17, 2018

II. Accomplishments of the Commission

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

Regulation: On August 9, 2017, the Public Health Commission approved the revision of 105 CMR 720: *Massachusetts List of Interchangeable Drug Products*, changing its name to *"Drug Formulary Commission"* and substituting the outdated purpose of the regulation, to provide for a means of determining which generic drugs can be substituted for brand name drugs, with the current purpose, to guide the work of the DFC and publish the Formulary. The regulation is awaiting final promulgation.

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

I. Administration

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

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

II. Accomplishments

Covered Recipient List: The program must create an annual list of recipients covered by 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.

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 Drug Enforcement Administration (DEA) 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 Act reports must be published by PCOC within 90 days of receipt from the DEA.

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

As a result of this federal change, PCOC regulations, 105 CMR 970, must be reviewed and amended to ensure compliance in FY19.

IV. Registration Statistics

PCOC staff received 39 initial registrations since July 1, 2017 and 361 registration renewals in the same period, for a total of 400 registered drug and device manufacturers. A total of 19,240 payments were reported to 10,890 recipients. These figures do not include preempted Federal Sunshine Act payments.

V. Compliance: Disciplinary Statistics

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

The Prescription Monitoring Program

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

I. Administration

About the Program

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

Nationwide, PMPs are important tools to support safe and appropriate prescribing. Information provided by PMPs help prescribers and pharmacists identify individuals who may be misusing, abusing, or diverting prescription controlled 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[23], 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.

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

MassPAT is also made available to Law Enforcement and Regulatory agents who complete a 4-hour training in the use of MassPAT, and substance abuse. Utilization of MassPAT by law enforcement and regulatory agents during FY2018 required an open and ongoing drug related investigation. The PMP provided regular training opportunities in various locations throughout the state to promote effective use of MassPAT by these agents.

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

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

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

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

The Prescription Monitoring Program Medical Review Group (MRG)

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

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

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

MRG Members:
Dr. Douglas Brandoff, MD, physician member
Dr. Alfred DeMaria, MD, physician member
Dr. Edward Michna, MD, physician member
Dr. Mina Paul, DMD, dentist member
Scott DeCesare, PharmD, R.Ph., pharmacist member
Karen Horbowicz, PharmD, R.Ph., pharmacist member
Emily Rowe, PharmD, R.Ph., pharmacist member
Christopher Shaw, NP, advanced practice registered nurse member
Dawn Williamson, NP, advanced practice registered nurse member
Angelo Pucillo, PA, physician assistant member

FY18 MRG Meeting Dates:
July 27, 2017
September 28, 2017
November 30, 2017
January 25, 2018
May 24, 2018

II. Accomplishments of the PMP

MassPAT Enhancements: During FY18, the PMP concentrated on enhancements to MassPAT to improve user experience and value as a clinical tool, improvements to the statutorily required Prescriber Reports (M.G.L. c. 94C, sec.24B), and the integration of the MassPAT data into provider's EHR systems and pharmacy software programs. In addition, the PMP continued its efforts to improve the timeliness and accuracy of the data collected in the PMP Clearinghouse.

Utilization: In FY18, MassPAT searches topped 6,330,000, an increase of over 1 million searches from FY17. As a result, the PMP shifted focus in FY18 from promoting registration to compliance with the law that requires a practitioner to utilize MassPAT. A prescriber must utilize MassPAT prior to:

1. Each issuance of a prescription to a patient for a narcotic drug in Schedule II or III; and
2. Prescribing a benzodiazepine to a patient for the first time.

With the goal of compliant utilization, in the spring of 2018, the PMP launched a monthly compliance report for program administrators and a "Compliance Report" tab in MassPAT, allowing each prescriber to view a list of their prescriptions that require MassPAT utilization and verify that a search had been conducted on that patient prior to the issuance of the prescription. PMP staff is hopeful that this feature will remind prescribers to be diligent in following this mandate.

Prescriber Reports: On March 1, 2017, the first prescriber report[24] was sent to each prescriber of at least 1 Schedule II or III opioid during the 2016 calendar year, as required by M.G.L. Chapter 94C, §24B. The individual reports were produced by the PMP staff with considerable assistance from the Executive Office of Health and Human Services Information Technology Department (EHS IT). Reports were sent via encrypted email to registered MassPAT users and via certified mail to those prescribers who were not registered in MassPAT (accompanied by notice of the legal requirement to register).

Stakeholder Feedback on Prescriber Reports: Stakeholders and individual practitioners provided feedback largely critical of the content, frequency, and delivery method of these reports. The availability of CDC grant funds to make improvements to the Prescriber Reports enabled the PMP staff to largely incorporate this feedback.

Report Content
Feedback indicated that the mean and median of prescription quantity and solid dose volume of a practitioner, even when measured within the specialty of the practitioner, did not provide enough information to be helpful to the practitioner. The following new data fields have been incorporated into future prescriber reports:

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

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

Frequency
Many stakeholders indicated a desire to review these reports more often than the annual statutory frequency, to keep their prescribing practices in the forefront and promote greater opportunity for reflection and change. The PMP agreed to produce quarterly prescriber reports, each time looking back over the previous six months.

[24] Chapter 94C, Section 24B states: The department shall annually determine, through the prescription drug monitoring system established in section 24A, the mean and median quantity and volume of prescriptions for opiates contained in Schedules II and III of section 3 issued by practitioners registered under section 7; provided, however, that mean and median prescription quantities and volumes shall be determined within categories of practitioners of a similar specialty or practice type as determined by the department.

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

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

The PMP enlisted 4 HCEs to serve as integration pilots: Partners Health, Atrius Health, Cambridge Health Alliance and UMass Memorial Medical Center. The PMP integration plan was to provide 4 options for integration – 3 Application Program Interfaces (APIs) that would utilize the PMP Gateway for transmission of data (Appriss's 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 the security measures of the Commonwealth of Massachusetts.

By the close of FY17, EHS IT had cleared the Mass HIway (HIE) and the ASAP API that would be used to transmit PMP data through Appriss's PMP Gateway, however neither option was preferred by health care providers. The 2 remaining APIs (Appriss's V5 and NCPDP) had not passed the security review, and significant work was needed to bring the preferred option, V5, up to Massachusetts security standards. After lengthy negotiations, MassPAT vendor, Appriss Health, agreed to build an API, version 5.1 (V5.1), that incorporates the security requirements outlined in a document produced by the MA PMP and EHS IT.

Partners Health began functional testing in April 2018 and went live across all their facilities on May 16, 2018. Walmart coded their pharmacy software system to V5.1 and were approved for integration on June 20. 2018. Finally, Boston Medical Center pharmacies coded to the ASAP API and launched in early 2018.

The 3 remaining HCE pilots, all Epic EHR customers, were delayed for a variety of reasons but continued to test, with the goal of going live in FY19. Atrius Health is expected to begin testing in early FY19 and the Cambridge Health Alliance and UMass Memorial are awaiting upgrades to their Epic systems scheduled for Q2 of FY19 before beginning the integration process.

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.

Law Enforcement Trainings: Six trainings were offered to Law Enforcement and Regulatory agents in FY18, certifying 57 agents for access to MassPAT.

This PMP training is designed for those law enforcement officers and prosecutors assigned to cases involving prescription drug abuse or diversion. The training 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; and
- A review of the statutory requirements of M.G.L. c. 94C, §24A and federal HIPAA requirements for law enforcement.

Changes to Law Enforcement Agency and personnel access to PMP data included in pending state legislation may require additional outreach and training by PMP staff in FY19.

Interstate Data Sharing: The PMP continues to expand and improve interstate data sharing. Currently, the PMP has entered into data sharing agreements with 32 states and the District of Columbia.[25] 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.

[25] See Appendix U: *Interstate Data Sharing*.

