



Commonwealth of Massachusetts
The Office of Health and Human Services
Department of Public Health
75 State Street, Boston, MA 02108-4619

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

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

March 22, 2017

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

William F. Welch
Senate Clerk
State House Room 335
Boston, MA 02133

Dear Mr. Clerk,

Pursuant to Section 35X of Chapter 10 of the Massachusetts General Laws, please find enclosed a report from the Department of Public Health entitled "Annual Report for Quality in Health Professions Trust Fund."

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

Annual Report
for
Quality in Health Professions
Trust Fund

Fiscal Year 2016



Table of Contents

Legislative Mandate	4
Executive Summary	5
Introduction	6
Quality in Health Professions Trust Fund Revenue, Services and Activities for FY2016...	8
Conclusion	25
Appendix	26

Legislative Mandate

The following report is hereby issued pursuant to Section 35X of Chapter 10 of the Massachusetts General Laws as follows:

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.

Executive Summary

In accordance with provisions of M.G.L. Chapter 10, Section 35X, the Massachusetts Department of Public Health (DPH) and its Division of Health Professions Licensure (HPL) are pleased to submit this Fiscal Year 2016 Annual Report for Quality in Health Professions Trust Fund to the Senate and House Committees on Ways and Means. This statute requires the Commissioner to annually report on the following: (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.

Introduction

HPL is comprised of nine boards of registration and certification: the Board of Certification of Community Health Workers (CHW Board), the Board of Registration in Dentistry (Dentistry Board), the Board of Registration of Genetic Counselors (GC Board), the Board of Registration in Nursing (Nursing Board), the Board of Registration of Nursing Home Administrators (NHA Board), the Board of Registration of Perfusionists (Perfusionists Board), the Board of Registration in Pharmacy (Pharmacy Board), the Board of Registration of Physician Assistants (PA Board), and the Board of Registration of Respiratory Care (RC Board).

Background

Chapter 184 of the Acts of 2002 (FY03 GAA) transferred seven Boards of Registration (Nursing, Pharmacy, Dentistry, Physician Assistants, Respiratory Care, Nursing Home Administrators and Perfusionists) from the Office of Consumer Affairs and Business Regulations, Division of Professional Licensure (OCA/DPL) to DPH, effective January 1, 2003. The primary mission of the Boards of Registration is to protect the health, safety, and welfare of the public by licensing qualified health care professionals, services, and facilities through the fair and consistent application of statutes. Rules and regulations are established, implemented, and enforced to ensure that minimum qualifications for entry-level practice are met. The Boards also regulate the practice of professions falling within their jurisdiction, and take disciplinary action against licensees who threaten or harm the public by engaging in unethical, incompetent, or improper conduct.

Since the transfer of the seven boards to DPH in 2003, HPL has been impacted by several statutes that have created new Boards of Registration, or required the regulation of additional health professionals:

- Chapter 46 of the Acts of 2015 authorizes the Pharmacy Board to issue registrations to resident and non-resident Outsourcing facilities. The Pharmacy Board promulgated regulations at 247 CMR 21.00, Registration of Outsourcing Facilities, and amendments to 247 CMR 11.00, Registration under the Controlled Substance Act. The draft regulations and fee proposal was submitted to the Administration and Finance Department on October 14, 2015. On December 10, 2015 a Public Hearing was held and the final regulations were filed with the Secretary of the Commonwealth, effective on January 29, 2016.
- Chapter 159 of the Acts of 2014 requires the Pharmacy Board to issue new specialty licenses to the pharmacy community, including sterile compounding, institutional sterile compounding, non-sterile complex compounding, non-resident pharmacies, and non-resident pharmacist Managers of Record. The Pharmacy Board has made significant strides towards the implementation of this legislation in FY2016 and this work will continue in FY2017.
- Chapter 322 of the Acts of 2010 established the CHW Board, effective January 1, 2012. The CHW Board convened an Advisory Work Group, comprised of stakeholders and

community health workers, to advise and assist in developing draft regulations that govern community health worker certification, practice, education, and training requirements. The CHW Board, along with its Advisory Work Group, began developing standards for the education and training curricula for community health workers and community health worker trainers. These standards include requirements for community health worker certification and renewal of certification. The CHW Board anticipates promulgating final regulations after reviewing public comment in FY2017.

- Chapter 530 of the Acts of 2008 requires dental assistants working in the Commonwealth to register with the Dentistry Board. The Dentistry Board established a multi-disciplinary work group to develop draft regulations governing the training, qualifications, registration requirements, and practice standards of dental assistants. It held a public hearing on the proposed regulations in December 2011. This initiative also required Administration and Finance to establish a new fee for original and renewal registration of dental assistants. A public hearing on the proposed fee was held on March 27, 2012. The Dentistry Board reviewed public comments on the regulations and subsequently promulgated the regulations on October 10, 2014.
- Chapter 170 of the Acts of 2006 created the GC Board. A Genetic Counselor is a person who provides individuals and families with information on the nature, inheritance, and implications of genetic disorders in order to help them make informed medical and personal decisions. HPL began licensing Genetic Counselors in January, 2009.

As of July 1, 2016, HPL licensed, registered, certified, or authorized 213,438 health care professionals and businesses. HPL is comprised of over 90 full-time equivalent active staff.

Quality in Health Professions Trust Fund Revenue, Services, and Activities for Fiscal Year 2016

(i) Revenue Credited to the Trust Fund

FY2015 Carry Forward	\$ 9,224,633.00
FY2016 Revenue Collections:	\$ 10,716,048.50
FY2016 Expenditures:	\$(10,548,182.60)
FY2016 End of Year Balance:	\$ 9,392,499.38
FY2016 Carry Forward into FY2017:	\$ 9,392,499.38

(ii) 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

Administration and support services for the Boards of Registration are centralized within HPL and shared among the Boards of Registration. These centralized administration and support services provide economies of scale and promote consistency in the application and enforcement of requirements. Furthermore, these centralized services permit streamlined and efficient operations for the issuance of licenses, collection of revenues, budgeting and accounting, provision of information technology services, enforcement, investigations, legal services, and adjudicatory hearings. All funds expended from the trust fund are attributable to the shared licensing and enforcement activities of the nine Boards of Registration, including expenditures attributed to shared administrative costs.¹

Information Technology

In FY2016, the information technology department (IT) of HPL made multiple modifications and improvements to MyLicense Office (MLO), the licensure database utilized by HPL, to improve efficiency in various licensure processes. These modifications and improvements are also vital to HPL becoming more data focused.

