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April 25, 2016

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
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Quality in Health Professions Trust Fund Annual Report

Fiscal Year 2015



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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 2015 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 General Appropriations Act) 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 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 will continue implementation of this legislation in Fiscal Year (FY) 2016.
- 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 will continue to draft regulations in FY16.
- 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, 2015, HPL licensed, registered, certified, or authorized 218,556 health care professionals and businesses. HPL is comprised of over 80 full-time equivalent staff.

Quality in Health Professions Trust Fund Revenue, Services, and Activities for Fiscal Year 2015

(i) Revenue Credited to the Trust Fund

| | |
|-----------------------------------|-------------------|
| FY2014 Carry Forward | \$ 8,404,360.00 |
| FY2015 Revenue Collections: | \$ 8,837,228.00 |
| FY2015 Expenditures: | \$ (8,016,961.00) |
| FY2015 End of Year Balance: | \$ 9,224,633.00 |
| FY2015 Carry Forward into FY2016: | \$ 9,224,633.00 |

(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 FY15, the Information Technology unit (IT) of HPL made multiple advancements to increase efficiency in various licensure processes. IT developed and implemented the creation of the Dental Assistant license type in MyLicense Office (MLO), the licensure database utilized by HPL, including a process for self-registration that allows Dental Assistant applicants to apply for initial licensure and license renewal online. Additionally, five new processes were created, four of which were implemented, for self-registration, allowing applicants to apply for initial licensure online as a Physician Assistant, Respiratory Therapist, Perfusionist, or Genetic Counselor. The processes for self-registration of applicants applying for initial licensure as a Nursing Home Administrator were created and the self-registration and online initial licensure application is anticipated to be available to applicants in early FY16.

¹ See Appendix A: FY Expenditures for Account 45100727

Also during FY15, IT worked with the Board of Registration in Pharmacy to lay groundwork for the implementation of specialty and non-resident licenses, by creating license types in MLO. In FY15, IT created 12 of the anticipated 20 new specialty and non-resident facility licensure categories, as well as the Pharmacy Technician Trainee license type, and three license types for Outsourcing Facilities. IT will continue to work with staff to develop the remaining specialty and non-resident licensure categories in FY16.

With the help of IT, HPL maintained a strong 90% success rate for online licensure renewal. IT continues to work on the Health Care Professions Workforce Data Collection Initiative, providing the results of the Physician Assistant and Dental Hygienist surveys from the online renewal system to DPH.

(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 FY15, trust fund expenditures totaling \$8,016,961.00 supported the shared costs of the HPL Boards. For example, the HPL Boards participated in administrative and programmatic reviews resulting in strategies for enhancing the current platform. Strategic priorities across HPL include policy development and implementation, revisions to Board policies, Board composition recruiting, continuing education audits, Just Culture² development and implementation, and improved transparency through centralized management of public records requests 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 FY15 and funded by the trust is provided in item (iv) below.

² A *Just Culture* recognizes that individual practitioners should not be held accountable for system failings over which they have no control. A *Just Culture* also recognizes many individual or “active” errors represent predictable interactions between human operators and the systems in which they work. However, in contrast to a culture that touts “no blame” as its governing principle, a *Just Culture* does not tolerate conscious disregard of clear risks to patients or gross misconduct (e.g., falsifying a record or performing professional duties while intoxicated). Marx D. Patient Safety and the “*Just Culture*”: A Primer for Health Care Executives. New York, NY: Columbia University; 2001. Available at: <http://www.safer.healthcare.ucla.edu/safer/archive/ahrq/FinalPrimerDoc.pdf>.

(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 FY15 are outlined below:

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

The HPL Boards license, register, or certify approximately 218,556 health care professionals and businesses as shown in Appendix A.³ The CHW Board aims to begin issuing certificates to community health care workers in FY16.

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 FY15, the Boards resolved 616 formal complaints against health professional/facility licenses. Two-hundred and eleven (211) formal complaints (34%) 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 523 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.

Statistics about the number of cases opened during FY15, the number of cases resolved during FY15, and the number and percentage of complaints that were resolved by imposition of a disciplinary action, are shown in Appendix B.⁴

³ See Appendix B: *Active Licenses, Registrations, Certifications, Permits and Approvals as of FY2015*.

⁴ See Appendix C: *Number of Complaints and Investigations During Fiscal Year 2015*.