III. Prescribing Trends

Prescriptions: Prescribing trend information demonstrated a 30% decline in Schedule II opioid prescriptions reported to the PMP from 841,990 in the first quarter of 2015 to approximately 568,000 in the second quarter of 2018.[26]

Patients: Just over 258,000 individuals in Massachusetts received prescriptions for Schedule II opioids in the second quarter of 2018. This is a small decrease from the previous quarter and greater than a 30% decrease from 390,532 in the first quarter of 2015.[27]

Multiple Provider Episodes (MPE) Trend: One of the most important contributions of the PMP has been the rapid reduction in individuals with activity of concern: a 56% drop from the fourth quarter of 2013 to the fourth quarter of 2017.[28]

[26] See Appendix V: *Schedule II Opioid Prescriptions and MassPAT Search Activity Trends: Q1 2015 - Q2 2018.*
[27] See Appendix W: *Individuals Receiving Schedule II Opioid Prescriptions and MassPAT Search Activity Trends: Q1 2015 - Q2 2018.*
[28] See Appendix X: *Rate of Individuals with Activity of Concern in MA (2013–2017).*

Conclusion

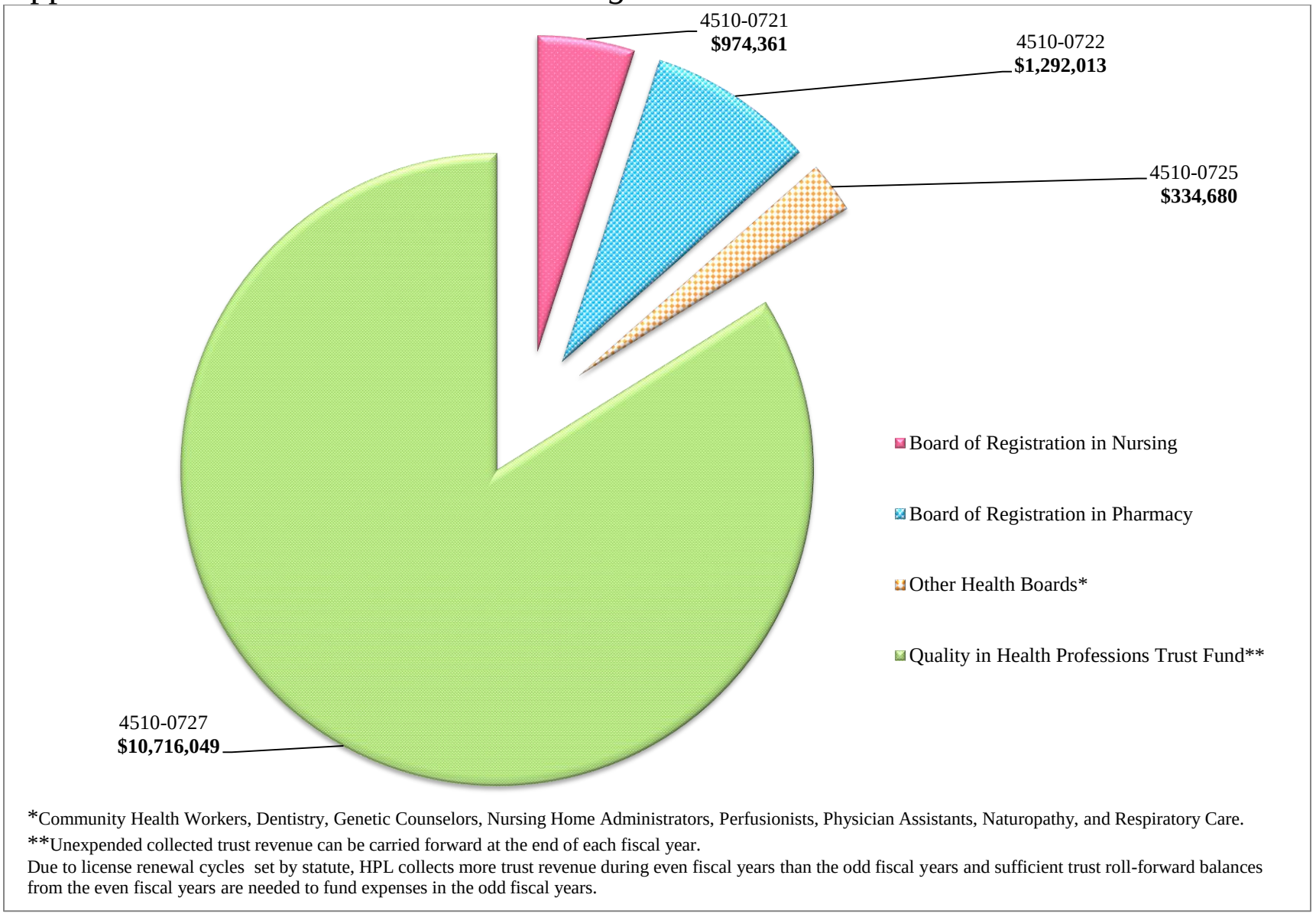
The foregoing accomplishments and statistics are highlights from FY18. BHPL, including its 10 boards, DCP and PMP have maintained a continued commitment to establishing and improving practice standards for the health professions under BHPL oversight, and makes strides every day to fulfill the mandate to protect the public health, safety, and welfare in Massachusetts. The review of existing regulations, continued emphasis on board composition and outreach efforts, and integration of DCP and PMP within BHPL reinforce the overall goal of BHPL to improve public health and safety.

Contact Us/Feedback

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

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

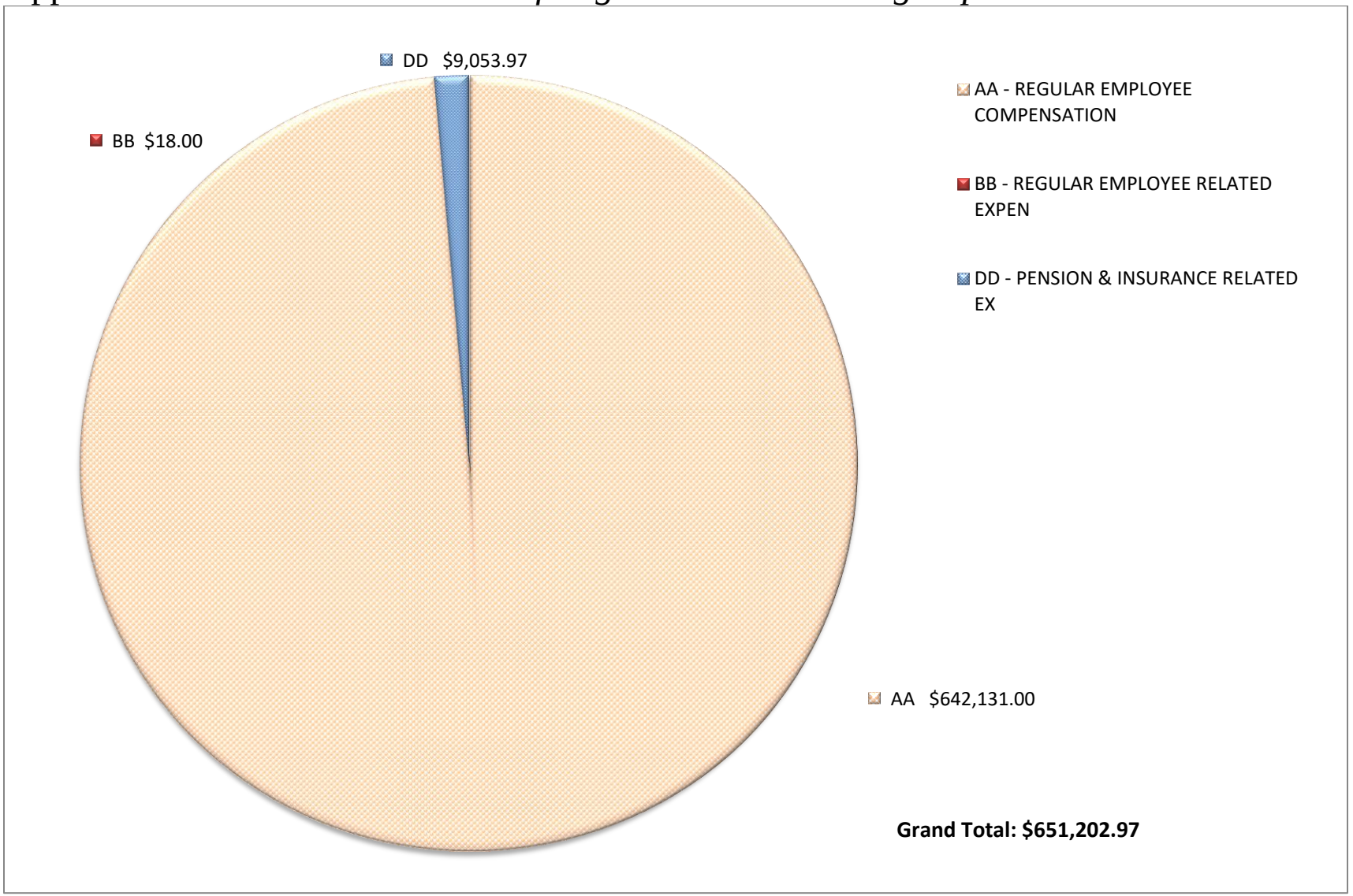
Appendix A: *BHPL FY18 Board Funding*



*Community Health Workers, Dentistry, Genetic Counselors, Nursing Home Administrators, Perfusionists, Physician Assistants, Naturopathy, and Respiratory Care.

**Unexpended collected trust revenue can be carried forward at the end of each fiscal year.
Due to license renewal cycles set by statute, HPL collects more trust revenue during even fiscal years than the odd fiscal years and sufficient trust roll-forward balances from the even fiscal years are needed to fund expenses in the odd fiscal years.

