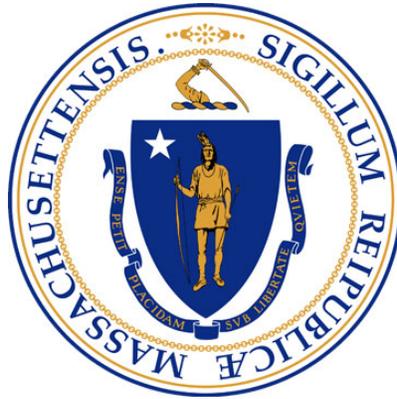


# **Commonwealth of Massachusetts**

## **Division of Health Professions Licensure**



## **Fiscal Year 2014 ANNUAL REPORT**

### **Commonwealth of Massachusetts**

Deval L. Patrick, Governor

### **Executive Office of Health and Human Services**

John W. Polanowicz, Secretary

### **Department of Public Health**

Cheryl Bartlett, RN, Commissioner

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## Message from the Commissioner



The Division of Health Professions Licensure (HPL) of the Massachusetts Department of Public Health is pleased to submit this report of Fiscal Year 2014 activities.

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

HPL, which includes nine separate Boards, is charged with evaluating the qualifications of applicants for licensure and granting licenses to those who qualify. HPL establishes rules and regulations to ensure the integrity and competence of licensees. The Boards promote public health, welfare, and safety by ensuring that licensed professionals and entities meet statutory requirements.

This report summarizes and highlights statistics and accomplishments undertaken in fulfilling the mandate to protect the public health, safety, and welfare in Massachusetts. It also reflects HPL's continued commitment to establishing and improving standards.

Under the leadership of James Lavery, the Director of Health Professions Licensure, during the Fiscal Year 14, HPL has met many of the strategic goals and priorities referenced in its [Strategic Planning Interim Report](#). The Interim Report highlights strategic planning efforts by HPL that were in progress when the report was written, as well as efforts anticipated in the near future. HPL staff has worked diligently over this past fiscal year to strengthen their policies and procedures and improve uniformity across all 9 Boards where feasible. Implementation of new regulations continues to bolster HPL's overall goals and accomplishments in improving public safety.

On March 27, 2014, Governor Deval Patrick declared a public health emergency. To address the significant increase in opioid-related overdose deaths in the Commonwealth, the Department of Public Health, through multiple Boards of registration, promulgated emergency regulations regarding Hydrocodone-Only Extended Release Medications that are not in an abuse deterrent form.

On July 10, 2014, the Governor signed Chapter 159 of the Acts of 2014: *An Act Relative to Pharmacy Practice in the Commonwealth*. This legislation requires new specialty licenses for the practice of pharmacy, including sterile compounding. The Board of Registration in Pharmacy (BORP) continues to take considerable steps forward, improving the delivery and oversight of pharmacy services in the Commonwealth.

Leading the way in the implementation of the pharmacy reforms is David Sencabaugh, who joined HPL on September 22, 2013 as the Executive Director of the Board of Registration in Pharmacy. David's background spans more than 30 years in community pharmacy, with emphasis on legislative affairs, regulatory compliance, and quality assurance.

During this fiscal year, the hard work and commitment of the BORP staff led to an increased number of pharmacy inspections and general advancements towards improving public safety. In appreciation of this effort, I awarded the BORP's four senior pharmacy inspectors with the Performance Recognition Award for going above and beyond the call of duty in what was an extremely challenging year.

The following pages give a more comprehensive perspective of how all of the Boards at HPL work on behalf of the Commonwealth.

We look forward to your [feedback](#), and to working with you in the future.

Cheryl Bartlett, RN, Commissioner  
Massachusetts Department of Public Health

## **Introduction**

The Division of Health Professions Licensure (HPL) is comprised of 9 Boards of Registration: Community Health Workers, Dentistry, Genetic Counselors, Nursing, Nursing Home Administrators, Perfusionists, Pharmacy, Physician Assistants and Respiratory Care.

### ***Mission Statement***

To protect the public health, safety, and welfare by licensing qualified health care professionals, services, and facilities through the fair and consistent application of statutes. Through our Boards of Registration and in an open forum, we develop, implement, and enforce regulations and policies that assure and promote the safe practice of those we license and regulate.

### ***Vision Statement***

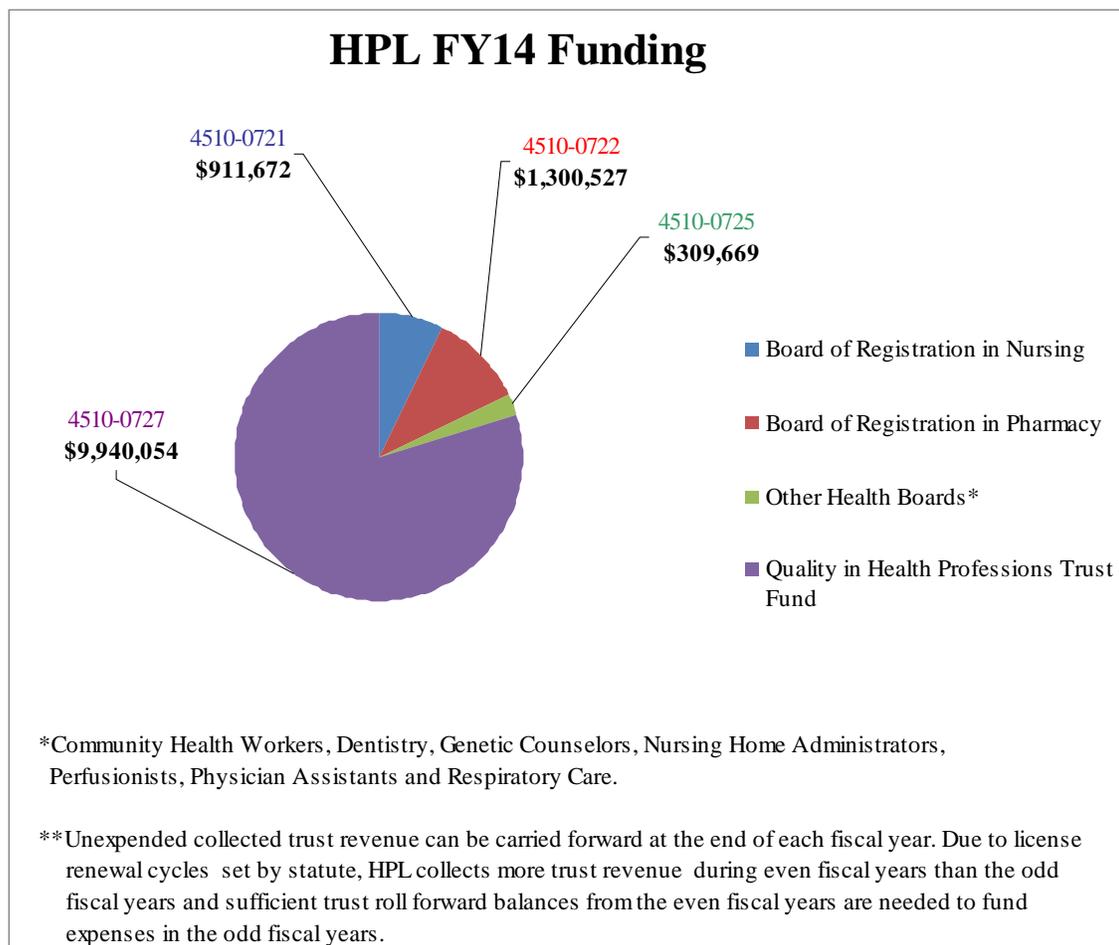
- I. We believe that the citizens of Massachusetts deserve the highest quality of health care provided by qualified healthcare professionals who practice, and by facilities that operate, with the highest degree of ethics and integrity.
- II. We recognize and value the contributions of our volunteer Board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