Most importantly, IT set up and tested new versions of MLO, [MyLicense Verification \(Verification\)](#), the public-facing Health Care Safety & Quality (HCSQ) license verification website, and [MyLicense eGov \(eGOV\)](#), the DPH online licensing website that allows licensees and applicants to electronically apply, renew, and change personal information on file with the Department. This undertaking involved a complete data conversion, 19 software fixes, reorganization and simplification of possible license statuses, and the conversion of over 300

¹ See Appendix A: FY Expenditures for Account 45100727

templates in Expression Templates to Word Merge templates directly in MLO. IT anticipates launching these new versions of MLO, Verification and eGOV in FY2017.

IT added a new training module to the applicant checklist in MLO in order for staff of the Board of Registration in Dentistry to ensure applicants had completed the required pain management and opioid prescribing training as required by M.G.L. c. 94C, §18, as amended by St. 2016, c. 52. The same modification will also be made for other boards with license types that may have prescribing authority in FY2017. Also in response to the legislation, IT coordinated the emailing of over 155,000 HPL licensees to serve as immediate notification of the changes in law mandated by St. 2016, c. 52.

As in FY2015, during the course of FY2016, IT developed and added additional license types to MLO. IT configured and activated Outsourcing Registrations, Outsourcing Controlled Substance Registrations, and Non-resident Outsourcing Registrations for the Board of Registration in Pharmacy.

Additionally, in FY2016, IT configured and activated an Advanced Practice Registered Nurse Permit, which the Board of Registration in Nursing anticipates launching in FY2017. IT laid the groundwork to facilitate the transition to issuing these permits by establishing fields in eGOV that will capture basic Advanced Practice Registered Nurse demographic information, such as expiration date, education facility and certification type upon the new renewal of Registered Nurse licenses. This advancement in the licensure database will assist the Board of Registration in Nursing to monitor regulatory compliance of Advanced Practice Registered Nurses.

In early FY2016, the self-registration and online application for initial licensure was launched for Nursing Home Administrators on eGOV. IT had previously laid the ground work for the launch, creating the processes for self-registration of initial licensure applicants for Nursing Home Administrator in FY2015, and launching online initial licensure applications for Nursing Home Administrators, Physician Assistants, Respiratory Therapists, Perfusionists, and Genetic Counselors. In FY2016, IT moved on to develop self-registration and online applications for provisional licensure of Genetic Counselors, Perfusionist, and Respiratory Therapists, temporary Physician Assistant licenses and Nursing Home Administrator in Training licenses. Additionally, the online renewal process for newly licensed Dental Assistants was developed and launched.

In FY2016, IT also established new license renewal surveys in eGOV for Dentists, Registered Nurses, and Licensed Practical Nurses. Renewal surveys are developed by each respective Board of Registration in collaboration with the Massachusetts Health Care Workforce Center, then the survey is developed by IT. After each renewal period, the Massachusetts Health Care Workforce Center reviews and analyzes the survey responses to develop the Health Professions Data Series publications.

(iii) Itemized list of the amount of funds expended by board or unit

As noted above in item (ii), the costs attributable to administrative and support services (such as license renewal processing, information technology software and equipment, revenue collection,

budgeting and accounting, investigations, enforcement, legal services, adjudicatory hearings, and regulation review) are centralized within HPL in order to provide economies of scale and promote consistency in application and enforcement of requirements. In FY2016, trust fund expenditures totaling \$10,548,182.60 supported the shared costs of the HPL Boards. For example, the HPL Boards participated in administrative and programmatic reviews resulting in strategies for enhancing current practices and standards. Strategic priorities across HPL include regulatory review, Board composition recruiting, quality improvements for increased process efficiency, and the posting of Board meeting minutes and disciplinary consent agreements to Board websites. Where feasible, these strategies focus on creating uniformities across all nine Boards in order to improve health care quality and safety within the practice arenas regulated by HPL. Further information concerning license volumes, services, and activities performed during FY2016 and funded by the trust is provided in item (iv) below.

(iv) 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

The mission of HPL is to protect the public health, safety, and welfare of its citizens by licensing qualified health care professionals, services, and facilities through the fair and consistent application of statutes. Through the Boards of Registration, and in an open forum, HPL develops, implements, and enforces regulations and policies that assure and promote the safe practice of those we license and regulate. Services provided by HPL's Boards of Registration during FY2016 are outlined below:

1. Licensing, registration, and certification of health care professionals and businesses

The HPL Boards license, register, or certify approximately 213,438 health care professionals and businesses as shown in Appendix B.²

Registration of Outsourcing Facilities: The Pharmacy Board promulgated regulations at 247 CMR 21.00, Registration of Outsourcing Facilities, and amendments to 247 CMR 11.00, Registration under the Controlled Substance Act to implement the registration of Outsourcing Facilities as required by St. 2015 c.46. On December 10, 2015 a Public Hearing was held and the final regulations were filed with the Secretary of the Commonwealth of Massachusetts, effective on January 29, 2016. As of June 30, 2016, the Pharmacy Board issued registrations to eight non-resident outsourcing facilities.

Registration of Dental Assistants: The Dentistry Board began accepting initial licensure applications, as required by M.G.L. c. 112, §51½, in October 2014. As of June 30, 2016, the Dentistry Board has issued 7,861 licenses to Dental Assistants. The Dentistry Board continues to receive new Dental Assistant licensure applications daily.

² See Appendix B: *Active Licenses, Registrations, Certifications, Permits and Approvals as of FY2016.*

VALOR Act to Assist Active Military, Military Spouses, and Veterans: Under St. 2012, c. 108, otherwise known as the VALOR Act (VALOR Act), and St. 2014, c. 62, otherwise known as the VALOR Act II, the following statutory provisions have been implemented:

- I. Each of the HPL boards will accept relevant education, training, and service completed by a license applicant as a member of the armed forces or the military reserves toward the qualifications required for licensure pursuant to M.G.L. c. 112, §1B(b);
- II. The license of a member of the armed forces who is on active duty remains valid until he or she is released from active duty, and for 90 days thereafter pursuant to M.G.L. c. 112, §1B(c);
- III. HPL 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. HPL 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).

HPL began receiving inquiries about the VALOR Act from service members, veterans and service member spouses in July 2013. Since 2013, HPL has processed 63 applications for licensure by service members, veterans, or spouses, and logged the active duty status of 59 licensed service members.

In FY2016 HPL received a total of 16 licensure applications subject to the VALOR Act, comprised of 12 spouses of active duty service members and four veterans.³ The greatest concentration of applicants is military spouses applying for RN licensure.

As of June 30, 2016, 55 licensed service members were on active duty status. During FY2016, 28 active duty service licenses were manually renewed. Appendix D shows the distribution of active service duty licensees, with the greatest concentration among Army dentists.⁴ As in previous years, dentists remain the most highly represented licensee group across all active duty service licensees.