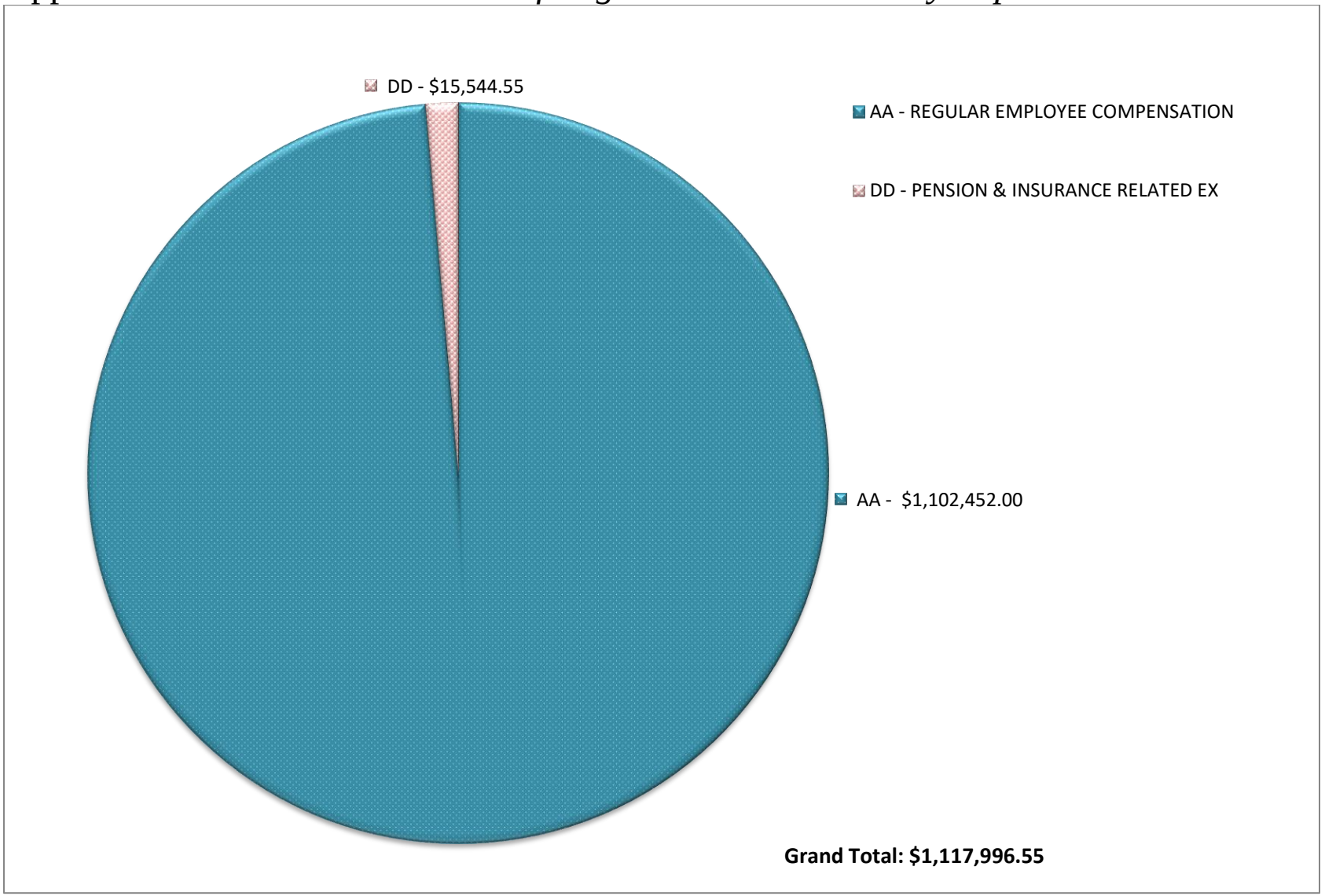
Appendix B: *BHPL FY18 Board of Registration in Nursing Expenditures Overview*



Appendix C: *BHPL FY18 Board of Registration in Nursing Expenditures Detail*

See attached Excel spreadsheet for detailed expenditures.

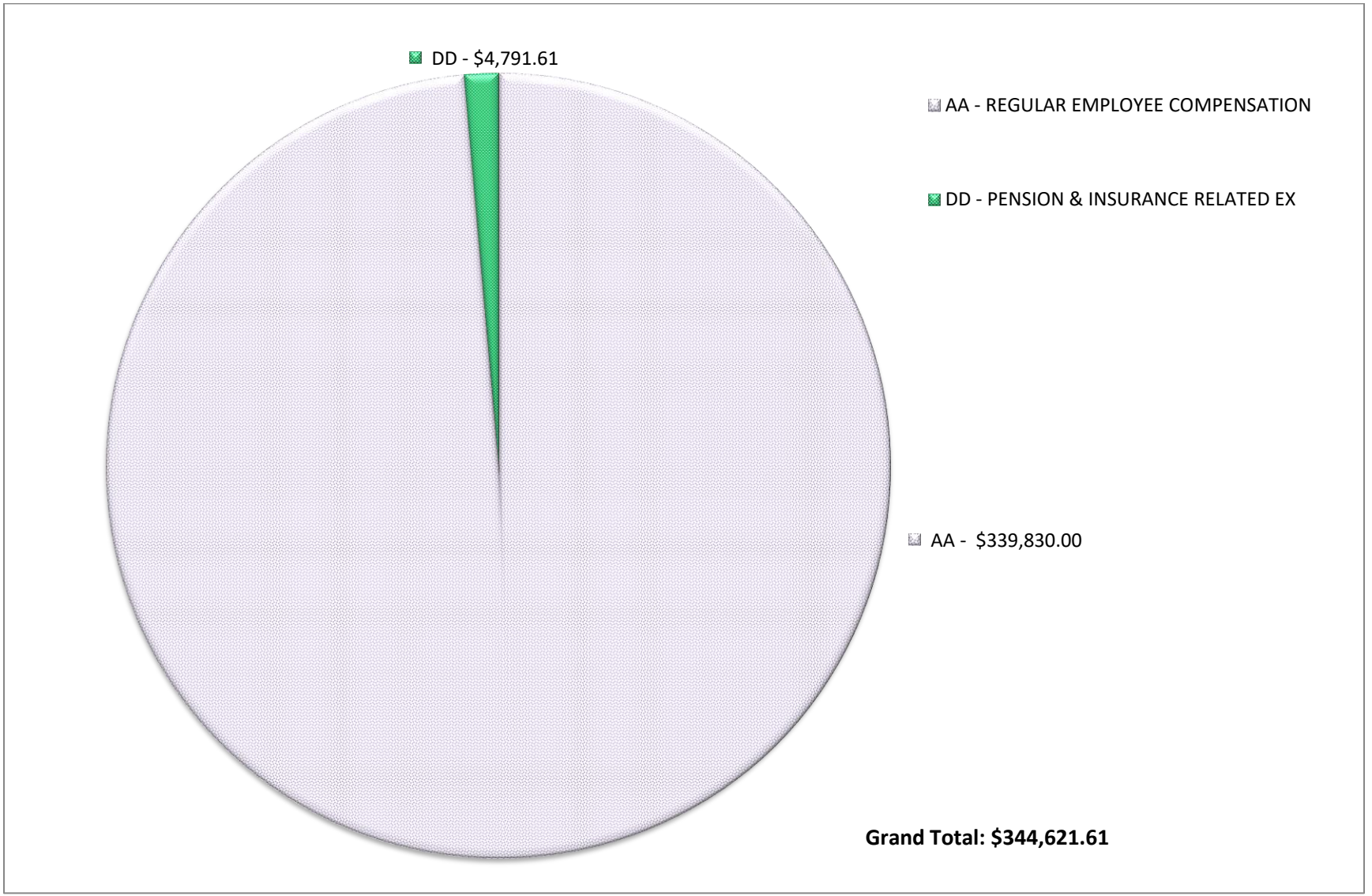
Appendix D: *BHPL FY18 Board of Registration in Pharmacy Expenditures Overview*



Appendix E: *BHPL FY18 Board of Registration in Pharmacy Expenditures Detail*

See attached Excel spreadsheet for detailed expenditures.