### ***Budget***

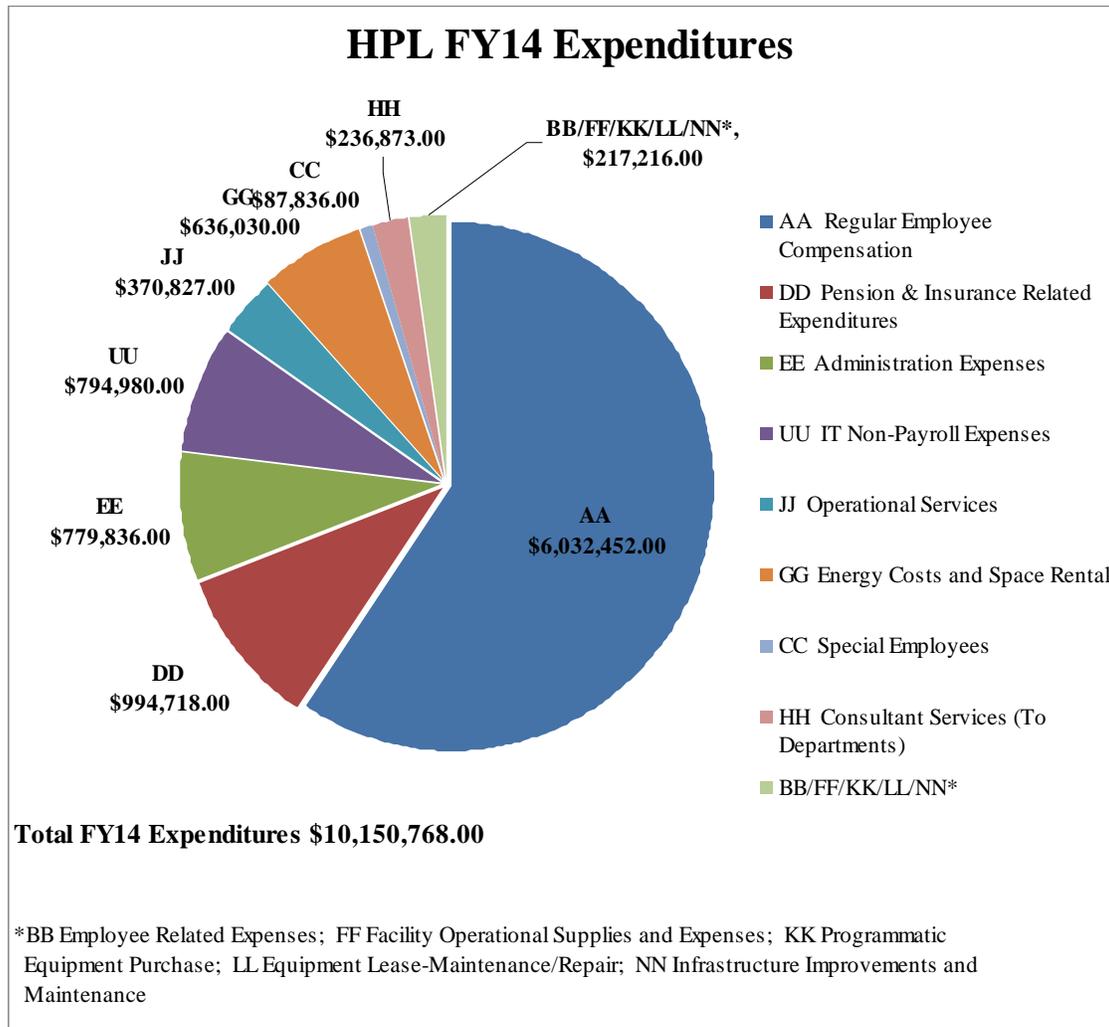
As of July 1, 2014, HPL licensed, registered, certified or authorized approximately 199,118 health care professionals and businesses and its staffing level included over 70 full-time equivalent active staff.

HPL and its 9 health Boards of Registration are funded by a combination of three state appropriations and the Quality in Health Professions Trust Fund.

- I. Appropriation account 4510-0721 supports the Board of Registration in Nursing.
- II. Appropriation account 4510-0722 supports the Board of Registration in Pharmacy.
- III. Appropriation account 4510-0725 supports the remaining seven Boards: Community Health Workers, Dentistry, Genetic Counselors, Nursing Home Administrators, Perfusionists, Physician Assistants, and Respiratory Care.
- IV. The Quality in Health Professions Trust Fund, account 4510-0727, supports the operations of all nine Boards. The trust is funded by a complex statutory formula that directs a portion of each license fee to be deposited in the trust. Unexpended collected trust revenue can be carried forward at the end of each fiscal year. Due to license renewal cycles set by statute, HPL collects more trust revenue during the even fiscal years than odd fiscal years. Sufficient trust roll forward balances from the even fiscal years are needed to fund expenses in the odd fiscal years.



The FY14 GAA supports an expansion of pharmacy inspections and investigations with an additional \$1.3M appropriated to the Board of Registration in Pharmacy (4510-0722). This increased funding is being utilized by the Board to perform heightened inspections and monitoring of sterile and non-sterile compounding pharmacies and unannounced inspections of all pharmacy facilities in the Commonwealth.



Administration and support services for the Boards of Registration are centralized within HPL and shared among the Boards to provide economies of scale, promote consistency in the application and enforcement of requirements, and permit streamlined and efficient operations for the issuance of licenses, collection of revenue, budget and accounting, provision of information technology services, enforcement, investigations, legal services and adjudicatory hearings. All funds expended on the trust fund are attributable to the shared licensing and enforcement activities of the nine Boards.

## ***Compliance***

HPL's compliance activities are essential to its mission. HPL conducts inspections and investigations of licensees, prosecutes cases and takes disciplinary action against the licenses of individuals and/or businesses who engage in conduct that may pose a threat to the health, safety and welfare of the public. During FY14, collectively the Boards resolved 628 formal complaints against health professional/facility licenses; 36% or 226 formal complaints were resolved by imposition of disciplinary action.

HPL administers the Massachusetts Professional Recovery System (MPRS) for licensed health professionals (dentists, pharmacists, respiratory therapists, physician assistants, perfusionists, nursing home administrators, and genetic counselors). 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. MPRS consists of an advisory panel of 7 health care professionals. It takes 5 years to successfully complete the program. As of June 30, 2013, MPRS was monitoring the compliance of 30 participants. Since 2010, MPRS has successfully graduated 33 participants.

The Substance Abuse Rehabilitation Program (SARP) is a voluntary, non-disciplinary approach to substance abuse among licensed nurses. Established at G.L. c. 112, § 80F, it 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. It takes five years to successfully complete the program. 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 participants' ongoing recovery and their return to safe nursing practice. As of June 30, 2014, SARP was monitoring the compliance of 174 participants.

## ***Information Technology Department***

In FY14, HPL's Information Technology (IT) department made advancements to increase the efficiency in a multitude of processes, the most important being a complete upgrade and expansion of the eLicensing system architecture in the Managed Services area at the Information Technology Division (ITD). This included 17 new virtual servers, new firewalls, routers, and switches, as well as an operating system upgrade to Windows Server 2008, all of which enhanced system scalability and security. HPL had a 93% success rate for online licensing renewal in FY14. Additional accomplishments include new architecture and system components, along with an upgrade to the entire MyLicense Office ("MLO") software suite, and setup of Interchange software to facilitate secure communication of data between HPL staff and public Board members and other organizations. IT also continues to work on the Health Care Professions Workforce Data Collection Initiative by providing the results of the Pharmacist and Licensed Practical Nurse surveys from the online renewal system to DPH.

***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 provisions relating to HPL are in effect:

- 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. G.L. c. 112, § 1B(b).
- II. The license of a member of the armed forces who is on active duty will remain valid until he or she is released from active duty, and for 90 days thereafter. G.L. c. 112, § 1B(c). Note that the Board of Registration in Nursing provides a 6 month grace period pursuant to St. 1954, c. 627, § 51 and St. 1991, c. 110, § 4.
- III. HPL will expedite 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. 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, the Board has processed 34 applications for licensure by service members, veterans or spouses, and logged the active duty status of 27 licensed service members.

License applications have been submitted by active duty service members (2), spouses of active duty service members transferring in to Massachusetts (20) and veterans (12). Licenses have been issued for all but 1 of these applications; the outstanding applicant is a veteran and who has been cleared to sit for the NCLEX-RN examination. The table below shows the distribution, of these applicants; note the greatest concentration of applicants is military spouses applying for RN licensure.