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

Continuing Education Audit: The RC Board conducted a random continuing education audit to ensure that licensees were in compliance with its continuing education requirements. The RC Board voted to randomly select 10% of licensees, as well as all licensees with issues related to CEU documentation within the last three years, to submit CEU documentation for the renewal period of July 1, 2012 - June 30, 2014. IT randomly selected 10% (303) of licensees and provided staff with the name, license number, and contact information of the selected licensees. Staff reviewed minutes and identified an additional three licensees with prior issues related to CEU documentation, thus the total number of licensees to be audited was 306. On January 26, 2015, a letter and form approved by the RC Board was forwarded to each of the selected licensees' address of record. The RC Board subsequently reviewed all CEU documentation submitted by the selected licensees.⁵

At the close of the audit, 92 licensees were found to be non-compliant with continuing education requirements, while 17 licensees failed to respond to the RC Board. The 92 licensees that were found to be non-compliant had an investigation opened, each of which was later closed with a cautionary letter informing the licensees that they would be audited during the next renewal cycle. During FY16, the RC Board will issue an advisory to all licensees regarding compliance with continuing education requirements.

HPL has continued to conduct random CEU audits for the Boards of Registration in FY2016.

4. Approval of Continuing Education programs and credit units

The approval of continuing education programs by the Pharmacy Board, one of three ways a continuing education program is authorized by regulation, is a valuable service provided to the pharmacy community at no charge. The Board of Registration in Pharmacy approved 199 continuing education programs in FY15.

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, 2015, the Nursing Board approved the operation of a total of 75 Registered Nurse and Practical Nurse education programs:

- 27 Practical Nurse Programs;
- 20 Registered Nurse – Associate Degree Programs;
- 20 RN – Baccalaureate Degree Programs;

⁵ See Appendix D: *RC Board Continuing Education Audit Results*.

- 1 RN - Hospital-based Diploma Program; and
- 7 RN – Entry Level Graduate Degree Programs.

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

Registration of Dental Assistants: M.G.L. c.112, §51½ requires Dental Assistants working in the Commonwealth to register with the Dentistry Board. During FY15, the Executive Office of Administration and Finance established fees for the initial registration and renewal of Dental Assistants. Regulations applicable to the practice of Dental Assistants were promulgated in September 2014. The Dentistry Board began accepting initial registration applications in October 2014. The Dentistry Board processed and issued more than 5,000 Dental Assistant registrations by the close of FY15.

Amendments and Additions to 247 CMR: Pharmacy Board staff initiated a thorough review of current regulations, drafted and presented proposed new language, and the Pharmacy Board conducted a line-by-line review of each section during the open session of meetings.

The following regulations were drafted by Board staff and approved for administrative review by the Pharmacy Board during FY15:

- 247 CMR 4.00, Personal Registration Renewal and Continuing Education Requirements
- 247 CMR 6.00, Licensure of Pharmacies
- 247 CMR 9.00, Code of Professional Conduct and Practice Standards for Pharmacists, Pharmacies and Pharmacy Departments
- 247 CMR 18.00, Non-Sterile Compounding

Copies of [the draft regulations](#), as proposed, are available on the Pharmacy Board’s website. Each section of the regulations will be open for public comment during FY16 and the draft regulations may be revised based on consideration of the public comments received. After any revisions are made, the final regulations will be brought before the Pharmacy Board for final approval.

Regulations Governing Advanced Practice Registered Nursing: The Nursing Board approved final amendments to Board regulations governing advanced practice nursing on July 9, 2014. The final amendments reflect the Board’s consideration of input that was received from a variety of stakeholders beginning in 2006 with recommendations made by the Board’s 244 CMR 4.00 Task Force; the Board’s subsequent collaboration, as required by law, with the Boards of Medicine and Pharmacy, and the August 2013 public comment period during which the Board received testimony from professional medical and nursing organizations, the business community, and individual registered nurses. The amended regulations at 244 CMR 4.00 incorporate many of the standards of contemporary advanced practice nursing promoted by the national Advanced Practice Registered Nurse Consensus Model, and recognize the ability of Advanced Practice Registered Nurses (APRNs) to provide safe, cost-effective, and high quality care. Effective August 1, 2014, the amended regulations at 244 CMR 4.00: *Massachusetts Regulations Governing Advanced Practice Registered Nursing*:

- Require a graduate degree or postgraduate certificate (post-masters or doctorate) for *initial* APRN authorization, as well as course completion in advanced assessment, pathophysiology and pharmacotherapeutics;
- Specify APRN initial and ongoing competencies and scopes of practice for each practice category;
- Change the titles of the four APRN practice categories authorized by the Board, fostering uniform recognition regardless of the state in which an APRN practices;
- Create a fifth APRN practice category - the non-psychiatric Clinical Nurse Specialist (CNS) - providing title protection for qualified registered nurses;
- Require Registered Nurses who meet the academic preparation and certification requirements to apply for and be granted Board authorization as a CNS in order to continue to use the CNS title;
- Identify CNS-equivalent competency conditions to grandfather eligible Registered Nurses until December 31, 2016. The CNS who is authorized by the Nursing Board on the basis of this equivalent competency will be eligible to renew his or her CNS authorization;
- Clarify that requirements for written guidelines developed with a supervising physician apply solely to the Certified Registered Nurse Anesthetist (CRNA), Certified Nurse Practitioner (CNP), and Psychiatric Clinical Nurse Specialist (PCNS) who registers for prescriptive practice (the Certified Nurse Midwife (CNM) is exempted from this requirement in light of M.G.L. c. 112, §80G, which no longer requires a CNM to engage in practice with a supervising physician or to have written guidelines); and
- Requires professional malpractice liability insurance for all APRNs with direct patient care responsibilities.

Draft Community Health Worker Regulations: During FY15, numerous draft regulations were developed by the CHW Board. The CHW Board and CHW Advisory Work Group will continue to work on the remaining regulations in FY16.

Draft Community Health Worker Fee Proposal: A licensure fee proposal was drafted on behalf of the CHW Board during FY15 and a public comment period will take place during FY16.

Prescription Monitoring Program Regulatory Amendments: On November 12, 2014, the Massachusetts Public Health Council approved amendments relative to the use of the state's Prescription Monitoring Program (PMP), fulfilling the mandate of M.G.L. c.94C, §24A. The amendments at 105 CMR 700.000: *Implementation of M.G.L. c. 94C* will improve public health and safety by:

- Requiring certain PMP participants to utilize the PMP prior to issuing to a patient, for the first time, a prescription for a Schedule II or III narcotic drug, or for a drug product containing a benzodiazepine;
- Outlining those times when a registered individual prescriber does not have to utilize the PMP, such as during emergency care, or other identified circumstances;
- Enabling DPH to issue guidance on PMP utilization prior to prescribing commonly abused and addictive prescription drug products in Schedules IV and V;

- Allowing for the use of delegates, a class of PMP users who, as authorized support staff, may use the system (as designated by DPH) on behalf of a registered participant; and
- Creating a process by which access to the PMP may be suspended or revoked if a user violates the terms and conditions for use of the system.

Prescribing APRNs and Physician Assistants (PAs) will automatically be enrolled in the online PMP. The automatic PMP enrollment of all prescribers, including physicians, dentists, and podiatrists, in addition to APRNs and PAs, will occur simultaneously with the renewal of the prescribers' Massachusetts Controlled Substance Registration.

Dentistry Staff Action Policy regarding Disposition of Selected Complaints (Unlicensed Practice): On September 3, 2014, the Dentistry Board adopted a policy authorizing and allowing for the timely review and disposition of staff assignments and complaints pertaining to the unlicensed practice of dentistry and dental hygiene, and for the employment by dentists of unlicensed dentists and dental hygienists. Under this policy, after investigation and review of a complaint, the Executive Director may act on a complaint for the unlicensed practice of dentistry or dental hygiene and the employment by a licensed dentist of an unlicensed dentist and/or dental hygienist. Where the specified criteria are not met, the Executive Director must submit the complaint to the Dentistry Board for review and disposition. The Executive Director (or designee) must notify the Dentistry Board quarterly of those complaints of unlicensed practice that have been resolved through the staff action policy.

Dentistry Staff Action Policy regarding the Issuance and Renewal of Limited Licenses: On September 3, 2014, the Dentistry Board adopted a policy authorizing the Executive Director to direct the issuance and renewal of limited licenses pursuant to M.G.L. c. 112, §45A on the Board's behalf while specifying criteria that limits the scope of the Executive Director's authority.

Nursing Board English Proficiency Policy Recognizes MELAB among Other English Proficiency Exams: At their November 2014 meeting, members of the Nursing Board approved revisions to Licensure Policy 06-01: Board-designed Test of English Proficiency and Required Minimum Cut Scores to recognize the Michigan English Language Assessment Battery (MELAB). In taking this action, the Nursing Board considered the findings and recommendations of the Standard Setting Panel convened by the National Council of State Boards of Nursing, which used a recognized standard setting process to identify cut scores sufficient for safe and effective entry-level nursing practice.

The policy is designed to identify those tests of English proficiency and their corresponding minimum cut score that the Nursing Board has designated as acceptable in fulfilling compliance with its regulations at 244 CMR 8.02(1)(c), 8.03(1)(c), and 8.04(1)(c), (2)(d), and (3)(d), which require an applicant for initial nurse licensure by examination or by reciprocity to demonstrate English proficiency if the applicant is a graduate of an approved nursing education program whose language of instruction or textbooks, or both, was not English. It is available on the [licensing page](#) of the Nursing Board's website.