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

³ See Appendix C: *FY2016 VALOR Act Licensure Applications*.

⁴ See Appendix D: *FY2016 Active Service Duty Licensees*.

2. Complaint investigation, prosecution, and disciplinary action against licensees who threaten or harm the public by engaging in unethical, incompetent or improper conduct

HPL's compliance activities are integral to its mission. HPL conducts investigations of licensees, prosecutes cases, and takes disciplinary action against the licenses of individuals and/or businesses who engage in conduct that may threaten or harm the public. During FY2016, the Boards resolved 564 formal complaints against health professional/facility licenses. 251 formal complaints (44%) were resolved by imposition of a disciplinary action. Disciplinary actions include reprimand, probation, license suspension, license revocation, and voluntary surrender.

In addition, the Boards completed the review of 490 staff assignments. A staff assignment is a comprehensive review and investigation or inspection related to a report received from a consumer, employer, national data system, or a regulatory/law enforcement agency to determine whether sufficient evidence may exist to proceed to a formal complaint against a healthcare professional or facility.

The Nursing Board established a Complaint Committee (CC) in March 2016 to facilitate the timely review of, and action on, allegations of licensee misconduct. The CC is, at a minimum, composed of the Nursing Board Chair, the Executive Director and the Supervisor of Investigators. The CC meets twice per month and reports its recommendations to the full Nursing Board prior to its next scheduled meeting. As of June 30, 2016, the CC recommended action to the Nursing Board on 156 cases. Following CC, a brief overview of the case and the CC's recommended action is presented to the Nursing Board for Board action.

In April 2016, the Dentistry Board held its first Complaint Committee (CC), pursuant to 234 CMR 9.02(2) to review pending investigations against licensees. The goal of the CC is to undertake a preliminary review of allegations filed against licensees and opened as staff assignments for a determination whether sufficient evidence exists to proceed with formal complaints. The CC is composed of three Dentistry Board members, two of which must be licensed dentists. The CC must agree by unanimous decision or the matter must be referred to the full Dentistry Board for its consideration at the next scheduled Dentistry Board meeting. The CC's membership is rotating, and is scheduled to meet every other month after regularly scheduled Board meetings. It is expected that this expedited review of allegations against licensees will result in a quicker resolution of allegations and better focused investigations.

Statistics about the number of cases opened during FY2016, the number of cases resolved during FY2016, and the number and percentage of complaints that were resolved by imposition of a disciplinary action, are shown in Appendix C.⁵

3. Auditing compliance with Continuing Education Unit requirements for Health Professionals

⁵ See Appendix E: *Number of Complaints and Investigations During Fiscal Year 2016.*

Dental investigators, on behalf of the Dentistry Board, collect and audit all 40 required CEUs for licensed dentists during the course of complaint investigations. During the course of investigating staff assignments, dental investigators collect and audit mandatory CEUs in infection control, safe and effective opioid prescribing and pain management.

Nursing investigators, on behalf of the Nursing Board, have begun to collect and audit the CEUs of APRNs for compliance with new safe and effective opioid prescribing requirements. This information is collected and audited when an APRN has a complaint or staff assignment opened against their license. Nursing investigators collect and audit the CEUs of all other licensees during the course of investigations as well.

Pharmacy investigators, on behalf of the Pharmacy Board, collect and audit the CEUs of the manager of record of each pharmacy that has a complaint opened against its license for inspectional deficiencies. Additionally, pharmacy investigators collect and audit the CEUs of pharmacists and certified pharmacy technicians who have contributed to a medication error or other quality related event.

The PA investigator, on behalf of the PA Board, has begun to collect and audit the CEUs of physician assistants for compliance with new safe and effective opioid prescribing requirements during the course of investigating all licensee complaints. PA Board staff also collects and audits all required CEUs for renewal applications of lapsed licenses.

4. Approval of Continuing Education programs and credit units

The approval of continuing education programs by the Pharmacy Board is a valuable service provided to the pharmacy community at no charge in order to provide continuing education credit for lectures provided by small groups of presenters such as pharmacy residents and interns. The Board of Registration in Pharmacy approved 206 continuing education programs in FY2016.

5. Monitoring of regulatory compliance of 75 Registered Nurse and Practical Nurse education programs

M.G.L. c. 112, §§81A and 81C authorize the Nursing Board to establish regulations governing approval and operation of Registered Nurse and Practical Nurse education programs located in the Commonwealth.

As of June 30, 2016, the Nursing Board approved the operation of a total of 75 Registered Nurse and Practical Nurse education programs:

- 27 practical nurse programs:
 - Pre-requisite approval: Salter College;
 - Approval with warning: Medical Professional Institute;
 - Full approval: all other practical nurse programs;
- 20 registered nurse associate degree programs with full approval;
- 20 registered nurse baccalaureate degree programs with full approval;
- 1 registered nurse hospital-based diploma program with full approval; and
- 7 registered nurse entry-level graduate degree programs with full approval.

The Nursing Board hosted its annual New Program Administrator Orientation in November 2015, introducing 18 new nurse administrators to the Nursing Board's regulations at 244 CMR 6.00, Approval of Nursing Education Programs and the General Conduct Thereof, and the regulatory requirements for Massachusetts nurse licensure by examination.

6. Development, promulgation, and enforcement of regulations, sub-regulatory guidance and staff action policies

Amendments to 801 CMR: During FY2016, CHW certification fee regulations were drafted and approved by the CHW Board. The regulations have been submitted for administrative review prior to a public comment period. Once the CHW Board reviews and considers public comment, the certification fee regulations will be finalized and approved by the CHW Board in FY2017.

Draft CHW Regulations: In FY2015 the CHW Board and CHW Advisory Work Group prepared draft regulations which were then submitted for administrative review. After a public comment period, the CHW Board will consider public comments and finalize the regulations in FY2017.

234 CMR Regulatory Review Workgroup: The Dentistry Board convened a workgroup in FY2015 comprised of Dentistry Board members, Dentistry Board staff, oral surgeons, pediatric dentists, orthodontists and dental assistants to undertake a section-by-section, line-by-line review of the Dentistry Board's August 2010 amendments to 234 CMR. The workgroup met on the following occasions during FY2016:

- July 15, 2015;
- November 18, 2015;
- December 16, 2015;
- April 27, 2016;
- May 9, 2016; and
- June 22, 2016.