	Spouses (20)	Veterans (12)	Active Duty (2)
RN (19, 1 pending)	14	4, 1 pending	1
LN (4)	0	4	0
DN (2)	1	0	1
DH (2)	2	0	0
RT (3)	1	2	0
PA (2)	1	1	0
NH (1)	1	0	0

HPL has logged the active duty service dates for 27 licensees. Of these, 24 licenses have been renewed for the next renewal cycle. There are 20 licenses scheduled for renewal during 2015 and 2016. The table below shows the distribution, with the greatest concentration among army dentists. Dentists remain the most highly represented group.

	Dentists (15)	Nurses (8)	Pharmacists (4)
Air Force (5)	3	1	1
Navy (7)	3	3	1
Army (15)	9	4	2

Consult the [HPL website](#) for additional information and the necessary affidavit forms. Please note that Active Military and Military Spouses must also identify themselves as such in order to obtain these benefits.

### ***Strategic Priorities for HPL***

HPL continues to implement strategies developed to enhance its current platform. One of the main focuses of HPL remains improving the uniformity across all 9 Boards, where it is both possible and beneficial to improving health care quality and safety within the practice arenas regulated by HPL. Strategic priorities include:

#### **I. Policy Development and Implementation**

- i. Division wide policies have been revised to improve consistency across the 9 Boards where feasible.
- ii. Policies have been reviewed and edited to reflect changes in procedures.
- iii. A review schedule has been developed to ensure that all policies and procedures remain current.

#### **II. Complete Revisions to Licensure Policy: *Determination of Good Moral Character (GMC) Compliance***

The licensure policy, *Determination of Good Moral Character (GMC) Compliance*, will be systematically reviewed and revised in a timely manner and information disseminated to licensure applicants. This GMC policy will be reviewed by all HPL Boards and adopted where appropriate.

### **III. Board Composition**

HPL focused on increasing recruiting efforts to fill vacant Board appointments across HPL. By the end of FY14, 82.5% of all Board appointments were filled.

### **IV. Continuing Education Unit (CEU) Management**

One priority of the Board of Registration of Nursing Home Administrators (“NHA Board”) for FY14, was to complete a random continuing education audit to ensure that licensees were in compliance with NHA Board regulations for CEU requirements. The NHA Board voted to randomly select 5% of its 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 5% (30) licensees and provided NHA Board staff with the name, license number, and contact information of the selected licensees. NHA Board staff reviewed minutes and identified (6) licensees with prior issues related to CEU documentation. On April 24, 2014, a letter and form approved by the NHA Board was forwarded to each of the selected licensees’ address of record. The NHA Board delegated members subsequently started the review process of all CEU documentation submitted by the selected licensees.

HPL plans to conduct random CEU checks in each of its Boards in the next fiscal year.

### **V. *Just Culture* Development in HPL**

In 2012, Governor Patrick convened a Special Commission on the Oversight of Compounding Pharmacies (“Special Commission”), charging it to analyze the needs of and gaps in the industry in order to formulate recommendations on necessary policy, regulatory, and legislative changes. The Special Commission recommended that the Board of Registration in Pharmacy and all of DPH adopt *Just Culture*<sup>1</sup> as the framework for assuring patient safety and quality of care. HPL has explored bringing or exploring various *Just Culture* training options. Staff has met with training professionals focusing on *Just Culture* development to discuss different approaches on how to best introduce it to HPL. A training for all of HPL is scheduled for January 2015.

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<sup>1</sup>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, performing professional duties while intoxicated). Excerpted from: 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>

## **VI. Improving Transparency**

### **i. Centralized Management of Public Records**

Public record request management is a critical part of maintaining transparency regarding Board processes. To assure consistent management and legal compliance, the management of all public record requests will be centralized and have new standardized processing policies across all Boards. All public record requests for HPL will be streamlined and directed to a Program Analyst specially assigned at HPL.

### **ii. 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 2 years on its website. In fiscal year 2015, HPL intends to begin posting consent agreements for all its licensees on each of the Board's websites going forward. HPL is starting with the Board of Registration in Dentistry ("BORID") website. All BORID consent agreements are being posted, dating back to 2012 through present day.

## **VII. Website Restructuring for the Board of Registration in Pharmacy**

The Board of Registration in Pharmacy (BORP) in conjunction with the ITD is working to develop a new website required by the passage of Chapter 159 of the Acts of 2014. The "searchable website", will allow the public to search for and obtain, at no charge, enforcement action records and records of serious adverse drug events pertaining to pharmacies licensed by the Commonwealth, as well as other relevant information related to pharmacy licensure. In addition to the contact information for all compounding and non-resident pharmacies, the searchable website will house among other things, public records of all enforcement actions taken against pharmacies, pharmacists, and pharmacy technicians over a 10 year period.

# **The Board of Certification of Community Health Workers**

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

## **I. Administration**

### **About the Board**

The Board of Certification of Community Health Workers (“CHW Board”) was established through Chapter 322 of the Acts of 2010, signed into law by Governor Deval Patrick on August 31, 2010, with an effective date of January 1, 2012. It was created as a result of state health care reform and is intended to help integrate Community Health Workers into the health care and public health systems in order to promote health equity, cost containment, quality improvement, and management and prevention of chronic disease.

The CHW Board is chaired by a designee of the Commissioner of the Department of Public Health and includes 10 additional members appointed by the Governor and nominated by organizations named in the authorizing legislation. Its makeup includes the following: 4 Community Health Workers, 1 Community Health Worker Training Organization Representative, 1 Community-Based Community Health Worker Employer, 1 Massachusetts Association of Health Plans Representative, 1 Massachusetts League of Community Health Centers Representative, 1 Massachusetts Public Health Association Representative, and 1 public member. Six (6) members are required to be present to constitute a quorum.

### **FY14 Board Members**

Jean Zotter, Department Public Health, Chair

Patricia Edraos, Massachusetts League of Community Health Centers (MLCHC), Representative

Joanne Calista, Community Health Worker Training Organization, Representative

Henrique O. Schmidt (formerly Oliveira), Community Health Worker, Secretary

Charles Joffe-Halpern, Community-Based Community Health Worker, Employer

Maritza Smidy, Community Health Worker

Denise Lau, Public Member

Sheila Och, Community Health Worker

### **FY14 Board Meetings**

August 13, 2013

October 8, 2013

November 12, 2013

January 14, 2014

March 11, 2014

May 13, 2014

June 10, 2014

### **Contact Information**

Mary A. Phillips, Executive Director  
Board of Certification of Community Health Workers  
239 Causeway Street, Suite 500  
Boston, MA 02114  
617-973-0806  
[www.mass.gov/dph/Boards/chw](http://www.mass.gov/dph/Boards/chw)  
CHW.admin@state.ma.us

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

The CHW Board holds an Advisory Work Group monthly meeting 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 primary focus of the CHW Board was to finalize the Core Competencies for Community Health Workers and continue to draft regulations.

### **III. Strategic Priorities**

**Certification of Community Health Workers:** The CHW Board, along with its Advisory Work Group, continues to work on developing standards for the education and training curricula for Community Health Workers and Community Health Worker trainers. These standards include the requirements for Community Health Worker certification and renewal of certification. The CHW Board and Advisory Work Group will continue its work on drafting regulations and aim to have the new regulations promulgated in FY15.

### **IV. License and Licensee Statistics**

Due to the recent establishment of the CHW Board, the CHW Board did not process any applications for certification in FY14.

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

Due to its recent establishment, the CHW Board took no disciplinary action in FY14.

# **The Board of Registration in Dentistry**

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

## **I. Administration**

### **About the Board**

The Massachusetts Board of Registration in Dentistry (“Dentistry Board”) is responsible for licensing dentists and dental hygienists for practice in the Commonwealth; establishing rules, regulations, and policies governing the practice of dentistry, dental hygiene and dental assisting; and investigating complaints against licensed dental professionals. The Dentistry Board is responsible for registering qualified applicants for licensure in dentistry and dental hygiene, including initial licensees and those who have licenses in other jurisdictions who wish to practice in Massachusetts. It also is responsible for issuing limited and faculty dental licenses, as well as facility and practitioner permits for anesthesia administration.