Joint Pharmacy Policy 2015-01⁶, Pharmacist and Pharmacy Intern Administration of Vaccines and FAQs: This policy allows Pharmacy Interns, under the supervision of a Pharmacist, to administer vaccines in the Commonwealth. The policy was also updated to allow Pharmacists to administer all vaccines approved by the CDC, rather than the specific list of vaccines previously authorized.

Pharmacy Policy 2015-02, Guidance for Changes to Pharmacist Continuing Education Requirements: The policy clarifies the new continuing education requirements for Pharmacists, pursuant to M.G.L. c. 112, §24A and provides the Pharmacy Board’s interpretation of what it means to be “engaged” in sterile or non-sterile compounding for the purposes of satisfying the newly required sterile and non-sterile compounding continuing education credits.

Genetic Counselor Policy 14-01 Use of Titles and Credentials by Genetic Counselors: In order to clarify the proper use of the title of Genetic Counselor, on October 2, 2014, the GC Board completed and posted Administrative Policy 14-01 Use of Titles and Credentials by Genetic Counselors.

Domestic Violence Training Requirement for Licensure: M.G.L. c. 112, §264 requires that the Nursing Board, the NHA Board, and the PA Board promulgate regulations establishing standards requiring training and education on the issue of domestic and sexual violence as a condition of licensure and license renewal. Additionally, the NHA Board plans to review regulations with the intent to revise the criteria for the educational requirements for the nursing home administrator in training program.

Amending Nursing Regulations: In FY16, the Nursing Board intends to focus on the promulgation of amendments to its regulations at 244 CMR. The Board will closely review 244 CMR 3.05, with respect to delegation to unlicensed persons, and 244 CMR 6.00, to identify changes to modernize the standards and streamline the process for approval of nursing education programs. The Board will also consider revisions to implement recent statutory changes relating to enrollment in MassHealth as either a provider of services or for the limited purpose of ordering and referring, licensing provisions applicable to service members, veterans and their family members, and training requirements relating to domestic and sexual violence and to substance abuse education and prevention. Additional regulatory updates will be reviewed to codify licensee and applicant responsibilities with respect to license renewal and the information submitted to the Board, aggregation of definitions into a single, separate section, corrections to provisions applicable to certified registered nurse anesthetist (CRNA) practice and the adoption of provisions that will promote investigation and handling of complaints in a manner that will be consistent across all boards within the Division.

Drafting Pharmacy Regulations: During FY16, the Pharmacy Board will continue to review draft regulations, including: 247 CMR 8.00, pertaining to the addition of a new licensure category for technicians in training; 247 CMR 17.00, pertaining to standards for sterile compounding; 247 CMR 19.00, pertaining to standards for hazardous compounding; and 247 CMR 20.00, pertaining to requirements to report information to the Board.

⁶ This joint policy is between the Board of Pharmacy and the Drug Control Program.

Dentistry Regulatory Review Workgroup: The Dentistry Board convened a working group comprised of Board members, staff, practicing oral surgeons, pediatric dentists, orthodontists, and dental assistants, to undertake a section-by-section, line-by-line review of the Board's August 2010 amendments to 234 CMR. The working group began meeting on January 21, 2015, and started its review with the sections pertaining to anesthesia and sedation. The working group will report its recommendations to the Dentistry Board after completing its review in FY16.

Amending Nursing Home Administrator Regulations: A Board Subcommittee was formed on August 21, 2014, to draft revisions to NHA Board regulations. The NHA Board Subcommittee met five times during FY15. When the NHA Board Subcommittee completes draft revisions to the regulations, their work will be presented to the NHA Board for draft approval.

Amending Perfusionist Regulations: Over the next fiscal year, the Perfusionists Board will be reviewing Board regulations and revising them as appropriate.

Amending Physician Assistant Regulations: Over the next fiscal year, the PA Board will be reviewing Board regulations and revising them as appropriate.

Amending Respiratory Care Regulations: Over the next fiscal year, the RC Board will be reviewing its regulations and revising them as appropriate.

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

Dental Board Advisory Ruling on Prescribing Authority: On September 3, 2014, the Dentistry Board issued an Advisory Ruling on the prescribing authority of limited license dental interns pursuant to M.G.L. c. 30A, §8 and M.G.L. c. 112, §43. The Board determined that limited registration dental interns and dental faculty are "dentists" with prescriptive authority, subject to limitations as to location and supervision, as set forth in M.G.L. c.112, §45A.