In FY2016, the workgroup completed its review of the Dentistry Board's regulations pertaining to anesthesia and sedation, 234 CMR 6.00. The workgroup's recommendations will be submitted to the full Dentistry Board for its consideration in FY17. If the recommendations are adopted by the Dentistry Board, the proposed amendments to 234 CMR will be submitted for further review by DPH/EOHHS prior to a public hearing. The workgroup anticipates continuing its review of 234 CMR in FY2017. The Board also approved draft regulations for 234 CMR 2.00, 4.00, 5.00, 8.00 and 9.00. These were approved by the Executive Office of Administration and Finance (EOAF) pursuant to Executive Order 562 (EO562) towards the end of FY2016 and will be published for comment during FY2017.

Amendments to 270 CMR: In FY2016, the GC Board continued its review of its regulations pursuant to EO562 and proposed draft amendments to 270 CMR 2.00 through 5.00. The amendments were approved by EOAF in June 2016 and will be published in FY2017.

Amendments to 244 CMR: The Nursing Board, at its December 2015 meeting, approved proposed revisions to its regulations at 244 CMR 3.00 through 9.00 as well as the creation of a new section 10.00 containing a single set of definitions applicable to all of the Nursing Board's regulation chapters. The proposed revisions were approved by the Executive Office of Health and Human Services and the Executive Office of Administration and Finance under to Executive Order 562 in June 2016 and will be published for comment in FY2017.

Amendments to 245 CMR: In FY2016, the NHA Board proposed and approved draft amendments to 245 CMR 2.00. The amendments included expanding section 2.00 with additional sections, as well as some minor changes, such as correcting grammatical errors and rearranging terms and provisions for greater readability, and several substantial amendments including: 245 CMR 3.04, requiring equivalency for non-resident administrator in training programs; and 245 CMR 4.03, requiring mandatory education on domestic violence as required by M.G.L. c. 112, §264. The amendments were approved by EOAF in June 2016 and will be published for comment in FY2017.

Amendments to 267 CMR: In FY2016, the Perfusionist Board proposed and approved draft amendments to 267 CMR 2.00 through 5.00. The amendments included some minor changes, such as correcting grammatical errors and one substantial amendment: 267 CMR 3.08,

establishing a retired license status. The amendments were approved by EOAF in June 2016 and will be published for comment in FY2017.

Amendments to 261 CMR: In FY2016, the PA Board proposed and approved draft amendments to 263 CMR 2.00 through 6.00. The amendments included some minor changes, such as correcting grammatical errors. Additionally, 263 CMR 3.07 was amended to include mandatory training on domestic violence, as required by M.G.L. c. 112, §264. The amendments were approved by EOAF in June 2016 and will be published for comment in FY2017.

Amendments to 261 CMR: In FY16, the RC Board proposed and approved draft amendments to 261 CMR 2.00 through 5.00. The amendments included some minor changes, such as correcting grammatical errors, and several substantial amendments including: 261 CMR 3.09, establishing a retired license status; and 261 CMR 5.06, clarifying continuing education requirements. The amendments were approved by EOAF in June 2016 and will be published for comment in FY2017.

Amendments to 247 CMR for Outsourcing Facilities: The Pharmacy Board promulgated regulations at 247 CMR 21.00, Registration of Outsourcing Facilities, and amendments to 247 CMR 11.00, Registration under the Controlled Substance Act to implement the registration of Outsourcing Facilities as required by St. 2015 c.46. On December 10, 2015 a Public Hearing was held and the final regulations were filed with the Secretary of the Commonwealth of Massachusetts, effective on January 29, 2016.

The following amendments to existing regulations were proposed by Pharmacy Board staff and approved by the EOAF in FY2016:

Proposed amendments drafted and approved for administrative review	FY2015 and FY2016	FY2016
247 CMR 2.00, Definitions		X
247 CMR 3.00, Personal Registration		X
247 CMR 4.00, Personal Registration Renewal and Continuing Education Requirements	X	
247 CMR 5.00, Orally & Electronically Transmitted Prescriptions		X
247 CMR 6.00, Licensure of Pharmacies	X	
247 CMR 7.00, Wholesale Druggists	none	
247 CMR 8.00, Pharmacy Interns and Technicians		X
247 CMR 9.00, Code of Professional Conduct and Practice Standards for Pharmacists, Pharmacies and Pharmacy Departments	X	
247 CMR 10.00, Disciplinary Proceedings		X
247 CMR 12.00, Restricted Pharmacy		X
247 CMR 13.00, Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies		X
247 CMR 14.00, Petition for Waiver		X
247 CMR 15.00, Continuous Quality Improvement Program		X
247 CMR 16.00, Collaborative Drug Therapy Management		X

The following proposed new regulations were drafted by Board staff and approved for administrative review by the Pharmacy Board during FY2016:

- 247 CMR 11.00, Controlled Substance Act;
- 247 CMR 17.00, Sterile Compounding; and
- 247 CMR 20.00, Reporting.

Copies of [the draft regulations](#), as proposed, are available on the Pharmacy Board’s website. The amendments to 247 CMR 4.00 were open for public comment during FY2016. A public hearing on the remaining proposed new regulations and amendments will take place during FY2017 in accordance with administrative approval, after which the draft regulations will be revised based on consideration of the comments received. After these revisions are made, the final regulations will be brought before the Pharmacy Board for final approval.

Nursing Board Policy Review: During FY2016, the Nursing Board reviewed its licensure-related policies in compliance with its Systematic Policy Review Plan. In doing so, the Nursing Board created Licensure Policy 16-02: Determination of Compliance with Provisions of 244 CMR 8.00 by the Nursing Board’s Nursing Education Coordinator that consolidated the following policies:

- 99-01: Staff Action to Determine NCLEX Administration Modifications;
- 99-02: Staff Action to Extend NCLEX Eligibility Period; and
- 99-05: Determination of Compliance with 244 CMR 8.04(1)(c)4.

Pharmacy Board Advisories and Policies: The Pharmacy Board issued several Advisories and Policies to address practice issues that came to the attention of Pharmacy Board staff through the complaint and inspection processes:

Advisory on Staff Ratios: This Advisory was approved by the Pharmacy Board to remind registrants of appropriate staff ratios. The Advisory became necessary after pharmacy investigators cited numerous pharmacies with certified pharmacy technicians that were not licensed by the Pharmacy Board. Pharmacies were reminded that any unlicensed pharmacy technician is to be counted as a technician in training for ratio purposes.

Pre-filled Insulin Syringes: This Advisory was approved by the Pharmacy Board to notify registrants that the Pharmacy Board considers the pre-filling of insulin syringes to be a sterile compounding activity. Through this Advisory, pharmacies were notified that the practice must cease immediately and a continuity of care plans for all effected patients was to be implemented.