Dentistry Board members monitor licensees’ practice of dentistry to ensure the public that services are provided in accordance with state statutes, Dentistry Board regulations and policies, including ethical standards of practice. The Board is made up of 11 members including 6 Dentists, 2 Dental Hygienists, 1 Dental Assistant, and two public members. By statute, 5 members are required to be present to constitute a quorum.

### **FY14 Board Members**

Dr. Cynthia M. Stevens, Dentist, Chair  
Lois Sobel, RDH, Dental Hygienist, Secretary  
Dr. Stephen C. Dulong, Dentist  
Dr. Milton Glicksman, Dentist  
Dr. John Hsu, Dentist  
Dr. Keith Batchelder, Dentist  
Dr. David Samuels, Dentist  
Jacyn Stultz, RDH, Dental Hygienist  
Kathleen Held, Dental Assistant\*  
Ward J. Cromer, PhD, Public  
Ailish M. Wilkie, CPHQ, Public  
Diane Grondin, CDA, Dental Assistant Advisor (non-voting)  
\* New Board Member during FY14

### **FY14 Board Meetings**

July 17, 2013  
September 18, 2013  
October 2, 2013  
November 6, 2013  
December 4, 2013  
January 15, 2014  
February 19, 2014  
March 5, 2014

April 2, 2014  
May 7, 2014  
June 4, 2014

**Contact Information**

Barbara A. Young, RDH, Executive Director  
Board of Registration in Dentistry  
239 Causeway Street, Suite 500  
Boston, MA 02114  
617-973-0971  
[www.mass.gov/dph/Boards/dn](http://www.mass.gov/dph/Boards/dn)  
dentistry.admin@state.ma.us

**II. Accomplishments of the Board**

**Hydrocodone-Only Extended Release Medications that are not in an Abuse Deterrent Form:** On May 7, 2014, the Dentistry Board promulgated emergency regulations in recognition of the public health emergency declared by Governor Deval Patrick in response to a significant increase in opioid-related overdose deaths. The emergency regulations were drafted as the result of an ongoing collaboration between the DPH and several Boards including the Board of Registration in Medicine, the Board of Registration in Pharmacy and the Board of Registration in Nursing. A public hearing on the dental emergency regulations was held on June 13, 2014. After several amendments, the Dentistry Board subsequently approved the regulations and made them permanent.

**III. Strategic Priorities**

**Registration of Dental Assistants:** Chapter 530 of the Acts of 2008, *An Act to Increase Access to Oral Healthcare*, includes a requirement for Dental Assistants working in the Commonwealth to register with the Dentistry Board. In response, 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 Executive Office of Administration and Finance to establish a new fee for original and renewal registration of Dental Assistants. The Dental Assistant regulations were promulgated in September 2014. The Dentistry Board began accepting applications in October 2014 and anticipates that approximately 16,000 Dental Assistants will register.

**Revision of Dental Facility Inspection Checklists:** The Dentistry Board 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, with the aim of publishing a checklist on the Dentistry Board's web site as a tool for use by licensees to prepare for compliance inspections. The checklist will

also be used to assess and evaluate applications for facility permits for administration of various types of sedation and anesthesia. The checklist was posted in November 2014.

#### IV. License and Licensee Statistics

<b>Board of Dentistry</b> Biennial licensure except Limited Faculty Licenses, which are annual	6,840	Dentists
	7,133	Dental Hygienists
	2,499	Dental Hygienists - Anesthesiology Permits
	399	Limited and Faculty License
	703	Facility Permits
	248	General Anesthesia Permits
	692	Nitrous Oxide Permits
	279	Conscious Sedation Permits
	34	Portable Dental Operation and Mobile Dental Facility Permits
<b>TOTAL</b>	<b>18,827</b>	

#### V. Compliance: Disciplinary Process and Statistics

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
175	126	181	175	56	32%

# **The Board of Registration of Genetic Counselors**

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

## **I. Administration**

### **About the Board**

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

Genetic Counselors work as members of a health care team, providing information and support to families who have members with birth defects or genetic disorders and to families who may be at risk for a variety of inherited conditions. They identify families at risk, investigate the issue present in the family, interpret information about the disorder, analyze inheritance patterns and risks of recurrence, and review available options with the family.

Genetic Counselors also provide supportive counseling to families, serve as patient advocates, and refer individuals and families to community or state support services. They serve as educators and resource contacts for other health care professionals and for the general public.

The Board of Registration of Genetic Counselors (“GC Board”) is charged with evaluating the qualifications of applicants for licensure and granting licenses to those who qualify. It establishes rules and regulations to ensure the integrity and competence of licensees.

The GC Board promotes public health, welfare, and safety by ensuring that licensed Genetic Counselors have the proper training and experience, have completed an accredited degree program, and meet other requirements set forth by the Board. The GC Board is made up of 5 members including 4 Genetic Counselors and 1 public member. Three (3) members are required to be present to constitute a quorum.

### **FY14 Board Members**

Gretchen Schneider, Genetic Counselor 2, Chair  
Kayla Sheets, Genetic Counselor 4, Vice-Chair  
Kristen Mahoney Shannon, Genetic Counselor 3  
Tomi Toler, Genetic Counselor 1

### **FY14 Board Meetings**

July 2, 2013  
September 26, 2013  
April 3, 2014  
June 16, 2014

**Contact Information**

Mary A. Phillips, Executive Director  
 Board of Registration of Genetic Counselors  
 239 Causeway Street, Suite 500  
 Boston, MA 02114  
 617-973-0806  
[www.mass.gov/dph/Boards/gc](http://www.mass.gov/dph/Boards/gc)  
 MultiBoard.Admin@state.ma.us

**II. Strategic Priorities****Guidelines for General Supervision of Provisionally Licensed Genetic Counselors:**

During the next fiscal year, the GC Board will prioritize the implementation of the Guidelines for General Supervision of Provisionally Licensed Genetic Counselors. These guidelines are meant to assist provisional licensees and their supervisors to comply with 270 CMR 3.03(3).

**American Board of Genetic Counseling Requirements:** Revisions have been made to the American Board of Genetic Counseling requirements for the exam cycle and need to be reflected in the regulations. The GC Board will amend these regulations to include all new requirements set forth by the American Board of Genetic Counseling.

**III. License and Licensee Statistics**

<b>Board of Genetic Counselors</b> Biennial licensure, except Provisional Licenses, which are triennial	<b>186</b>	<b>Genetic Counselors</b>
	<b>4</b>	<b>Provisional Genetic Counselors</b>
<b>TOTAL</b>	<b>190</b>	

**IV. Compliance: Disciplinary Process and Statistics**

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
2	3	2	2	1	50%

# **The Board of Registration in Nursing**

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

## **I. Administration**

### **About the Board**

The Board of Registration in Nursing (“Nursing Board”) protects the health, safety and welfare of the citizens of the Commonwealth through the fair and consistent application of the statutes and regulations governing nursing practice and education. The Nursing Board issues nursing licenses to qualified individuals; verifies licensure status; approves and monitors nursing education programs; authorizes practice in advanced roles; investigates and acts on complaints concerning the performance and conduct of licensed nurses; participates in workforce initiatives; promotes a culture of safety through community outreach and partnerships; and administers the Substance Abuse and Rehabilitation Program. The Nursing Board is made up of 17 members including 9 Registered Nurses, 4 Licensed Practical Nurses, 1 Physician, 1 Pharmacist, and 2 Consumers. Nine (9) Board members are required to be present to constitute a quorum.