Systematic Review of Nursing Board-issued Advisory Rulings: The following Advisory Rulings have been updated by the Nursing Board since July 2014:

- 9204: *Infusion Therapy*;
- 9301: *Peripherally Inserted Central Catheters*;
- 9305: *Foot Care*;
- 9324: *Accepting, Verifying, Transcribing and Implementing Prescriber Orders*; and
- 1001: *Management of Patients Receiving Analgesia by Catheter Technique*.

In addition, the Nursing Board has issued a new Advisory Ruling 14-01: *Enhancing the Disclosure of Unanticipated Outcomes*. This Advisory Ruling promotes effective disclosure of unanticipated outcomes to patients and their families by Licensed Practical Nurses, Registered Nurses, and Advanced Practice Nurses when applicable under M.G.L. c. 233, §79L and the policies of the employing facility. These and all other Advisory Rulings are based on a systematic review of numerous sources of information and evidence-based standards of practice

by the Board's Nursing Practice Advisory Panel. In each advisory, the Board affirms that the licensed nurse is responsible and accountable for acquiring and maintaining the knowledge, skills, and competencies necessary to practice in accordance with accepted standards.

Updates to Nursing Advisory Ruling 09-01: Management of Pain: The Nursing Board provided updated guidance to Licensed Practical Nurses, Registered Nurses and Advanced Practice Nurses in promoting patient access to appropriate, therapeutic and effective assessment, diagnosis and management of acute and chronic pain. This Advisory Ruling update incorporates a National Transportation Safety Board (NTSB) recommendation that health care providers educate their patients about the effect that their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation. The NTSB recommendation is based on its study, *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment* (September 2014), which examined the prevalence of over-the-counter (OTC), prescription, and illicit drug use, which was identified by toxicology testing of 6,677 pilots who died in a total of 6,587 aviation accidents between 1990 and 2012. The goals of the study were to describe the prevalence of drug use among fatally injured pilots over time and to evaluate the need for safety improvements.

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 followed by Probation, Surrender followed by Probation, Stayed Suspension, or Reprimand. The Probation Department is in the process of developing a new database to track all probation cases monitoring activity across all HPL boards. The new database will allow the Probation Department to track licensee progress on a more detailed level, as well as run reports on probation data and generate draft compliance summaries with that data. Completion of the new database is anticipated for FY16. As of June 30, 2015, the Probation Department was monitoring 215 participants. In addition, HPL has established a division-wide staff action policy, which is in the process of being adopted by all HPL boards, authorizing the handling of monitored cases in a more efficient and consistent manner.

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 abuse treatment is available to consult with both participants and HPL monitoring staff. The program takes five years to successfully complete. As of June 30, 2015, MPRS was monitoring the compliance of 27 participants.

9. Administration of the Substance Abuse Rehabilitation Program (SARP) for nurses

The Substance Abuse Rehabilitation Program (SARP) is a voluntary, non-disciplinary approach to substance abuse 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 ongoing recovery of participants and their return to safe nursing practice. As of June 30, 2015, SARP was monitoring the compliance of 169 participants. During FY15, staff from SARP and the Board of Registration in Nursing worked to expand community outreach and collaboration with stakeholders to provide information about 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 FY15, HPL focused on increasing recruiting efforts to fill vacant board seats across all HPL boards. By the end of FY15, 75.6% of all board appointments were filled. A total of 18 new board members were appointed during FY15.

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

Aggressive Pharmacy Compliance Inspections: During FY15, seven Pharmacist Investigators from the Office of Public Protection, on behalf of the Pharmacy Board, conducted 1,181 retail compliance inspections, 43 non-sterile compounding inspections, and 22 sterile compounding inspections and site visits. The inspections were made possible by the hiring and training of four new Pharmacist Investigators during FY14.

The Board of Registration in Pharmacy's focus on sterile and non-sterile compounding is in addition to investigating complaints involving pharmacy professionals and businesses. The Board of Registration in Pharmacy also conducts an inspection of all new applicants for retail/community-based pharmacy and wholesale distributor licenses, and periodic re-inspections of licensed retail pharmacies in an effort to resolve the increasing number of pharmacy complaints involving medication errors.

Staff Training: During FY15, two of the four new Pharmacist Investigators attended FDA sterile compounding training. The remaining two Pharmacist Investigators attended training in early FY16. Additionally, the Director of Quality Assurance attended advanced training in cleanroom microbiology, to assist in responding to reports of abnormal environmental monitoring in sterile compounding cleanrooms.

Multi-State Inspection Collaboration: In recognition of the need for a uniform inspection to evaluate non-resident pharmacies for licensure, the National Boards of Pharmacy created the Inspection Blueprint. During FY15, on behalf of the Pharmacy Board, 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 during FY16.