Zostavax Immunizations: This Advisory was approved by the Pharmacy Board to notify registrants of the appropriate guidelines for the administration of Zostavax immunizations. The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) declined to recommend the vaccine for use on patients age 50 to 59, despite approval issued by the Food and Drug Administration (FDA). Pharmacies were advised to immediately cease administration of the immunization to patients below the age of 60.

Controlled Substance Advisory: This Advisory was approved by the Pharmacy Board at the close of FY16, and is intended to serve as guidance for pharmacists in exercising their corresponding responsibility. The Advisory provides licensees with guidance for controlled substance dispensing and valuable tools to aid pharmacists in identifying potential red flags of prescription fraud and diversion.

Licensure Policy 16 – 01: Staff Action on Applications pertaining to Outsourcing Facilities: This policy authorizes Pharmacy Board staff to process and act on applications pertaining to outsourcing facilities, as described in 247 CMR 11.00 and 247 CMR 21.00, and to issue registrations, provided that the application meets criteria specified in this policy.

Licensure Policy 16 – 02: Requirements for reporting theft or loss of controlled substances to the Board of Registration in Pharmacy: This policy provides an extensive reference list of the required information to be submitted to the Pharmacy Board in the event of a loss or theft of controlled substances by a pharmacy. The policy was issued in an effort to efficiently streamline responses to controlled substance loss investigations. Pharmacies can immediately reference this policy to begin gathering required evidence and documentation in the event of a loss of controlled substances.

7. Issuance of advisory rulings and opinions to guide practice and education for health professions

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 FY16, the Nursing Board updated the following Advisory Rulings in accordance with its systematic review schedule:

0801: *Withholding Initiation of CPR in Long Term Care Facilities;*

9401: *The Role of the Licensed Nurse as Trainer or Consultant for the DPH MAP Program;*

0201: *Nurse Practitioner as First Assistant in Cardiac Catheterization;*

9802: *Licensed Practical Nurse as Charge Nurse/Nurse Supervisor;*

9801: *Holistic Nursing and Complementary/Alternative Modalities;*

0802: *The Use of a Vagal Nerve Stimulator Magnet; and*

9804: *Administration of Immunizing Agents or Vaccines.*

8. Monitoring of licensee compliance with terms of probation, consent agreements and final decisions and orders of the Boards

The Probation Department at HPL 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, 2016, the Probation Department was monitoring 168 participants.

In FY2016, HPL Boards adopted a Division-wide staff action policy, DP 15-01, authorizing the handling of monitored cases in a more efficient and consistent manner. The policy implements standard processes and procedures for the Probation Department and defines standard terms used by the Probation Department. In addition, the policy delegates Staff Action authority to Probation Monitors on behalf of each Board of Registration, for routine decisions like approving licensee Requests for Extensions and Restoration of License to Unrestricted Status (termination of probation monitoring). The Policy requires that the Probation Monitor or Executive Director report all Staff Action taken between Board meetings at each regularly scheduled Board meeting.

The Probation Department is also currently developing a new database for probation monitoring. The new database will automate reports and compliance summaries, in addition to allowing the Probation Department to track licensee progress on a more detailed level. The database is anticipated to launch in early FY2017.

HPL administers the Massachusetts Professional Recovery System (MPRS) for licensed health professionals (Dentists, Genetic Counselors, Nursing Home Administrators, Perfusionists, Pharmacists, Physician Assistants, and Respiratory Therapists). MPRS is a monitoring program

that assists licensed health professionals who have problems with alcohol and/or other drugs to return to practice while protecting the public's health, safety, and welfare. An advisory panel of seven health care professionals with experience in substance use disorder treatment is available to consult with both participants and HPL monitoring staff. The program takes five years to successfully complete. As of June 30, 2016, MPRS was monitoring the compliance of 26 participants. During FY2016, MPRS admitted 1 new participant, terminated 4 participants for unsuccessful completion of the program, and discharged 10 participants with successful completion of the program.

9. Administration of the Substance Abuse Rehabilitation Program for nurses

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

In FY2016, the SARP staff conducted outreach activities to educate healthcare providers on the prevalence of substance use disorders among nurses and the role of SARP at the following institutions:

- Massachusetts General Hospital- Grand Rounds on August 20, 2015;
- Partners Healthcare Employee Assistance Program on October 22, 2015; and
- Hallmark Health: Melrose-Wakefield Hospital on February 26, 2016.

On May 20, 2016 the SARP Coordinators hosted a Retreat for SARP Stakeholders at the Massachusetts College of Pharmacy and Health Sciences University in Worcester, MA. The attendees committed to team-building exercises and identified evidence-based practices to ensure SARP operates more efficiently.

As of June 30, 2016, SARP was monitoring the compliance of 166 participants. During FY2016, SARP admitted 34 new participants, terminated 14 participants for unsuccessful completion of the program, and discharged 21 participants after successful completion of the program.

10. Provision of executive management services for HPL's Boards of Registration

HPL coordinates the appointment of 87 Board members seats by the Governor and provides administrative support for these Board members. HPL manages the daily activities of Board staff, including the licensing of individuals and facilities, investigations of licensee compliance, and the implementation of legislative initiatives. During FY2016, HPL focused on increasing recruiting efforts to fill vacant board seats across all HPL boards. Maintaining an adequate

amount of appointed board members is crucial to ensure each board meets its respective quorum requirement and enables each board to conduct regular business at board meetings.

By the end of FY2016, 84.24% of all board seats were filled, up from 75.60% in FY2015. A total of 9 new board members were appointed by Governor Baker during FY2016.

11. Compliance Inspections of pharmacies, wholesale druggists, and dental offices

Pharmacy Compliance Inspections: During FY2016, 11 pharmacy investigators, on behalf of the Pharmacy Board, conducted a total of 1,981 pharmacy inspections broken down into the following categories: 1,833 retail compliance inspections, 53 non-sterile compounding inspections, 60 sterile compounding inspections and site visits, and 35 wholesale distributor inspections. The inspections were accomplished after the hiring and training of four new pharmacy investigators in FY2016, in addition to the four new pharmacy investigators hired and trained in FY2014. These vital positions were made possible by additional funding for the Pharmacy Board from the Legislature in fiscal year 2014 (FY2014), FY2015 and FY2016. The Pharmacy Board looks forward to continuing to increase inspection totals and maintain a strong field presence in FY2017 with a fully trained roster of pharmacy investigators.

Nuclear Pharmacy Inspections: During FY2016, an agreement was reached with the National Association of Boards of Pharmacy (NABP) to utilize contracted experts to conduct inspections of the six nuclear pharmacies in Massachusetts. The six inspections were completed in June 2016 and several of the pharmacy investigators shadowed the NABP inspector in order to gain knowledge in the highly specialized pharmacy practice area. The Pharmacy Board intends to utilize the contracted experts going forward, until pharmacy investigators have been adequately trained to conduct these inspections.