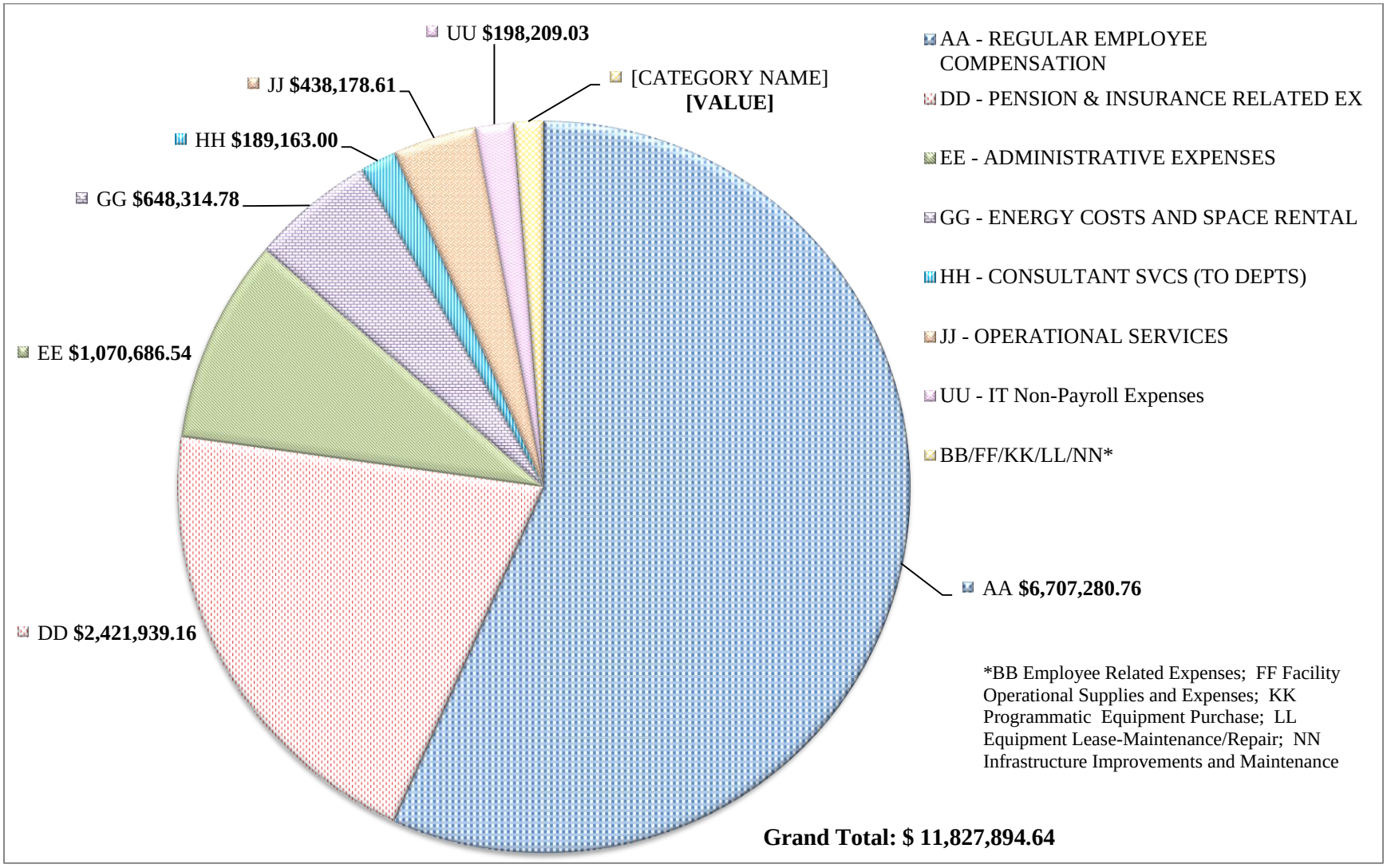
Appendix F: *BHPL FY18 Boards of Registration and Certification Expenditures Overview*



Appendix G: *BHPL FY18 Boards of Registration and Certification Expenditures Detail*

See attached Excel spreadsheet for detailed expenditures.

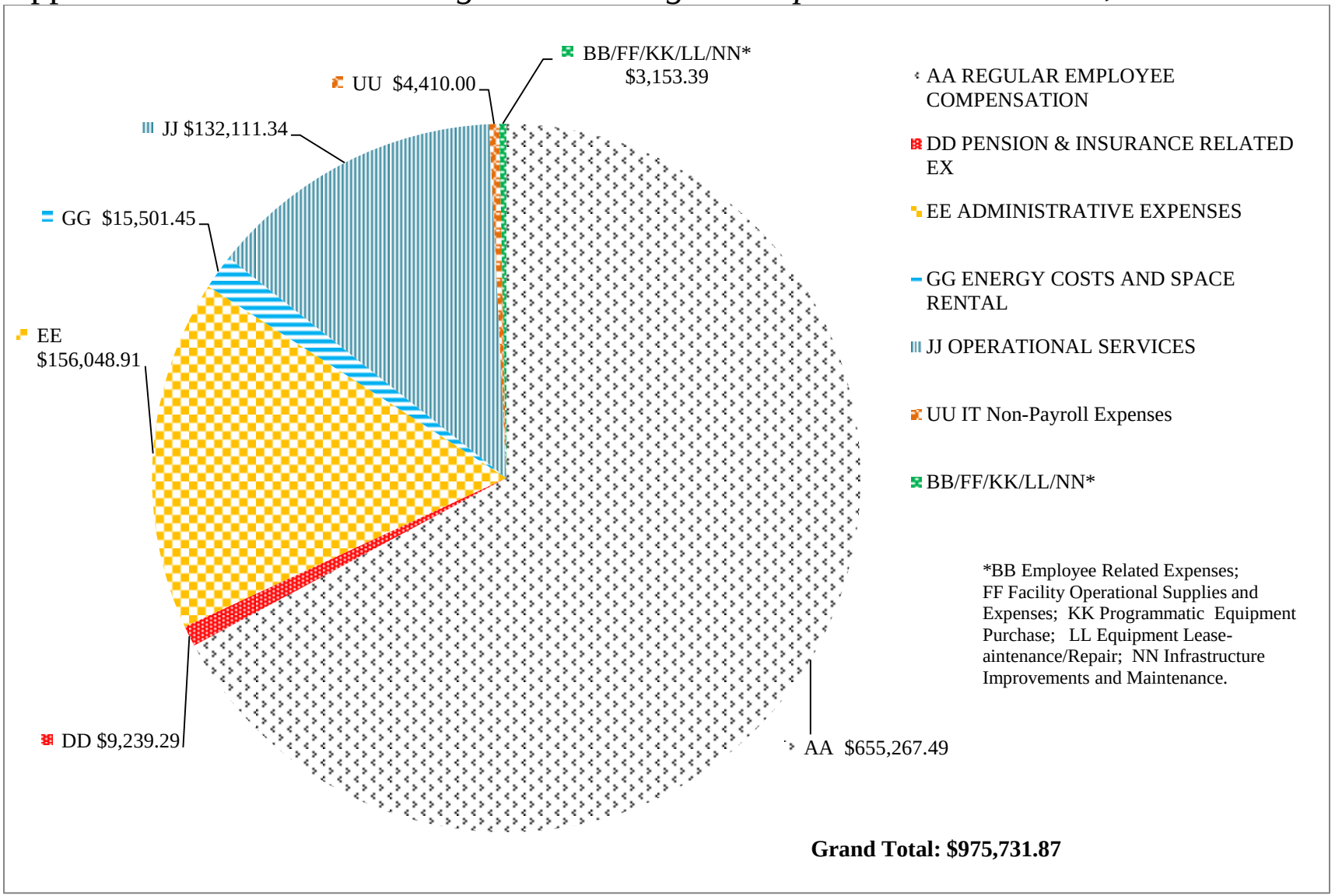
Appendix H: *BHPL FY18 Quality In Health Professions Trust Fund Expenditures Overview*



Appendix I: *BHPL FY18 Quality In Health Professions Trust Fund Expenditures Detail*

See attached Excel spreadsheet for detailed expenditures.

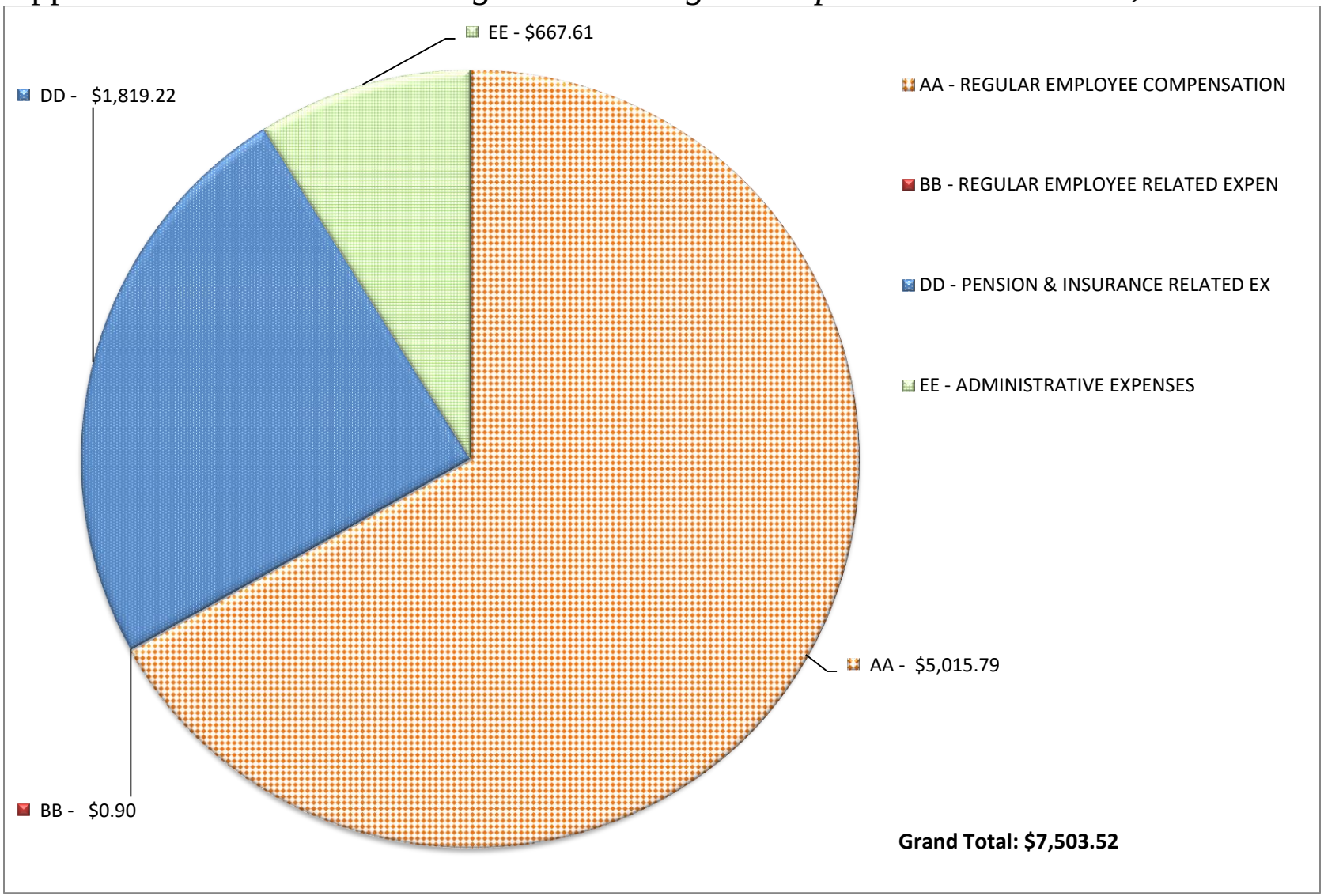
Appendix J: *BHPL FY18 Drug Control Program Expenditures Overview, 4510-0616*