During FY15, the Board of Registration in Dentistry completed a total of 70 facility inspections. The Board of Registration in Dentistry convened a working group comprised of general dentists, dental hygienists, and experts in infection control and dental anesthesia to review the current facility inspection checklists used by investigators. The checklist is used to prepare for compliance inspections, and assess and evaluate applications for facility permits for administration of various types of sedation and anesthesia. The revised checklist was approved by the Board and posted online in October 2014. The checklist will be updated and re-posted again in FY16.

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 Stakeholder Involvement: As the Pharmacy Board endeavors to promote transparency and is determined to improve public safety by working closely with its licensees, the Board considers stakeholder outreach paramount to success. To facilitate outreach to the pharmacy community, the Pharmacy Board staff held meetings and conference calls with many stakeholders, including representation from nuclear pharmacy, environmental monitoring vendors, specific pharmacy-related experts (such as microbiologists, HVAC engineers, USP <797> consultants, radiopharmaceutical consultants), other boards of pharmacy, NABP, and various pharmacists' associations. Stakeholder involvement will continue to be an important strategic component as the Board moves forward promulgating regulations in FY16.

Pharmacy Educational Outreach: Pharmacy Board staff made outreach a large focus of FY15 to engage the professional community in proposed new standards and provide guidelines for statutory changes. Board staff made an interagency presentation to the staff of the Bureau of Health Care Safety and Quality, illustrating the Board's sterile compounding inspection tool and progress, to date, with sterile compounding inspections. Outreach also included participation in the following Pharmacist continuing education programs, which attracted a wide range of Pharmacists in a variety of pharmacy practice settings:

- MassHealth Provider Training Series;
- PharmEd Conference Series;
- MCPHS University's 4th Annual Stoklosa Symposium; and
- Northeastern University's Implementing Best Practices for USP <795> and <797>.

Nursing Board Membership in Statewide Initiatives Promoting Safety and Workforce Development:

The Nursing Board's participation in statewide nurse workforce initiatives supports the practice of nurses to the full extent of their education, achievement of higher levels of education through seamless academic progression, partnerships among nurses, physicians, and other health care professionals in redesigning health care, and effective workforce planning and policy making. The Nursing Board is an active member of the following statewide initiatives promoting patient safety and nursing workforce planning:

- Massachusetts Coalition for the Prevention of Medical Errors;
- DHE Centralized Clinical Placement Task Force;
- Massachusetts Action Coalition
 - Leadership Committee
 - Advanced Practice Scope of Practice Team
 - RN/LPN Scope of Practice Team;
- Eastern Massachusetts Long-term Care Nursing Group, Massachusetts Senior Care Association;
- MA Prescription Monitoring Program Joint Policy Working Group;
- Prescription Drug Task Force, Office of the Norfolk County District Attorney; and
- Care Transitions Education Project Statewide Advisory Board.

In addition to active participation in the above-referenced initiatives, the Nursing Board collaborated with the DPH Health Care Workforce Center (HCWC) in the development of the 2015 Licensed Practical Nurse workforce survey to collect important information (demographics, education, employment, and future work plans) in order to assess, forecast and inform nursing workforce development. Data analysis is performed by the HCWC and [reports](#) are published on the Nursing Board's website.

Nursing Board Outreach: In FY15, staff focused on outreach to the stakeholder community. In April 2015, staff made a presentation to aspiring long-term care directors of nursing at MA Senior Care Association related to scope of practice, delegation, and responsibilities of a nurse in a management role. During FY15, staff made the following presentations to publicize the requirements and changes of the newly amended 244 CMR 4.00: *Massachusetts Regulations Governing Advanced Practice Registered Nursing (APRN)*:

- Massachusetts Chapter of American Nurses Association;
- Brigham and Women's Hospital;
- Hallmark Health Hospital;
- Massachusetts General Hospital;
- Boston College Graduate School of Nursing;
- Regis College MSN Program; and
- CRICO Risk Management Foundation of the Harvard Medical Institutions.

Nursing Board Staff Host Portuguese Nurse Regulators: On November 13, 2014, Germano Couto, President, and Raul Fernandes, Head of Office, Ordem do Enfermeiros, the regulatory agency governing nursing practice in Portugal, met with the Nursing Board Executive Director and Board staff to learn about nursing regulation in the United States and, in particular, the Nursing Board's use of best practices in its regulation of nursing practice and entry-level education in the Commonwealth.

Nurse Workforce Data: In collaboration with the MA HCWC, the Nursing Board continued to facilitate the collection of nurse workforce data (demographics, education, employment characteristics, and future work plans). The data, collected in conjunction with the online license renewal process, provides important information to assess, forecast, and inform nursing workforce development. Data analysis is performed by the HCWC and reports are published on the Nursing Board's [website](#).