Multi-State Inspection Collaboration: In recognition of the need for a uniform inspection to evaluate non-resident pharmacies for licensure, the National Association of Boards of Pharmacy created the Inspection Blueprint. During FY2015, and continuing in FY2016, the Executive Director, the Director of Pharmacy Compliance, and the Director of Quality Assurance participated in workshops and conferences to work with other member states and the National Association of Board of Pharmacy (NABP) to develop this collaborative tool, which will be instrumental in the smooth transition to non-resident licensure in Massachusetts in FY2017.

Pharmacy Investigator Training: During FY2016, three newly hired pharmacy investigators attended FDA sterile compounding training. Three pharmacy investigators that frequently handle investigations attended Statement Analysis Interviewing Techniques training, and two pharmacy investigators were trained by the U.S. Consumer Safety Commission to perform specialized inspections on their behalf. One pharmacy investigator attended the National Certified Investigator and Inspector Training held by the Council on Licensure, Enforcement and Regulation. Staff and investigator training continues to be a priority for the Pharmacy Board, with several trainings scheduled for FY2017.

Collaborating Agency Investigations: During FY2016, pharmacy investigators also partnered with the Massachusetts Attorney General’s Office, the United States Food and Drug Administration, the United States Drug Enforcement Administration, and the Department of Public Health’s Division of Health Care Facility Licensure and Certification, and on a number of joint investigations and inspections. Two pharmacy investigators also were Commissioned and performed targeted pharmacy inspections on behalf of the United States Consumer Products Safety Commission.

Audit Inspections of Facilities with Conscious Sedation Permits: In FY2016, dental investigators, on behalf of the Dentistry Board, began inspecting the offices of licensed dentists who were issued facility permits for conscious sedation prior to the Dentistry Board’s August 2010 amendments to 234 CMR. The 2010 amendments to 234 CMR created two separate categories for conscious sedation, minimum and moderate, where there previously was no distinction. The goal of these inspections is to determine whether each office is performing minimum conscious sedation or moderate conscious sedation, and to ensure compliance with the applicable regulations from 234 CMR. The inspections were completed prior to the end of FY2016 and results will be presented to the Dentistry Board in FY2017.

12. Provision of information, education and training for licensees and professional organizations on compliance with state statutes and board regulations and policies pertaining to the practice of nursing, dentistry, pharmacy, genetic counselors, nursing home administrators, physician assistants, perfusionists, respiratory therapists and community health workers

Pharmacy Board staff continued to make outreach a large focus of FY2016, engaging the professional community with proposed new standards and providing guidelines following statutory changes. Pharmacy Board staff made an interagency presentation to the staff of the Bureau of Health Care Safety and Quality, illustrating the Pharmacy Board’s sterile compounding inspection tool and progress with sterile compounding inspections to date. 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:

- Opioid Misuse and Addiction Summit (jointly sponsored by the US Attorney’s Office and the Massachusetts Medical Society);
- Safe Prescriber Working Group at Norfolk County District Attorney’s Office;
- MassHealth Provider Training Series;
- PharmEd Conference Series;
- MCPHS University’s 5th Annual Stoklosa Symposium;
- Northeastern University’s Compounding lecture series: “Compounding: Compliance with Sterile and Non-Sterile Practice in 2016”;
- Professionalism Panel for 5th Year Students at Northeastern University;
- Board of Pharmacy Inspections Overview at MCPHS;
- Board of Pharmacy Inspections Overview at MCPHS Worcester;
- Board of Pharmacy Inspections Overview at Western New England School of Pharmacy;
- Board of Pharmacy Inspections Overview at Massachusetts Pharmacists Association;

- Board of Pharmacy Inspections Overview at the Massachusetts Society of Health Systems Pharmacists;
- Board of Pharmacy Inspections Overview at the Massachusetts Independent Pharmacist Association; and
- Board of Pharmacy Inspections Overview at the Parenteral Drug Association.

In FY2016, the CHW Board hosted a variety of guest speakers who spoke to the CHW Board about technical and legal topics, as well as personal experiences in the CHW field. These guest speakers provided the CHW Board with valuable information that helped to develop the draft regulations. Guests included representatives of Greater Boston Legal Services, the Boston Public Health Commission, the Office of Community Health, and the Massachusetts Association of Community Health Workers (MACHW).

Several Dentistry Board members and Dentistry Board staff participated in the Yankee Dental Congress in January 2016, hosting a one-hour continuing education course on current Dentistry Board licensure requirements, regulations and policies. During FY2016, Dentistry Board staff also presented an ethics course to the current dental hygiene and dental assisting students at Quinsigamond Community College in March, 2016 and Mt. Ida College in April, 2016. Dentistry Board staff also participated in a live continuing education webinar in June 2016 hosted by the Massachusetts Dental Society in collaboration with the Forsyth Institute and the Centers for Disease Control and Prevention (CDC) on the CDC's recent publication, [*Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care*](#).

During FY2016, PA Board staff, along with the PA Board Chair, presented to graduating physician assistant classes at Northeastern University, Tufts, and Bay Path University. These presentations provided an overview of important information, including the PA Board's mission, the initial licensure process, license renewal, scope of practice issues, continuing education requirements, and the enforcement process.

(v) **Fiscal Year 2016 Initiatives**

In FY2016, HPL and the Boards of Registration began planning and undertaking the following activities:

1. **HPL Paperless Transition:** HPL staff will begin to lay the groundwork to reduce and eventually eliminate the retention of paper files and applications. To start, modifications will be made to the licensure database to store scanned historical documents in association with relevant licenses. HPL will initiate the bid and procurement process for scanning services, to scan all of the paper applications and files currently stored on site. Once completed, HPL staff will have instant access to necessary documents whenever necessary. The sizeable transition process is anticipated to extend over several fiscal years.
2. **Board Composition:** HPL will continue to focus on increasing recruitment efforts for board seat candidates to be appointed. Maintaining an adequate amount of

appointed board members is crucial to ensure each board meets its respective quorum requirement and enables each board to conduct regular business at board meetings. HPL will continue to recommend suitable candidates to the Governor for appointment during FY2017, with the goal of reaching 100% seat occupancy for all 9 boards of registration and certification.

- 3. Improving Transparency through Posting of Consent Agreements on Website:** By the end of FY2017, it is the goal of HPL to complete posting historical consent agreements to each respective Board's website. After the historical document repository is completed, new consent agreements will be added to each website within 30 days of each effective date.