Appendix K: *BHPL FY18 Drug Control Program Expenditures Detail, 4510-0616*

See attached Excel spreadsheet for detailed expenditures.

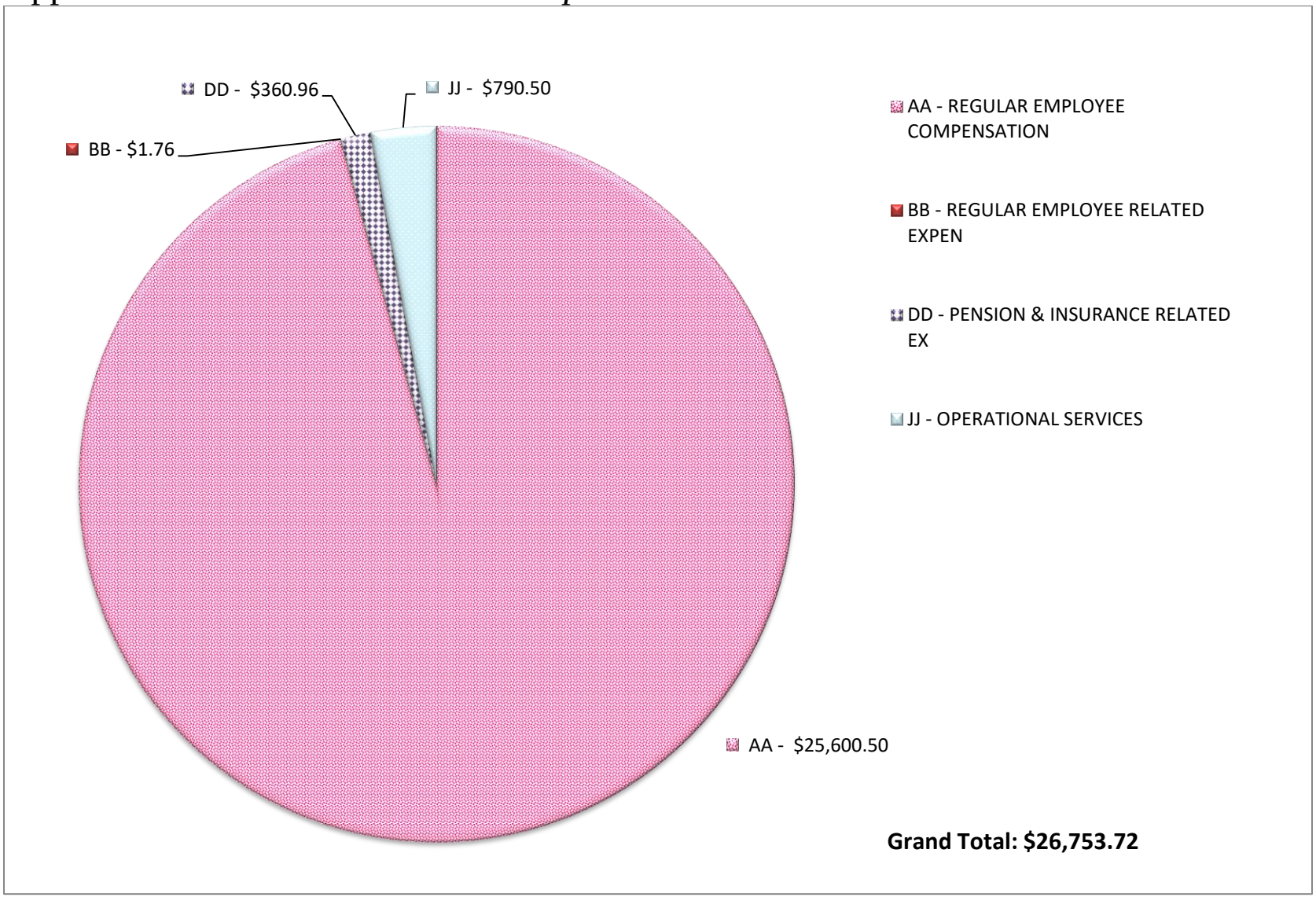
Appendix L: *BHPL FY18 Drug Control Program Expenditures Overview, 4510-0617*



Appendix M: *BHPL FY18 Drug Control Program Expenditures Detail, 4510-0617*

See attached Excel spreadsheet for detailed expenditures.

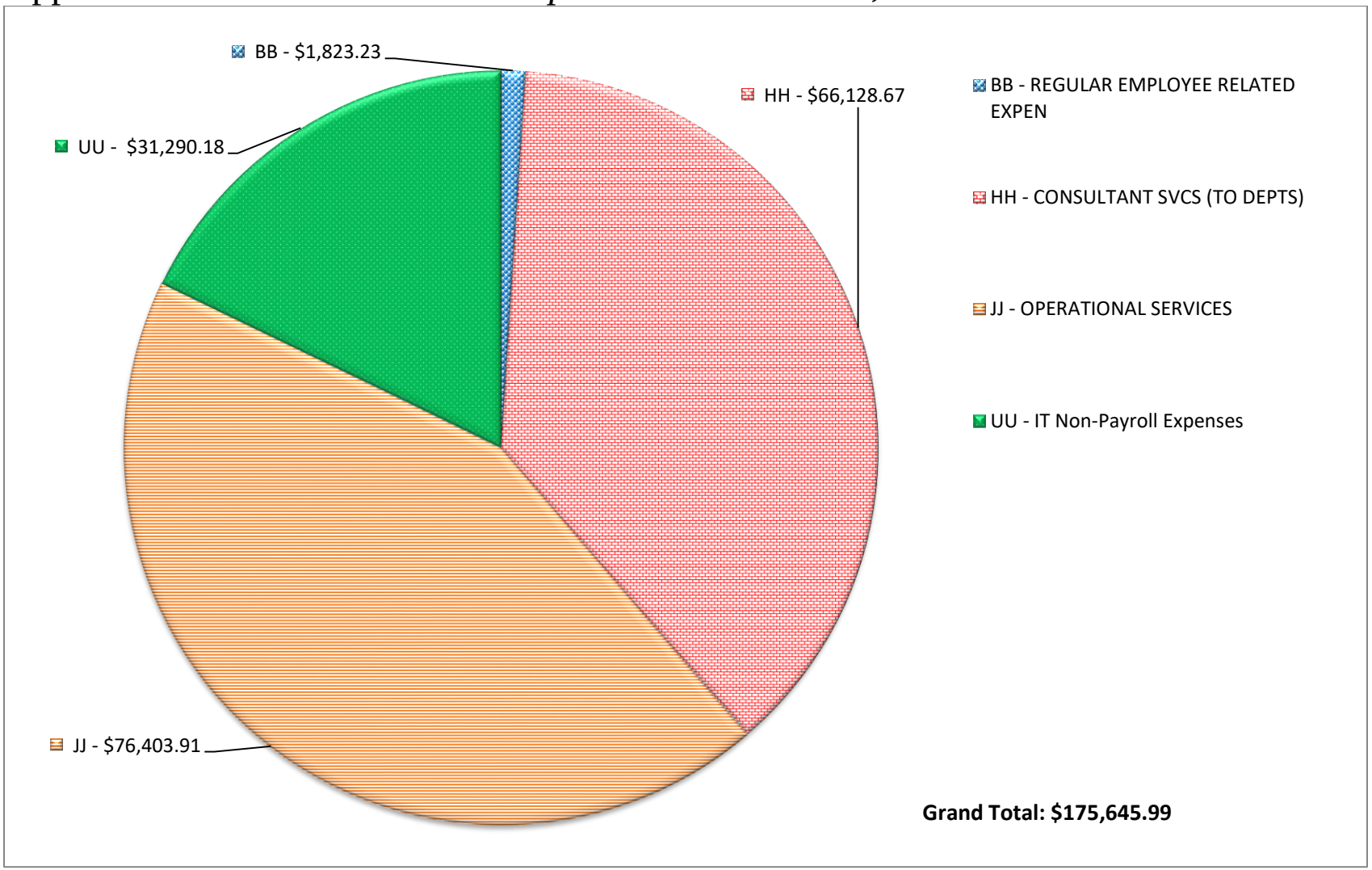
Appendix N: *BHPL FY18 PCOC Expenditures Overview*



Appendix O: *BHPL FY18 PCOC Expenditures Detail*

See attached Excel spreadsheet for detailed expenditures.