### **FY14 Board Members**

Sandra Kelly, RN, MS, NP, RN-Advanced Practice, Direct Care, Chairperson  
Katherine Gehly, RN, MSN, NP, Educator-RN Associate Degree, Vice Chairperson  
Margaret Beal, RN, PhD, NM, Educator-RN Bachelor’s Degree  
Patricia Gales, RN, MS, Educator-LPN Program (RN)  
Joan Killion, LPN, LPN, Acute Care (Hospital)  
Barbara Levin, RN, BSN, RN- Not Advanced Practice, Direct Care  
Catherine Lundeen, RN, RN-Not Advance Practice, Direct Care until 10/9/2013  
Ann-Marie Peckham, RN, MSN/MBA, RN Hospital Administrator  
E. Richard Rothmund, Consumer  
Mary Jean Roy, MS, MEd, RN, Educator- RN Diploma Program until 4/2014  
Catherine L. Simonian, RPh, PharmD, Pharmacist  
Susan Taylor, MSN, RN, Educator-RN Diploma Program started 5/2014  
Christine Tebaldi, RN, MS, NP, RN-Advance Practice, Direct Care

### **FY14 Board Meetings**

July 10, 2013  
September 11, 2013  
October 16, 2013  
November 13, 2013  
November 22, 2013 (Special Board Meeting)  
January 8, 2014  
February 12, 2014  
March 12, 2014  
June 11, 2014

### **Contact Information**

Rula Harb, MS, RN, Executive Director  
Board of Registration in Nursing  
239 Causeway Street, Suite 500  
Boston, MA 02114  
617-973-0900  
[www.mass.gov/dph/Boards/rn](http://www.mass.gov/dph/Boards/rn)  
Nursing.Admin@state.ma.us

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

### **Licensure Activities**

- Maintained current licensing records for 21,186 Licensed Practical Nurses, 112,100 Registered Nurses, and 10,352 Advanced Practice Registered Nurses, for a total of 143,638 nurses
- Licensed 1,273 Licensed Practical Nurses and 6,503 Registered Nurses and authorized 782 Advanced Practice Registered Nurses for a total 8,558 new licenses and/or authorizations issued
- 4,308 were licensed by exam (3,293 Registered Nurses and 1,015 Licensed Practical Nurses), 3,468 were licensed by reciprocity (3,210 Registered Nurses and 258 Licensed Practical Nurses)
- Of the 782 Advanced Practice Registered Nurses who were authorized to practice in the advance role: 88 were nurse anesthetists, 25 were nurse midwives, 661 were nurse practitioners and 8 were psychiatric clinical nurse specialists

### **Board-Approved Nursing Education Programs**

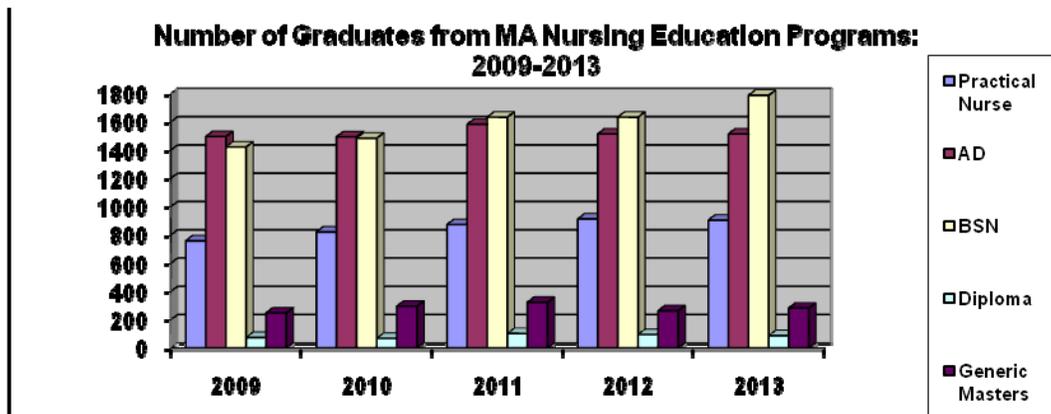
As of July 1, 2014, the Nursing Board approved the operation of a total of 75 Registered Nurse and Practical Nurse education programs:

- 27 Practical Nurse Programs
- 20 Registered Nurse – Associate Degree Programs
- 20 RN – Baccalaureate Degree Programs
- 1 RN - Hospital-based Diploma Program
- 7 RN – Entry Level Graduate Degree Programs

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

### **Increase in Graduates from Basic Baccalaureate Degree Programs**

The total number of graduates from Nursing Board-approved Registered Nurse and Practical Nurse education programs increased in 2013 compared to 2009. Of particular note, the number of graduates from pre-licensure Baccalaureate Degree nursing programs increased 26%, from 1,422 in 2009 to 1,787 in 2013.



### **Board Membership in Statewide Initiatives Promoting Safety and Workforce Development**

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
- Nursing & Allied Health Initiative Advisory Committee, Massachusetts Department of Higher Education (DHE)
- DHE Nurse of the Future Competencies for Education and Practice Workgroup
- DHE Centralized Clinical Placement Task Force
- The Massachusetts Action Coalition
- Eastern Massachusetts Long-term Care Nursing Group, Massachusetts Senior Care Association

### **III. Strategic Priorities**

**Complete revisions to Licensure Policy 00-01: *Determination of Good Moral Character (GMC) Compliance* and applications for nurse licensure by examination and reciprocity, and advanced nursing practice authorization:** Systematic review and revision of Licensure Policy 00-01 will be completed in a timely manner and information disseminated to licensure applicants and Nursing Board-approved schools of nursing. Applications for nurse licensure by examination and reciprocity, and advanced nursing practice authorization, will be revised and accurately reflect all changes made to Licensure Policy 00-01. This GMC policy will be reviewed by all HPL Boards and adopted where appropriate.

**Expand community outreach and collaboration with various stakeholders in the interest of public protection, patient safety and related nursing scope of practice issues:** Stakeholders, including nursing students, licensees, Nursing Board-approved nursing education programs, professional organizations and associations, regulatory agencies, risk managers, and consumer groups, as appropriate, will receive information about: (1) substance dependence and the Nursing Board's Substance Abuse

Rehabilitation Program; and (2) nursing practice breakdown or conduct to report to the Nursing Board, what kind of information or documentation to provide, and the Nursing Board's formal and informal complaint resolution process inclusive of probation. Participation in statewide nurse workforce initiatives will support 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.

**Complete Phase II, Nursys Data Integrity Project:** All fields for each nurse license record in the MLO licensing system will be complete and accurate.

#### **IV. Legislation and Regulations**

##### **New Regulations Governing the Prescribing of Hydrocodone-only Extended Release Medications**

On March 27, 2014, Governor Patrick issued a *Governor's Declaration of Emergency* concerning the widespread abuse of pharmaceutical opioids. Noting that unintentional opioid related overdoses have reached levels previously unseen in Massachusetts and the potential for abuse of these controlled substances, the Governor directed the DPH to take immediate action to address this public health emergency. In response, the Nursing Board approved emergency regulations at 244 CMR 4.28, thereby establishing measures to safeguard against diversion, overdose, and misuse of Hydrocodone-only extended release medications that are not in an abuse deterrent form.

Approved June 2014 and effective immediately, the new regulations require advanced practice nurses engaged in prescriptive practice to take the following actions for each prescription of a hydrocodone-only extended release medication that is not in an abuse deterrent form:

- Perform a thorough substance abuse risk assessment and check the Prescription Monitoring Program;
- Discuss the risks and benefits of the medication with the patient;
- Enter into a Pain Management Treatment Agreement based on the patient's diagnoses, treatment plan, and risk assessment;
- Supply a Letter of Medical Necessity that indicates, among others, that the Advanced Practice Registered Nurse ("APRN") and the patient have entered into a Pain Management Treatment Agreement; and
- Document the foregoing in the patient's record.

**V. License and Licensee Statistics**

<b>Board of Nursing</b>	112,100	Registered Nurses (RN)
Biennial licensure	480	RN Nurse Midwives
	7,752	RN Nurse Practitioners
	868	RN Psychiatric Clinical Nurse Specialists
	1,252	RN Nurse Anesthetists
	21,186	Licensed Practical Nurses (LPN)
<b>TOTAL</b>	143,638	

## VI. Compliance: Disciplinary Process and Statistics

One means by which the Nursing Board enforces laws and regulations governing nursing practice is through its evaluation of and action on “complaints” - reports alleging a nurse has engaged in conduct related to nursing practice that violates any law or regulation related to that practice - filed with the Nursing Board regarding an individual nurse’s practice. Complaints are submitted by employers and other regulatory agencies, such as DPH’s Division of Health Care Safety and Quality and Drug Control Program, and less frequently by patients, their family members, and other concerned individuals.