Conclusion

In Fiscal Year 2016, \$10,716,048.50 in revenue collections was deposited into the Quality in Health Professions Trust Fund. \$10,548,182.60 was spent during FY2016 to support the administrative, programmatic, and operational costs of the HPL's Boards of Registration. At the end of FY2016, an unexpended balance of \$9,392,499.38 was carried forward to FY2017.

Administration and support services are centralized within the Department's Division of Health Professions Licensure and shared among the boards to provide economies of scale, to promote consistency in the application and enforcement of requirements, and to permit streamlined and efficient operations for the issuance of licenses, collection of revenues, budgeting and accounting, provision of information technology services, enforcement, investigation, legal services, and adjudicatory hearings. Trust expenditures have been utilized to:

- Cover expenses associated with a number of improvements in complaint investigations and the prosecution and settlement of cases;
- Conduct pharmacy and dental inspections;
- Review and amend regulations, particularly for the Boards of Registration in Pharmacy, Dentistry and Nursing;
- Fund information technology advancements;
- Support a licensing and fee collection structure for HPL;
- Promulgate regulations necessary to regulate Dental Assistants;
- Establish the Board of Certification of Community Health Workers;
- Engage in a review of HPL, resulting in strategies for enhancing efficiencies, focusing on creating uniformities across all nine Boards in order to improve health care quality and safety within the practice areas regulated by HPL;
- Educate licensees and professional organizations about compliance with state statutes and board regulations and policies pertaining to the practice of health care professionals; and
- Improve medication safety in pharmacies and long term care facilities.

The Department and HPL wish to thank the Legislature for its foresight in establishing the Quality in Health Professions Trust Fund. The Trust Fund has been instrumental in achieving significant improvements in the administration, operations, and services of HPL, and in ensuring that the Boards are able to fulfill their important missions to protect the health and safety of all citizens and patients receiving health care services in the Commonwealth.

Appendix A: *FY2016 Expenditures*

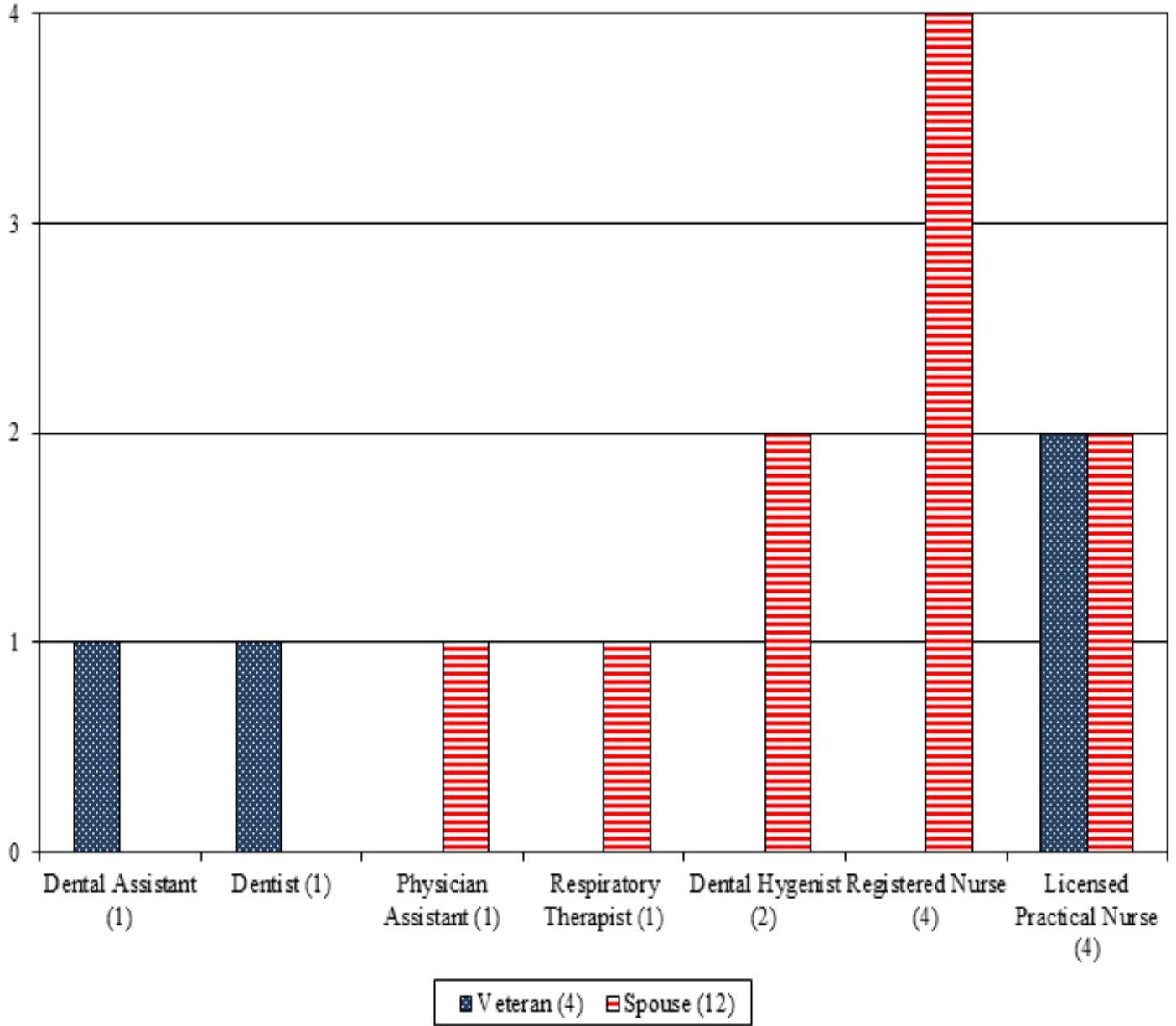
Please see separate Excel spreadsheet data.