(v) Fiscal Year 2015 Initiatives

In FY15, HPL and the Boards of Registration began planning and undertaking the following activities:

1. Policy Development and Implementation

- a) Division-wide policies have been revised to authorize staff to act on its behalf to improve consistency across the nine Boards where feasible.
- b) Policies have been reviewed and edited to reflect changes in procedures.
- c) A review schedule has been developed to ensure that all policies and procedures remain current.

2. Just Culture Development in HPL

In 2012, the Special Commission on the Oversight of Compounding Pharmacies (Special Commission) was charged to analyze the needs of and gaps in the pharmacy industry in order to formulate recommendations on necessary policy, regulatory, and legislative changes. The Special Commission recommended that the Board of Registration in Pharmacy, along with the entire Department of Public Health, adopt *Just Culture* as the framework for ensuring patient safety and quality of care. HPL explored various *Just Culture* training options and staff met with training professionals focusing on *Just Culture* development to discuss different approaches on how to best introduce *Just Culture* to HPL. HPL board members and staff attended a webinar on *Just Culture* during FY15.

3. Improving Transparency

a) Centralized Management of Public Records

Public record request management is a critical part of maintaining transparency regarding board processes. To ensure consistent management and legal compliance, the management of all public record requests was centralized in FY15 and new standardized processing policies were implemented across all boards. All public record requests presented to HPL were streamlined and directed to a specially assigned HPL Program Analyst.

b) Posting of Board Minutes and Consent Agreements on Website

Many recommendations from the Special Commission, as well as ongoing efforts within the boards, have focused on making board procedures, processes, and case disposition information more easily accessible. HPL has posted all board minutes and agendas for a minimum of the past two years on its website. In FY15, HPL compiled a database of all disciplinary Consent Agreements to prepare for posting to the respective board websites.

4. VALOR Act to Assist Active Military, Military Spouses and Veterans:

Under Chapter 108 of the Acts of 2012, "An Act Relative to Veterans' Access, Livelihood, Opportunity, and Resources", otherwise known as the VALOR Act (VALOR Act), the following statutes 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. 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. 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. M.G.L. c. 112, §1B(d).

HPL began receiving inquiries about the VALOR Act from service members, veterans and service member spouses in July 2013. Since that time, HPL has processed 49 applications for licensure by service members, veterans, or spouses, including two active duty service members, 30 spouses of active duty service members and 17 veterans.⁷ The greatest concentration of applicants is military spouses applying for RN licensure.

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.

⁷ See Appendix E: *FY15 Active Service Duty Licensure Applications*.

Conclusion

In Fiscal Year (FY) 2015, \$8,837,228 in revenue collections was deposited into the Quality in Health Professions Trust Fund. Over \$8,016,900 was spent during FY15 to support the administrative, programmatic, and operational costs of the HPL's Boards of Registration. At the end of FY15, an unexpended balance of over \$9,224,600 was carried forward to FY16.

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 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: *FY15 Expenditures*

Please see separate Excel spreadsheet data.

Appendix B: *Active Licenses, Registrations, Certifications, Permits and Approvals as of FY2015*