The Nursing Board’s duty and goal in investigating and evaluating complaints is to protect the public, not to punish the nurse who makes an error. The Nursing Board has employed the *Just Culture* principle for many years in its investigative and enforcement processes. In evaluating a complaint, the Nursing Board considers the totality of the evidence including; the nature and related circumstances of the nurses conduct, applicable remedial activities successfully completed by the nurse, employment performance evaluations of the nurse prior to and following the error, any acknowledgment by the nurse of the practice error and its significance, prior repeated or continuing practice-related issues, associated practice environment or systems-related factors, and whether there is a need, in the public’s interest, for an official record of the nurse’s practice-related error.

Subsequently, based on its evaluation, the Nursing Board may resolve a complaint by dismissing it or, under the terms of an agreement entered into between the nurse and the Nursing Board, or by order after an adjudicatory hearing, impose discipline in the form of a reprimand, probation, suspension, surrender or revocation of a nurse’s license to practice nursing. The Nursing Board’s regulations set forth the actions the Nursing Board may take on any complaint and are available on the Nursing Board’s website at 244 CMR 7.00: Action on Complaints.

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
160	122	281	217	107	49%

# **The Board of Registration of Nursing Home Administrators**

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

## **I. Administration**

### **About the Board**

Nursing Home Administrators provide sub-acute and long-term care services to residents of facilities in Massachusetts.

The principal mission of the Board of Registration of Nursing Home Administrators (“NHA Board”) is to protect the health and safety of nursing home residents by ensuring that nursing home administrators are competent and perform their responsibilities properly. The NHA Board monitors licensees' continuing education as part of the license renewal process.

The NHA Board is made up of 14 members including the Commissioner of Public Health or her designee, the Commissioner of Public Welfare (now known as the Department of Transitional Assistance) or his designee, the Secretary of Elder Affairs and 11 members including: 4 Nursing Home Administrators, 1 Nursing Home Administrator/Non-Proprietary, one Educator, 1 Physician, 1 Registered Nurse, two public members and one Hospital Administrator. Eight (8) members are required to be present to constitute a quorum.

### **FY14 Board Members**

Nancy Lordan, Nursing Home Administrator 3, Chair

Roxanne Webster, Registered Nurse, Secretary

Mary McKenna, Executive Office of Elder Affairs

Sherman Lohnes, Department of Public Health

James Divver, Nursing Home Administrator 4

Michael Baldassarre, Nursing Home Administrator 2

Patrick J Stapleton, Nursing Home Administrator 5 (Non-Proprietary Nursing Home)

Aaron Tobey, Public Member 2

William Graves, Nursing Home Administrator 1, Vice-Chair

Janet Cutter, Executive Office of Public Welfare

### **FY14 Board Meetings**

July 18, 2013

September 19, 2013

November 21, 2013

December 19, 2013

January 16, 2014

April 17, 2014

May 15, 2014

June 19, 2014

**Contact Information**

Mary A. Phillips, Executive Director  
 Board of Registration of Nursing Home Administrators  
 239 Causeway Street, Suite 500  
 Boston, MA 02114  
 617-973-0806  
<http://www.mass.gov/dph/boards/nh>  
 MultiBoard.Admin@state.ma.us

**II. Accomplishments of the Board**

The NHA Board conducted a random continuing education unit (CEU) audit of 36 Nursing Home Administrators. For this CEU audit which is still ongoing, 30 licensees have been selected at random with an additional 6 licensees who have a known history of noncompliance with continuing education.

**III. Strategic Priorities**

The NHA Board plans to review regulations with the intent to revise the criteria for the educational requirements for the administrator in training program. In addition the NHA Board intends to issue an advisory opinion regarding the use of the title of Executive Director versus Nursing Home Administrators.

**IV. License and Licensee Statistics**

<b>Board of Nursing Home Administrators</b>	927	Nursing Home Administrators
Annual licensure	59	Administrators in Training (Internship)
<b>TOTAL</b>	<b>986</b>	

**V. Compliance: Disciplinary Process and Statistics**

<b><u>Number of Staff Assignment Investigations Opened</u></b>	<b><u>Number of Staff Assignment Investigations Closed</u></b>	<b><u>Number of Formal Complaints Opened</u></b>	<b><u>Number of Formal Complaints Resolved</u></b>	<b><u>Number of Formal Complaints Resolved with Discipline Imposed</u></b>	<b><u>% of Formal Complaints Resolved w/Discipline Imposed</u></b>
22	12	0	3	0	0

# **The Board of Registration of Perfusionists**

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

## **I. Administration**

### **About the Board**

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

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

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

The Perfusionists Board is made up of seven members including 4 Perfusionists, 1 Anesthesiologist, 1 Cardiovascular Surgeon, and 1 Public member. By statute, 4 members are required to be present to constitute a quorum.

### **Board Members**

Adam Lerner, M.D., Anesthesiologist (Cardiac Anesthesia), Chair

Kevin Lilly, Certified Clinical Perfusionist 1, Vice-Chair

Raymond Hawkins, Perfusionist 3

Kyle Spear, Perfusionist 4

Sary Aranki, M.D., Cardiovascular Surgeon

### **FY14 Board Meetings**

October 1, 2013

March 4, 2014

**Contact Information**

Mary A. Phillips Executive Director  
 Board of Registration of Perfusionists  
 239 Causeway Street, Suite 500  
 Boston, MA 02114  
 617- 973-0806  
<http://www.mass.gov/dph/boards/pf>  
 MultiBoard.Admin@state.ma.us

**II. Strategic Priorities**

**Revisions to Regulations:** Over the next fiscal year, the Perfusionists Board will be reviewing the Board regulations and revising them as needed. In addition to the regulations, the Board will update and streamline licensee forms and work to improve the application process.

**III. License and Licensee Statistics**

<b>Board of Perfusionists</b>		
Biennial licensure, except	107	Full Licenses
Provisional Licenses, which are annual.	3	Provisional Licenses
<b>TOTAL</b>	<b>110</b>	

**IV. Compliance: Disciplinary Process and Statistics**

The Perfusionists Board opened no complaints and took no disciplinary action in FY14.

# **The Board of Registration in Pharmacy**

G.L. c. 13, §§ 9 and 22-25; G.L. c. 112, §§ 24-42A

## **I. Administration**

### **About the Board**

Pharmacists dispense and/or distribute prescription drug products and provide patient information services to consumers in hospitals, nursing homes, retail pharmacy departments, and home care settings. They consult directly with patients, or with their caregivers, explaining proper use and storage of drug products and provide information on contraindications for use.

The Board of Registration in Pharmacy (“Pharmacy Board”) provides a code of professional regulations for ensuring the highest degree of ethical and moral practice by Pharmacists, Pharmacy Interns and Pharmacy Technicians. The Pharmacy Board strives to assure that consumers are receiving the highest quality prescription drug products from pharmacists who have graduated from accredited colleges of pharmacy. The Pharmacy Board monitors Pharmacists to ensure they meet requisite continuing educational requirements and sets standards of quality assurance and best practices, requiring safe delivery systems in licensed pharmacies.

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

The Pharmacy Board is made up of 11 members including 7 Pharmacists, 1 Nurse, 1 Physician and 2 Public members. Six (6) members are required to be present to constitute a quorum. Legislation signed by Governor Patrick on July 10, 2014, changed the make-up of the Board and increased the number to 13 members, including 8 Pharmacists, 1 Pharmacy Technician, 1 Nurse, 1 Physician, and 2 Public members.

### **FY14 Board Members**

James T. DeVita, RPh, Chain Pharmacist, President until January 1, 2014

Karen M. Ryle, MS, RPh, Non-Profit Hospital Pharmacist, became President on January 1, 2014

Anita Young, EdD, RPh, Pharmacist Consultant, Secretary until January 1, 2014

Jane F. Franke, RN, Public

Patrick M. Gannon, RPh, MS, FABC, Pharmacist

Edmund Taglieri, MSM, RPh, NHA, LTC Pharmacist, became Secretary on January 1, 2014

Joanne M. Trifone, RPh, Chain Pharmacist

Anthony Perrone, MD, Physician

Richard Tinsley, MBA, MEd, Public  
Timothy Fensky, RPh, Independent

### **FY14 Board Meetings**

Except where otherwise noted, meetings are scheduled for the 1<sup>st</sup> Tuesday of each month.