Appendix B: *Active Licenses, Registrations, Certifications, Permits and Approvals as of FY2016*

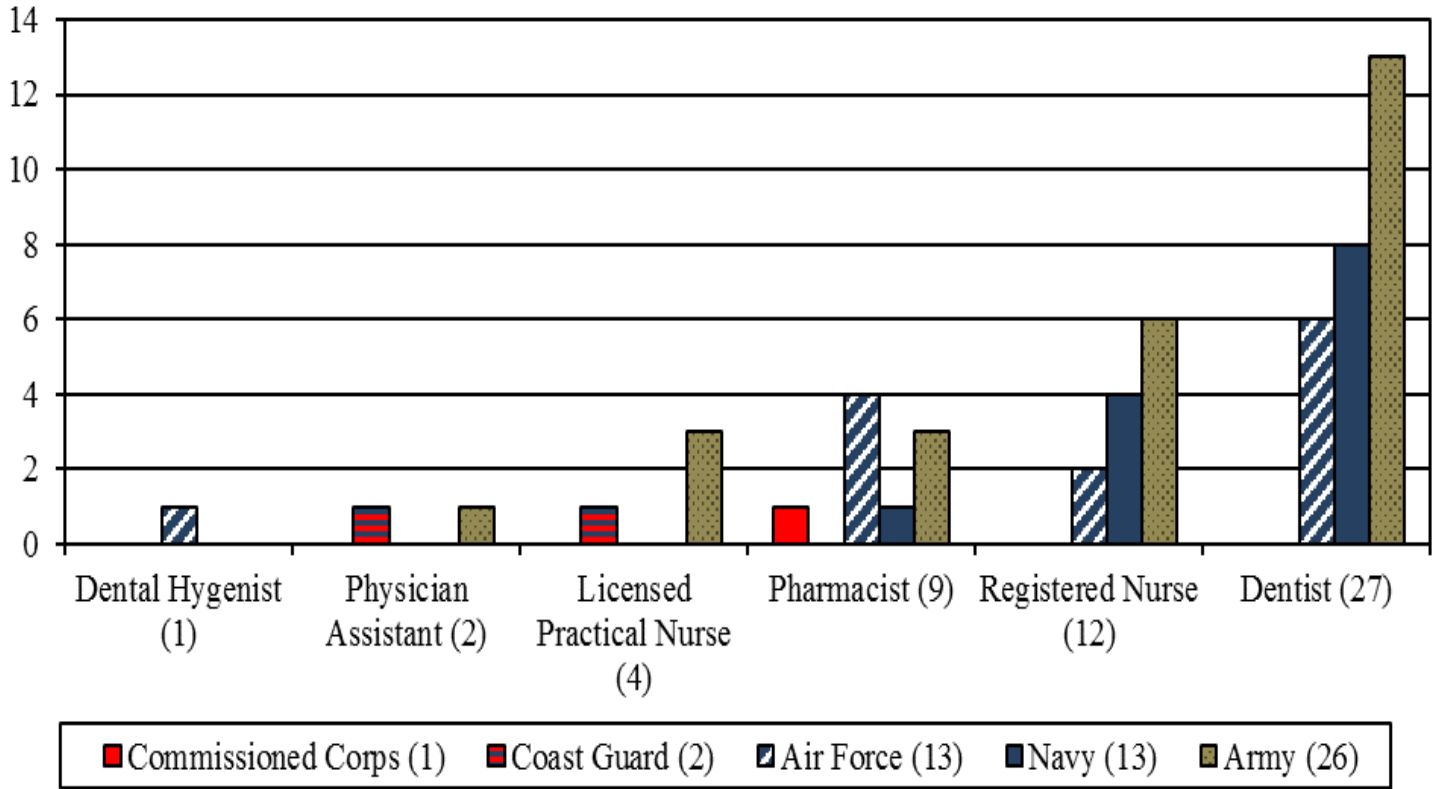
Board of Nursing <ul style="list-style-type: none"> • Biennial licensure 	115,342 479 8,567 48 766 1,264 21,206 147,672	Registered Nurses (RN) RN Nurse Midwives RN Nurse Practitioners RN Clinical Nurse Specialists RN Psychiatric Clinical Nurse Specialists RN Nurse Anesthesiologists Licensed Practical Nurses (LPN) Total
Board of Pharmacy <ul style="list-style-type: none"> • Biennial licensure (except Wholesale Distributor and Broker Licenses, which are annual) 	12,751 5,004 10,687 1,220 1,220 81 44 43 65 6 6 8 31,135	Pharmacists Pharmacy Interns Pharmacy Technicians Retail Pharmacies Retail Pharmacy Controlled Substance Permits Certificate of Fitness Permits Wholesale Distributors and Brokers Wholesale Distributor and Broker Controlled Substance Permits Nuclear Pharmacists Nuclear Pharmacies Nuclear Pharmacy Controlled Substance Permits Non-Resident Outsourcing Facilities Total
Board of Dentistry <ul style="list-style-type: none"> • Biennial licensure (except Limited Faculty Licenses, which are annual) 	6,809 7,155 7,861 2,969 439 243 690 300 38 677 27,181	Dentists Dental Hygienists Dental Assistants Dental Hygienists - Anesthesiology Permits Limited and Faculty Licensees General Anesthesia Permits Nitrous Oxide Permits Conscious Sedation Permits Portable Dental Operation and Mobile Dental Facility Permits Facility Permits Total
Board of Nursing Home Administrators <ul style="list-style-type: none"> • Annual licensure 	909 73 982	Nursing Home Administrators Administrator in Training (Internship) Total
Board of Physician Assistants <ul style="list-style-type: none"> • Biennial licensure 	3,261 1 3,262	Physician Assistants Temporary Physician Assistants Total
Board of Respiratory Care <ul style="list-style-type: none"> • Biennial licensure (Limited licenses cannot be renewed) 	2,794 64 2,858	Respiratory Therapists Limited Respiratory Therapists Total
Board of Perfusionists <ul style="list-style-type: none"> • Biennial licensure (except Provisional licenses, which are annual) 	106 0 3 109	Perfusionists Limited Perfusionists Provisional Licenses Total
Board of Genetic Counselors <ul style="list-style-type: none"> • Biennial licensure (except Provisional licenses, which are triennial) 	235 4 239	Genetic Counselors Provisional Genetic Counselors Total

Due to the recent establishment of the Board of Certification of Community Health Workers, no applications for certification were processed in FY2016.

Appendix C: *FY2016 VALOR Act Licensure Applications*



Appendix D: *FY2016 Active Service Duty Licensees*



Appendix E: Number of Complaints and Investigations During Fiscal Year 2016

Board	Staff Assignment Investigations Opened	Staff Assignment Investigations Closed	Formal Complaints Opened	Formal Complaints Resolved	Formal Complaints Resolved with Discipline Imposed	Formal Complaints Resolved with Discipline Imposed (%)
Nursing	230	214	251	175	97	55%
Pharmacy	190	145	147	245	94	38%
Dentistry	230	110	130	123	49	39%
Nursing Home Administrators	27	14	7	4	2	50%
Physician Assistants	6	3	5	7	6	85%
Respiratory Care	3	4	9	10	3	30%
Genetic Counselors	1	0	0	0	0	0%
Perfusionists	0	0	0	0	0	0%
Community Health Workers	0	0	0	0	0	n/a
Total	687	490	549	564	251	44%