Appendix P: *BHPL FY18 PMP Expenditures Overview, 4510-0643*



Appendix Q: *BHPL FY18 PMP Expenditures Detail, 4510-0643*

See attached Excel spreadsheet for detailed expenditures.

Appendix R: *Drug Control Program Enforcement Unit Disciplinary Statistics*

Drug Incident Intake	Drug Incident Field Interaction[29]	891
	Tampering Investigations	45
	Desk Audits[30]	136
	Investigations On-Site	221
	Field Interaction Report (FIR)[31]	51
Registration Activity	New Registrations	396
	Registration Desk Audits	151
	Registration On-Site Inspections	146
Routine Audits & Re-Inspections	Site Visits and Complaint Investigations	8
Criminal Investigations	Practitioners Diverting or Tampering	12
Embargo[32]		0

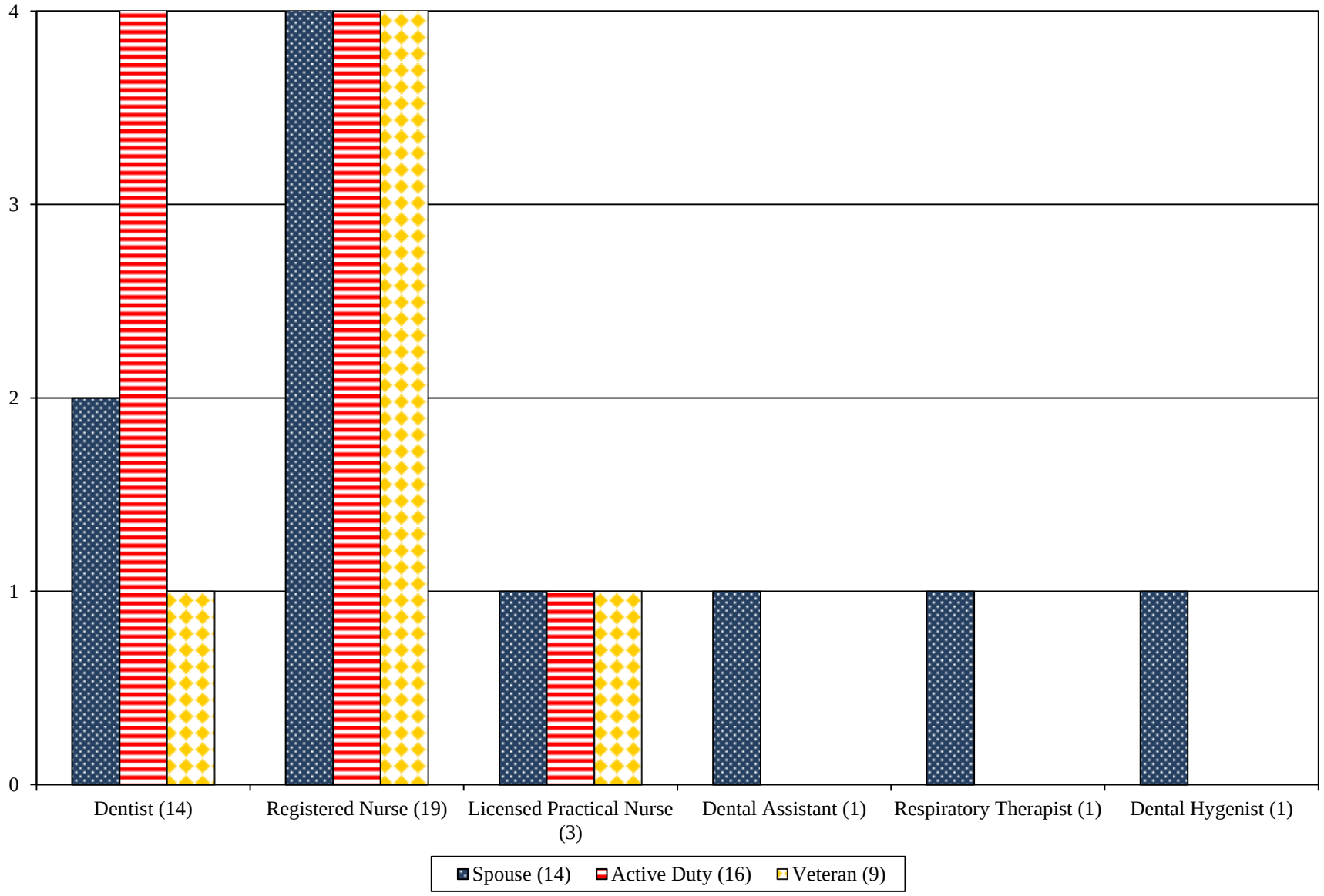
[29] Field interaction may involve, but is not limited to, telephone calls to health care facilities, employment agencies, requesting documentation, review of documentation and/or interaction with regulatory or law enforcement agencies.

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

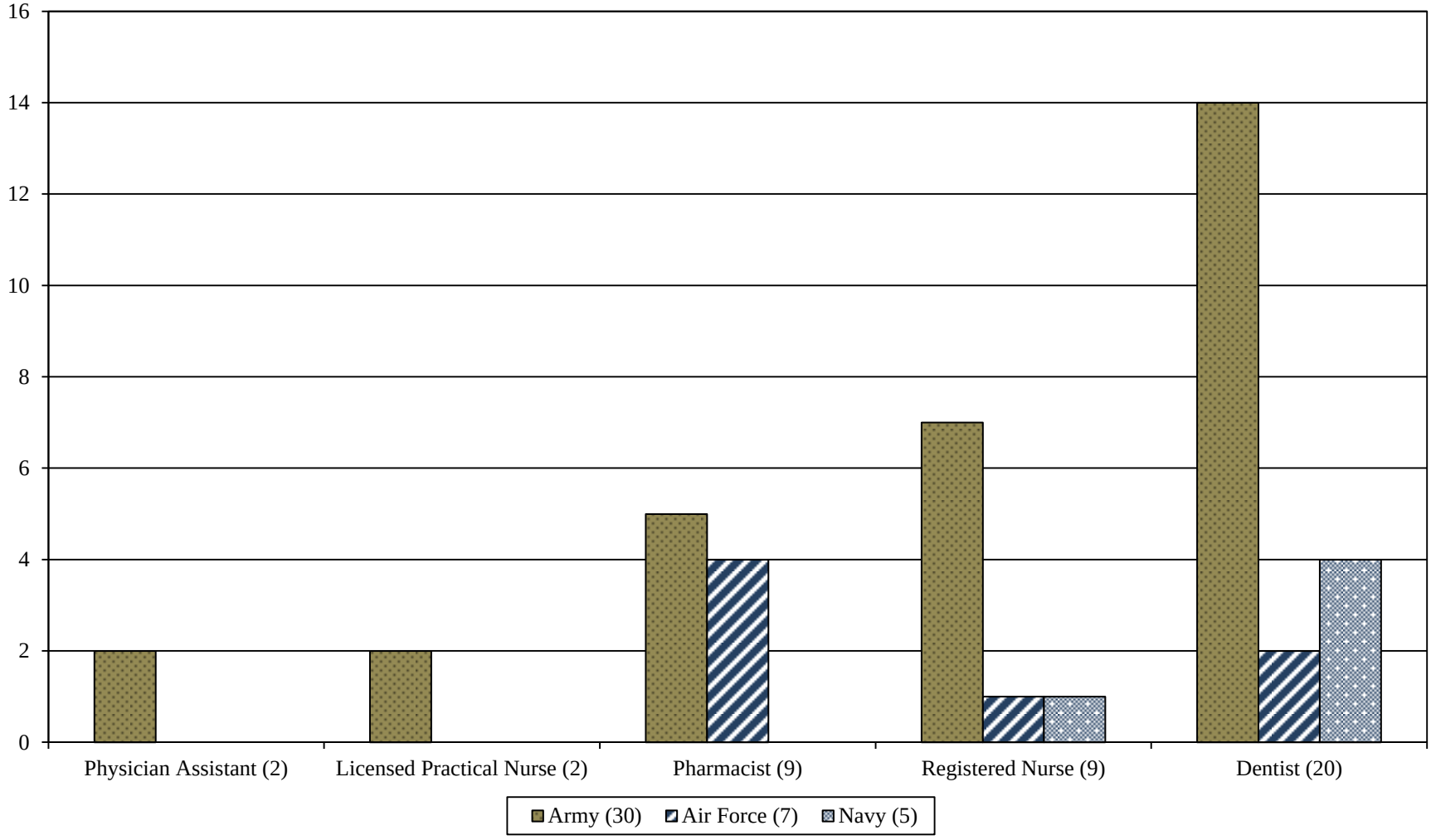
[31] FIRs are DCP generated intelligence reports involving a drug diversion incident. These reports do not always warrant the threshold for referral to a regulatory or law enforcement agency.