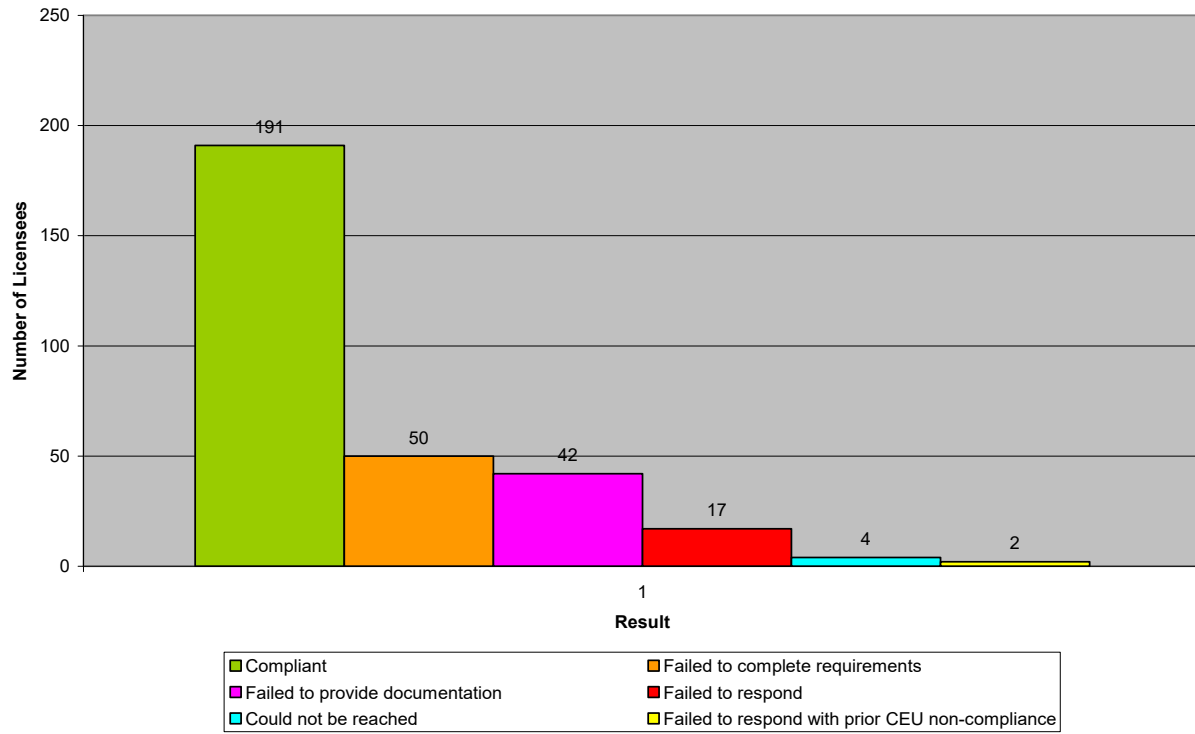
| | | |
|--|--|--|
| Board of Nursing • Biennial licensure | 125,229 489 8,242 35 830 1,271 21,129 157,225 | Registered Nurses (RN) RN Nurse Midwives RN Nurse Practitioners RN Clinical Nurse Specialists RN Psychiatric Clinical Nurse Specialists RN Nurse Anesthesiologists Licensed Practical Nurses (LPN) Total |
| Board of Pharmacy • Biennial licensure (except Wholesale Distributor and Broker Licenses, which are annual) | 11,904 4,904 10,518 1,175 1,175 90 49 49 59 6 6 29,935 | 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 Total |
| Board of Dentistry • Biennial licensure (except Limited Faculty Licenses, which are annual) | 7,113 6,852 5,067 2,638 374 253 741 298 41 736 24,113 | 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 • Annual licensure | 932 64 996 | Nursing Home Administrators Administrator in Training (Internship) Total |
| Board of Physician Assistants • Biennial licensure | 2,905 1 2,906 | Physician Assistants Temporary Physician Assistants Total |
| Board of Respiratory Care • Biennial licensure (Limited licenses cannot be renewed) | 2,995 69 3,064 | Respiratory Therapists Limited Respiratory Therapists Total |
| Board of Perfusionists • Biennial licensure (except Provisional licenses, which are annual) | 117 0 4 121 | Perfusionists Limited Perfusionists Provisional Licenses Total |
| Board of Genetic Counselors • Biennial licensure (except Provisional licenses, which are triennial) | 188 8 196 | Genetic Counselors Provisional Genetic Counselors Total |
| Board of Community Health Workers | Due to the recent establishment of the Board of Certification of Community Health Workers, no applications for certification were processed in FY2015. | |

Appendix C: Number of Complaints and Investigations During Fiscal Year 2015

| 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 | 136 | 160 | 236 | 189 | 95 | 50% |
| Pharmacy | 150 | 136 | 186 | 272 | 56 | 20% |
| Dentistry | 168 | 114 | 109 | 146 | 53 | 36% |
| Nursing Home Administrators | 15 | 8 | 2 | 0 | 0 | 0% |
| Physician Assistants | 6 | 9 | 3 | 3 | 2 | 66% |
| Respiratory Care | 103 | 96 | 24 | 5 | 4 | 80% |
| Genetic Counselors | 0 | 0 | 0 | 1 | 1 | 100% |
| Perfusionists | 1 | 0 | 0 | 0 | 0 | 0% |
| Community Health Workers | 0 | 0 | 0 | 0 | 0 | n/a |
| Total | 579 | 523 | 560 | 616 | 211 | 34% |

Appendix D: RC Board Continuing Education Audit Results

2015 Board of Respiratory Care CEU Audit



Appendix E: *FY15 Active Service Duty Licensure Applications*

| | Spouses (30) | Veterans (17) | Active Duty (2) |
|---------------------------|---------------------|----------------------|------------------------|
| RN (28, 3 pending) | 20, 2 pending | 8, 1 pending | 1 |
| LN (5) | 1 | 4 | 0 |
| DN (3) | 2 | 0 | 1 |
| DH (2) | 2 | 0 | 0 |
| RT (3) | 1 | 2 | 0 |
| PA (3) | 1 | 2 | 0 |
| NH (1) | 1 | 0 | 0 |