July 2, 2013

September 10, 2013

September 26, 2013 (Thursday evening meeting, applicants only)

October 1, 2013

November 5, 2013

December 3, 2013

January 7, 2014

February 4, 2014

March 4, 2014

April 1, 2014

May 6, 2014

June 3, 2014

### **Contact Information**

David Sencabaugh, RPh, Executive Director

239 Causeway Street, Suite 500

Boston, MA 02114

617-973-0993

[www.mass.gov/dph/Boards/pharmacy](http://www.mass.gov/dph/Boards/pharmacy)

Pharmacy.Admin@state.ma.us

## **II. Compounding Pharmacies**

Following the multi-state meningitis outbreak that has been attributed to products from a Massachusetts-based pharmacy, Governor Patrick created the Special Commission on the Oversight of Compounding Pharmacies. Governor Patrick subsequently filed legislation based on the Special Commission's recommendations to prevent a similar tragedy.

Governor Patrick's legislation included numerous provisions to insure public safety such as requiring a special license for sterile compounding, monetary fines for compounders that violate laws or regulations, whistleblower protection, and licensing of out-of-state pharmacies that do business in Massachusetts.

Subsequent to the Governor's legislation, the House and Senate released proposed bills that maintain the core principals of the Governor's reform, keeping patient safety at the forefront and enhancing and strengthening the regulation of compounding pharmacies. A legislative conference committee was convened and on July 10, 2014, Governor Patrick signed Chapter 159 of the Acts of 2014 into law. The Board of Registration in Pharmacy will be responsible for promulgating regulations to implement the changes to the law in FY15.

### **III. Accomplishments of the Board**

**Pharmacy Compliance:** The Pharmacy Board of Registration in Pharmacy continued the annual unannounced inspections of all sterile compounding pharmacies in FY14. In FY 14, the Pharmacy Board licensed 37 sterile compounding pharmacies. Over the course of the unannounced sterile compounding inspections, 1 Cease and Desist Order was issued. In addition, the Pharmacy Board continues to monitor pharmacies engaged in sterile compounding through collecting, reviewing, and responding to reports of abnormal results and positive environmental sampling tests.

As part of the Pharmacy Board's continuing effort to track pertinent information from licensed Massachusetts pharmacies, all licensed pharmacies have also submitted documentation, signed under the penalties of perjury, attesting to whether they engage in non-sterile compounding and if so, that they follow all laws and regulations of the Commonwealth. The Pharmacy Board initiated unannounced inspections of all non-sterile compounding pharmacies in FY14. The first wave of unannounced non-sterile compounding inspections is anticipated to be completed in mid FY15.

Frequent communication with compounding pharmacies and noticeable field presence of inspectors has been ongoing. The Pharmacy Board continues to monitor pharmacies' corrective actions and educate pharmacy staff on appropriate responses.

### **IV. Strategic Priorities**

**Stakeholder Involvement:** In an effort to promote outreach to the pharmacy community, the Pharmacy Board convened a meeting of key stakeholders to introduce the new inspection tool for United States Pharmacopeia ("USP") <797> (sterile) compounding. The meeting was held at Northeastern University on April 10, 2014, and included representation from academia (MCPHS, WNEU, NEU), hospital (MHSP), chain pharmacy (MCPC), independent pharmacy (MIPA), pharmacists (MPhA), FDA, and home infusion pharmacy. Feedback from the meeting was considered in the final draft of the inspection tool, which will become the basis for implementation of the new regulations for sterile compounding moving forward. Stakeholder involvement will continue to be an important strategic component as the Board moves forward with the USP <795> (non-sterile) compound inspection tool, also developed in FY14.

**New England Compounding Pharmacy Consortium:** The Pharmacy Board created a New England Compounding Pharmacy Consortium to facilitate a timely inter-state information exchange with all 6 New England states and New York. The first meeting took place on November 21, 2013 at the Massachusetts College of Pharmacy and Health Sciences in Worcester, MA, with the main topic of discussion covered being sterile compounding. During the meeting, the USP <797> (sterile) compounding inspection tool was introduced. The meeting was a great success with an excellent turnout from the various states as well as representatives from the FDA, all of whom provided valuable feedback to the Pharmacy Board staff members.

**More Aggressive Retail Pharmacy Inspections:** Increased funding for the Pharmacy Board during FY14 allowed for the development of a more aggressive schedule of retail pharmacy inspections. Inspections are now conducted based on a new priority system, considering factors such as date of last inspection, volume of business, and level of (non-complex) non-sterile compounding. The Pharmacy Board anticipates bi-annual inspections of retail pharmacies without specialty compounding licenses going forward, utilizing the Board's new Retail Compliance Inspection, developed in FY14.

**Increased Inspectors and Investigator Training:** Increased funding during FY14 also allowed for the addition of 4 new pharmacy investigators. During their first year the investigators received hands-on training in all facets of conducting retail pharmacy compliance inspections.

The Pharmacy Board's senior investigators attended FDA sterile compounding training in FY14. It is the Pharmacy Board's priority to have the new investigators formally trained in USP <797> and all investigators formally trained in USP <795> in FY15.

**Website Reconstruction:** Pharmacy Board staff has made the restructuring and reorganization of the Pharmacy Board's website a priority in FY14, with the aim to better service the needs of the pharmacy community. The website contains updated forms for mandatory reporting, a template of the Pharmacy Board's new retail compliance inspection for pharmacies to conduct self-inspections, as well as important news, updates and alerts to the pharmacy community and consumers. The website revamp will continue in FY15 as the Pharmacy Board implements new licensing categories and promulgates new regulations.

**Contacting the Board:** After a tremendous influx of communication to the Pharmacy Board in FY13, the Pharmacy Board created several new e-mail accounts in FY14. The new organization of communications from the public and the pharmacy community has allowed Pharmacy Board staff to cut down response times, assisting Pharmacy Board staff in achieving their goal of better serving the needs of the pharmacy community. The following email addresses should now be used to contact the Pharmacy Board:

[naloxonestandingorders@MassMail.State.MA.US](mailto:naloxonestandingorders@MassMail.State.MA.US) for Naloxone Standing Orders  
[Pharmacy.Admin@MassMail.State.Ma.US](mailto:Pharmacy.Admin@MassMail.State.Ma.US) for Pharmacy Practice Questions  
[abnormalresults@MassMail.State.MA.US](mailto:abnormalresults@MassMail.State.MA.US) for Abnormal Results Reporting Forms  
[Pharmacy.Admin@MassMail.State.Ma.US](mailto:Pharmacy.Admin@MassMail.State.Ma.US) for Applicant/Licensee Questions  
[DHPL-OPP.ADMIN@MassMail.State.Ma.US](mailto:DHPL-OPP.ADMIN@MassMail.State.Ma.US) for DEA 106 Loss Reports, Complaints and Investigations  
[dhpl.poc@MassMail.State.MA.US](mailto:dhpl.poc@MassMail.State.MA.US) for Inspection-related Documents and Plans of Correction

## V. Legislation and Regulations

**New Legislation:** On July 10, 2014, Governor Deval Patrick signed *Chapter 159 of the Acts of 2014* into law, thus setting the stage for major pharmacy reform in FY15, and beyond. Although the bill was signed in FY15, the final product represented months of tireless work by the Administration, Legislature, DPH staff, Pharmacy Board staff, and Pharmacy Board members, throughout FY14. This legislation is based on the premise that patient safety is paramount and it addresses critical gaps in state oversight. There are several parts making up the new law, with various milestone dates throughout FY15.

The new law is multifaceted and contains, among other items, measures that will require new pharmacy license categories, both for in-state pharmacies and (for the first time) out-of-state pharmacies. It also increased requirements for both sterile and complex non-sterile compounding, a change in the Pharmacy Board make-up, the establishment of an Advisory Council to the Pharmacy Board, increased Continuing Education for pharmacists, and specific training requirements for the investigation team.