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

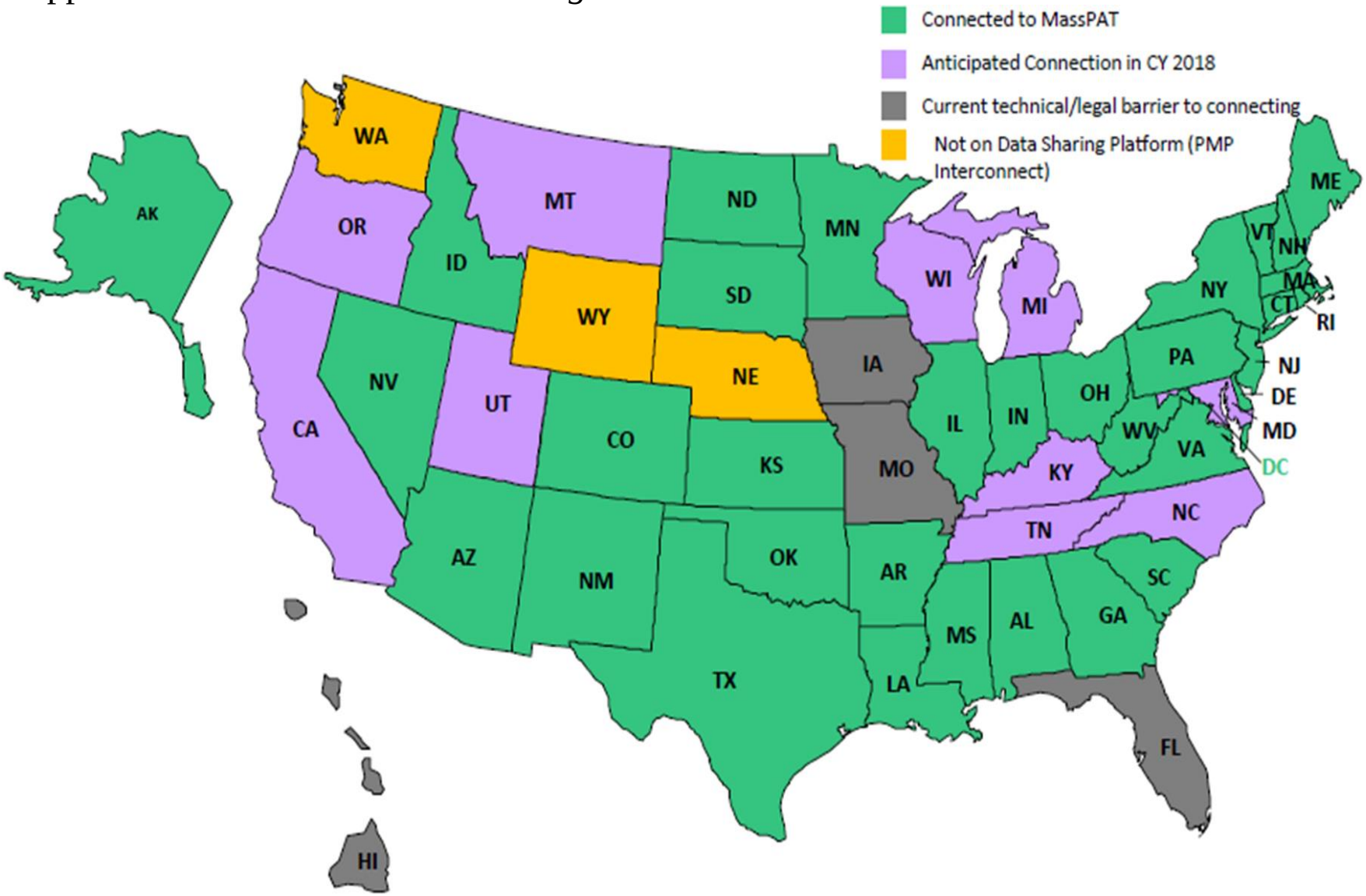
Appendix S: *FY18 VALOR Act Licensure Applications*



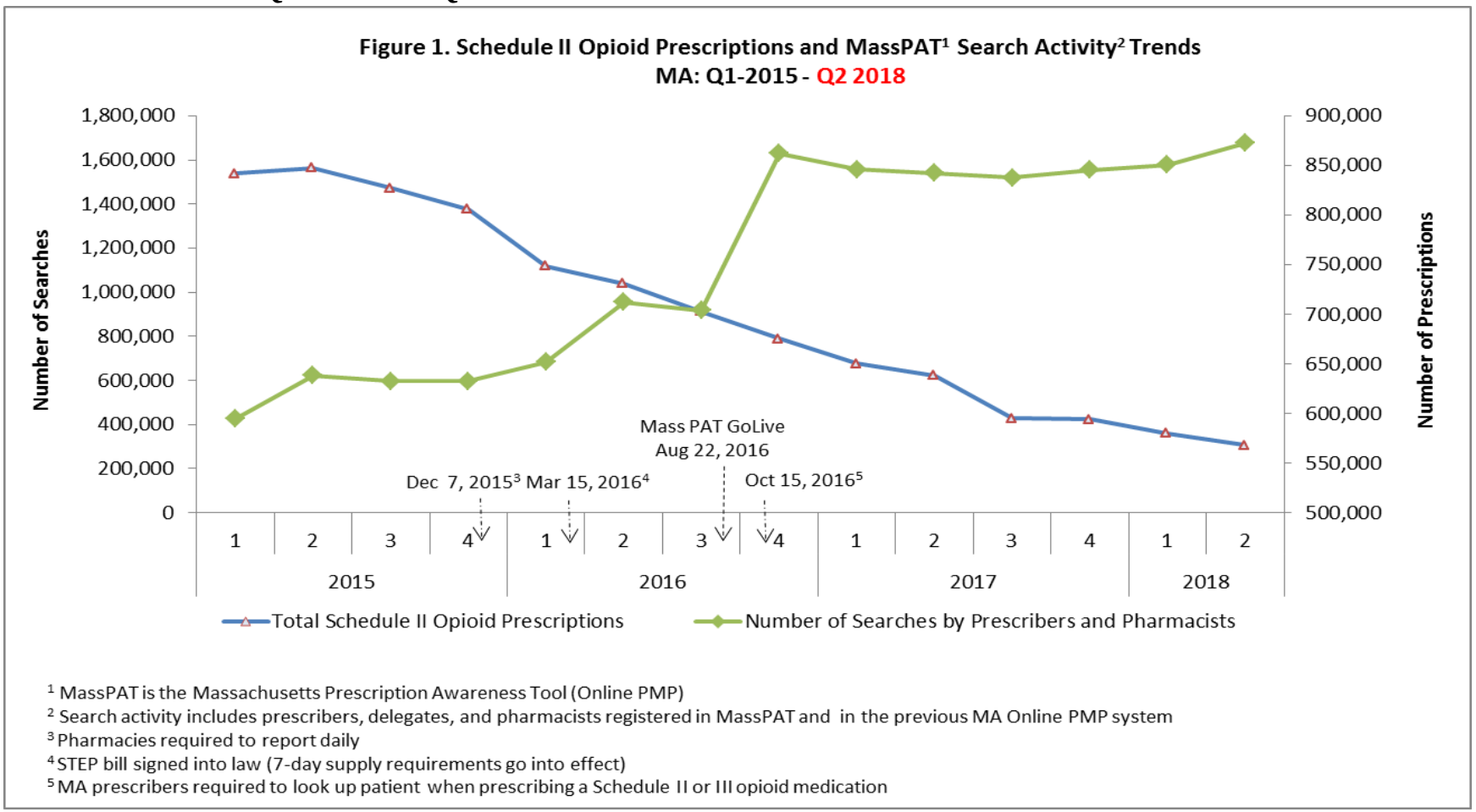
Appendix T: *FY18 Active Service Duty Licensees*



Appendix U: *Interstate Data Sharing*



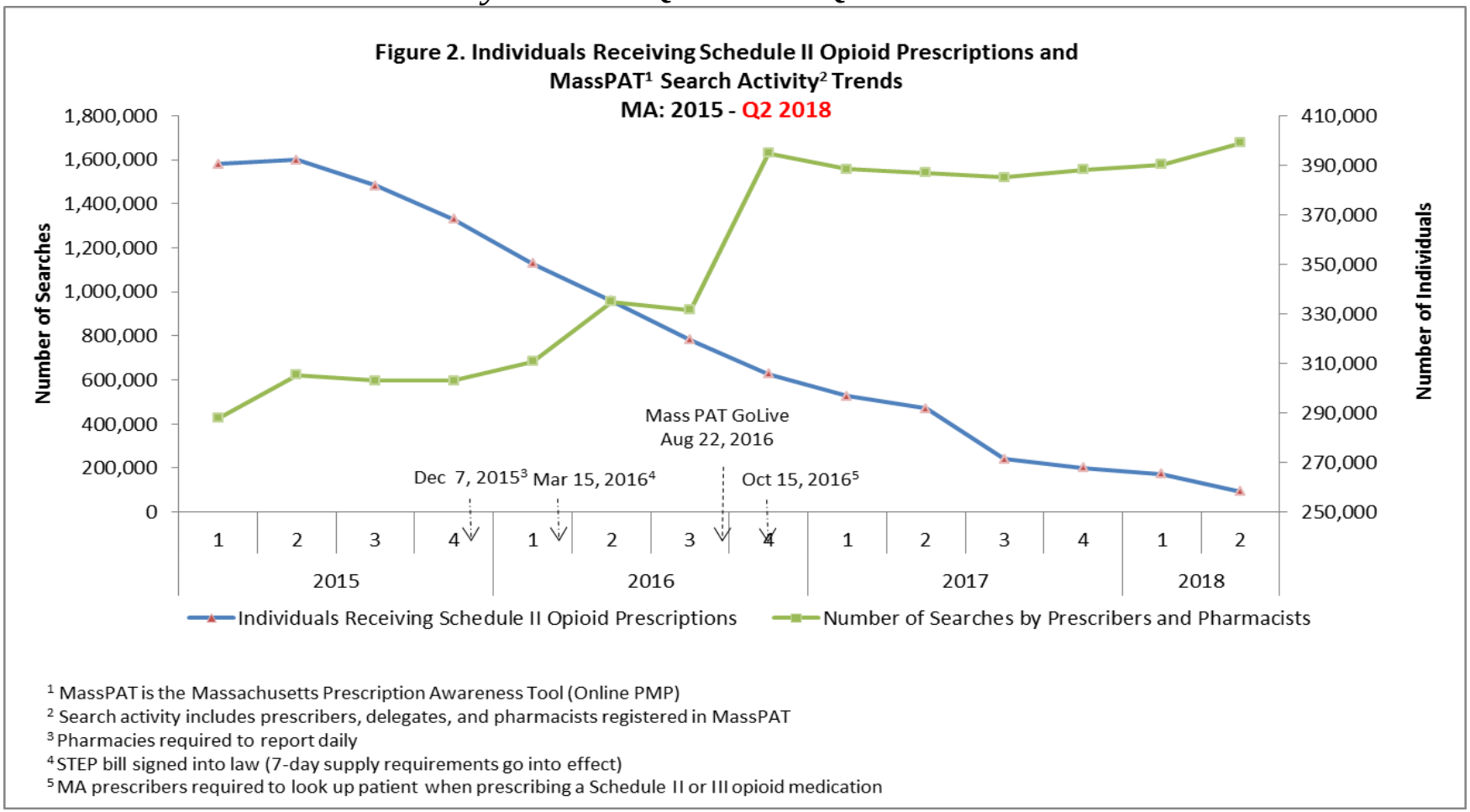
Appendix V: *Schedule II Opioid Prescriptions and MassPAT Search Activity Trends: Q1 2015 - Q2 2018*[33]



[1] MassPAT is the Massachusetts Prescription Awareness Tool (Online PMP)
[2] Search activity includes prescribers, delegates, and pharmacists registered in MassPAT and in the previous MA Online PMP system
[3] Pharmacies required to report daily
[4] STEP bill signed into law (7-day supply requirements go into effect)
[5] MA prescribers required to look up patient when prescribing a Schedule II or III opioid medication

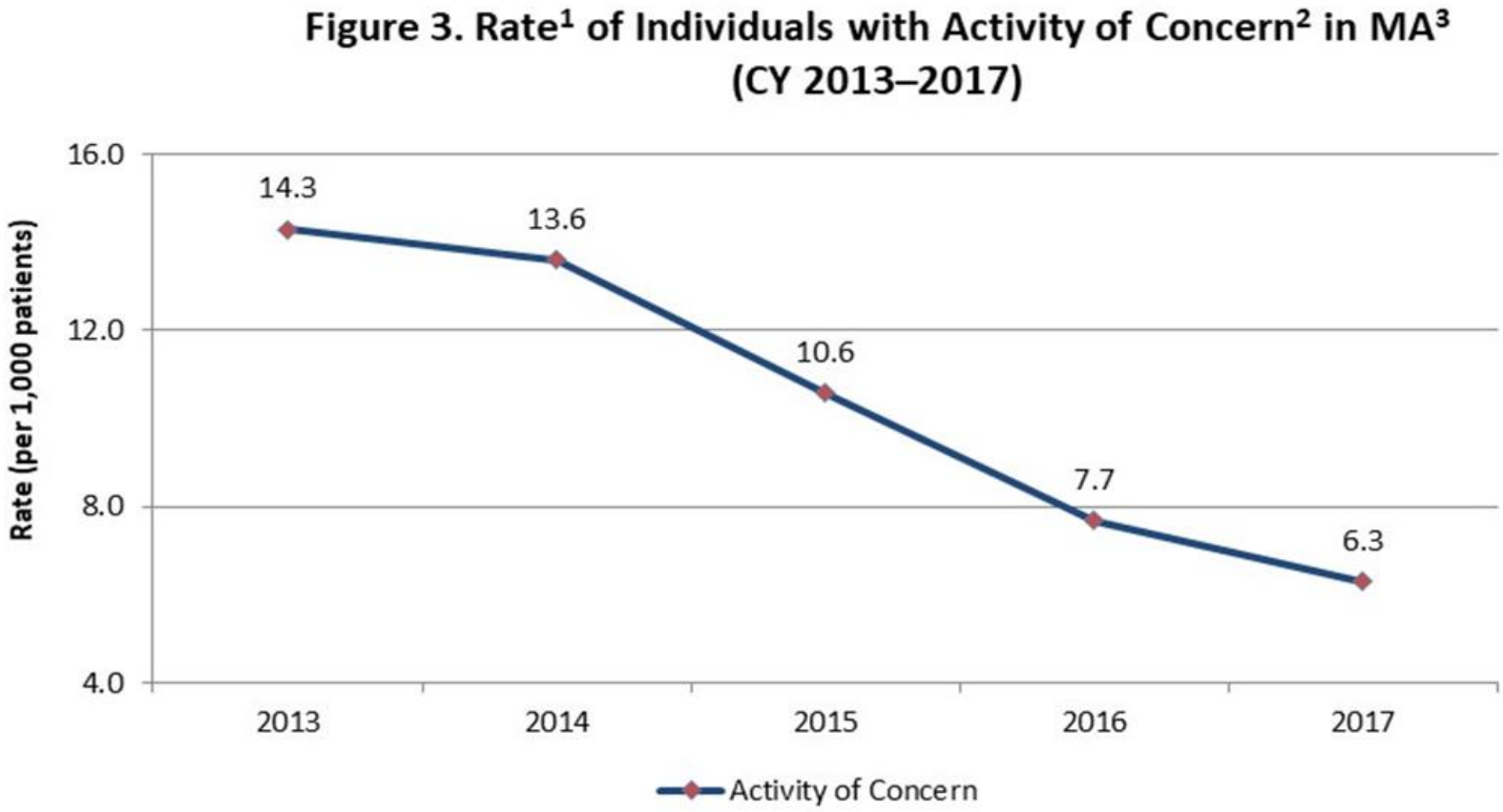
[33] PMP data are subject to updates. The MA PMP database is continuously updated to allow for prescription record correction data submitted by pharmacies. The data for the quarterly trends were extracted on 7/12/2018.

Appendix W: *Individuals Receiving Schedule II Opioid Prescriptions and MassPAT Search Activity Trends: Q1 2015 - Q2 2018*[34]



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

Appendix X: *Rate of Individuals with Activity of Concern in MA (2013–2017)*



[1] Rates of individuals with activity of concern are based on the population of individuals who have received one or more Schedule II opioid prescriptions.

[2] "activity of concern" is defined as an individual who received prescriptions for one or more Schedule II opioid drugs from four or more different prescribers and had them filled at four or more pharmacies during the specified time period.

[3] Activity of concern rates include only MA Residents