**Declaration of Emergency:** On March 27, 2014, Governor Patrick declared a State of Emergency in Massachusetts, due to the number of opiate-related drug overdoses. The Declaration gave the Commissioner of Public Health the authority to take certain measures. One of the important measures allowed pharmacists in Massachusetts to dispense naloxone rescue kits, by standing order, to any person or bystander who is, or knows someone who is, at risk for opiate overdose. The rescue kits can allow a bystander to administer a potentially life-saving dose of naloxone to someone who is believed to be suffering from an overdose of an opiate drug, after notifying 911. Previously, pharmacists were only able to dispense the drug to a person pursuant to a prescription.

Another key component of the Declaration involved the dispensing of hydrocodone-only extended release medication. The Pharmacy Board subsequently promulgated regulations with specific requirements for the handling, storage, security, and dispensing of hydrocodone extended release medications.

**Sections of Chapter 244 of the Acts of 2012 were implemented on December 1, 2013:** Included in the implementation was the important change in out-of-state prescriptions. Schedule II narcotic prescriptions, written by physicians and other mid-level practitioners located out-of-state, were no longer allowed to be dispensed unless written by physicians from contiguous states and Maine, and are now valid for only 5 days, instead of 30. Non-narcotic Schedule-II controlled substances, can still be dispensed if written by physicians in the other 49 states, but are only valid for 5 days, instead of 30.

**POLICY 2014- 01: Permitted Staff Action for Good Moral Character Candidate Review:** The Board voted to approve staff action regarding applicants who declared “Good Moral Character” issues from past actions, un-related to drugs or alcohol.

**Board Delegated Case Review:** In 2014, the Pharmacy Board voted to approve an enhanced Board Delegated Review process, whereby a specific work group, including 1 Pharmacy Board Member, the Executive Director of the Pharmacy Board, the Director of Pharmacy Compliance, the Director of Pharmacy Quality Assurance, and Pharmacy Board Counsel, can review certain approved file cases, conserving valuable Pharmacy Board time for more complex matters. In FY14, 5 of these sessions were held. A few of the cases were forwarded to the full Pharmacy Board, but in all 103 case files were reviewed by the work group and the results were as follows:

103	Case File Reviews	
35	Case File - resulted in discipline	34%
27	Staff Assignments - closed	26%
23	Case Files - referred for full Board consideration	22%
14	Pharmacy Complaints - closed	14%
4	New Complaints - requested	4%

**VI. License and Licensee Statistics**

<b>Board of Registration in Pharmacy</b> Biennial licensure, except Wholesale Distributors, which are annual	12,010	Pharmacists
	58	Nuclear Pharmacists
	10,403	Pharmacy Technicians
	4,709	Pharmacy Interns
	1,172	Retail Pharmacies
	87	Certificate of Fitness Permits
	1,172	Retail Pharmacy Controlled Substance Permits
	6	Nuclear Pharmacies
	6	Nuclear Pharmacy Controlled Substance Permits
	49	Wholesale Distributors
	49	Wholesale Distributors Controlled Substance Permits
<b>TOTAL</b>	<b>29,721</b>	

**VII. Compliance: Disciplinary Process and Statistics**

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
112	112	282	225	61	27%

# **The Board of Registration of Physician Assistants**

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

## **I. Administration**

### **About the Board**

The Board of Registration of Physician Assistants (“PA Board”) licenses individuals of good moral character who hold a baccalaureate degree from an educational institution on the list of accredited colleges of the United States Office of Education, or any like institution approved by the PA Board, have graduated from a Physician Assistant training program which holds a valid certificate of program approval issued by the PA Board, and has passed the certifying examination of the National Commission on Certification of Physician Assistants.

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

The PA Board is made up of 9 members including 4 Physician Assistants, 1 Physician Assistant Educator, 2 Public members, and 2 Physicians, one that is a member of the Massachusetts Medical Society. By statute, 5 members are required to be present to constitute a quorum.

### **FY14 Board Members**

Dipu Patel-Junankar, PA-C, Physician Assistant 1, Chair  
Miguel Valdez, PA-C, Physician Assistant 3, Vice-Chair  
Laura Hilf, RN, MS, Public Member 1  
Nicole Meregian, PA-C, Physician Assistant 2  
Richard Baum, MD, Massachusetts Medical Society  
Edward Glinski, MD, Physician  
Shannon Sheridan-Geldart, PA-C, Physician Assistant, Educator

### **FY14 Board Meetings**

July 11, 2013  
August 1, 2013  
September 12, 2013  
October 10, 2013  
November 14, 2013  
December 12, 2013  
January 9, 2014  
March 13, 2014  
April 10, 2014  
May 8, 2014  
June 12, 2014

### Contact Information

Mary A. Phillips, Executive Director  
239 Causeway Street, Suite 500  
Boston, MA 02114  
617-973-0806  
[www.mass.gov/dph/Boards/pa](http://www.mass.gov/dph/Boards/pa)  
MultiBoard.Admin@state.ma.us

## II. Strategic Priorities

**Revisions to Regulations:** Over the next fiscal year, the PA Board will be reviewing board regulations and revising them as needed.

## III. Legislation and Regulations

**New Regulations Governing the Prescribing of Hydrocodone-only Extended Release Medications.** The PA Board revised 263 CMR 5.07, Prescription Practices of a Physician Assistant, and enacted emergency regulations regarding the prescribing of Hydrocodone-Only Extended-Release Medication at 263 CMR 5.07(12), as outlined below.

- Perform a thorough substance abuse risk assessment and check the Prescription Monitory Program;
- Discuss the risks and benefits of the medication with the patient;
- Enter into a Pain Management Treatment Agreement based on the patient’s diagnoses, treatment plan and risk assessment;
- Supply a Letter of Medical Necessity that indicates, among others, that the APRN and the patient have entered into a Pain Management Treatment Agreement; and
- Document the foregoing in the patient’s record.

## IV. License and Licensee Statistics

<b>The Board Registration of Physician Assistants</b>	2,806	Full Licenses
Biennial licensure	2	Temporary Certifications
<b>TOTAL</b>	<b>2,808</b>	

V. Compliance: Disciplinary Process and Statistics

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
10	4	0	1	0	0%

# **The Board of Respiratory Care**

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

## **I. Administration**

### **About the Board**

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

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

The RC Board of Respiratory Care is made up of 7 members including 2 Respiratory Therapists, 1 Nurse, 2 Physicians, and 2 Consumers of respiratory care services. Four (4) members are required to be present to constitute a quorum.

### **FY14 Board Members**

David Polanik, Respiratory Therapist 2, Board Chair

Annemarie Patten, R.N., Nurse, Board Vice-Chair

Edward Burns, Respiratory Therapist 1

Sadeq Ali Quraishi, M.D., Physician 1

Susan Binall, Consumer 1

### **FY14 Board Meetings**

July 23, 2013

August 20, 2013

February 25, 2014

March 18, 2014

April 15, 2014

### **Contact Information**

Mary A. Phillips, Executive Director

Board of Respiratory Care

239 Causeway Street, Suite 500

Boston, MA 02114

617-973-0806

<http://www.mass.gov/dph/boards/rc>

MultiBoard.Admin@state.ma.us

## II. Strategic Priorities

The RC Board plans to revise and update the regulations during FY15. In addition, the RC Board intends to conduct a random continuing education audit to determine compliance with the RC Board's regulations.

## III. License and Licensee Statistics

<b>Board of Respiratory Care</b>	2,766	Full Licenses
Biennial licensure	72	Limited Permits (no renewals)
<b>TOTAL</b>	2,838	

## IV. Compliance: Disciplinary Process and Statistics

<u>Number of Staff Assignment Investigations Opened</u>	<u>Number of Staff Assignment Investigations Closed</u>	<u>Number of Formal Complaints Opened</u>	<u>Number of Formal Complaints Resolved</u>	<u>Number of Formal Complaints Resolved with Discipline Imposed</u>	<u>% of Formal Complaints Resolved w/Discipline Imposed</u>
3	5	0	1	1	100%

## **Contact Us/Feedback**

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

Division of Health Professions Licensure  
239 Causeway Street, Suite 500  
Boston, MA 02114  
800-414-0168  
[www.mass.gov/dph/Boards](http://www.mass.gov/dph/Boards)