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December 31, 2015

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 24 of Chapter 159 of the Acts of 2014 and Section 42C of Chapter 112 of the Massachusetts General Laws, please find enclosed a report from the Department of Public Health entitled "Report of the Advisory Committee to the Board of Registration in Pharmacy."

Sincerely,

Monica Bharel, MD, MPH
Commissioner
Department of Public Health

Charles D. Baker
Governor

Karyn Polito
Lieutenant Governor



Marylou Sudders
Secretary

Monica Bharel, MD, MPH
Commissioner

Report of the Advisory Committee to the Board of Registration in Pharmacy

2015



Legislative Mandate

The following report is hereby issued pursuant to Section 24 of Chapter 159 of the Acts of 2014 as follows:

St. 2014, c. 159, § 24

Notwithstanding any general or special law to the contrary, the department of public health, in consultation with the board of registration in pharmacy and the advisory committee established by section 42C of chapter 112 of the General Laws, shall conduct an investigation of emerging models of coordinated, remote and shared pharmacy services, including but not limited to: central fill pharmacies; central processing pharmacies; outsourcing facilities; and telepharmacy. The department shall also issue a report indicating its support for or opposition to the adoption of certain pharmacy models in the commonwealth and identifying those elements of said models that should be promoted in support of the commonwealth's efforts to promote efficient, cost-effective and patient-centered health care in community settings and within integrated care systems. The report shall also include recommendations for appropriate regulations and standards of practice necessitated by said models to ensure compliance with state and federal pharmacy practice restrictions to safeguard patient safety in dispensing. The department shall file the report on its investigation, including its recommendations and drafts of any legislation, if necessary, by filing the same with the clerks of the senate and house of representatives who shall forward a copy of the report to the joint committee on public health and the joint committee on health care financing not later than December 31, 2015.

Executive Summary

St. 2014, c. 159, § 24, *An Act Relative to Pharmacy Practice in the Commonwealth*, established an Advisory Committee (“Committee”) to the Board of Registration in Pharmacy (“Board”). Several requirements of the Act, in addition to those required under M.G.L. c. 112, §42C, charged the Committee with investigating and evaluating the following:

- emerging models of coordinated, remote and shared pharmacy services, including but not limited to: central fill pharmacies; central processing pharmacies; outsourcing facilities; and telepharmacy;
- regulations and standards of practice necessitated by said models;
- the development of quality assurance, inspection and testing procedures for compounding;
- the application of accountability documentation requirements in licensed sterile pharmacies and complex non-sterile pharmacies;
- the development of regulations to supplement the U.S. Pharmacopeial Convention (USP), all chapters; and
- the establishment of specialty pharmacy licensure categories.

Because the legislative mandate specifies multiple tasks for the Committee to address, the Committee, at the direction of the Board, prioritized those issues for review in 2015, including emerging models of coordinated, remote and shared pharmacy services, central fill pharmacies, central processing pharmacies, outsourcing facilities, telepharmacy, abnormal environmental monitoring results, and sterile compounding regulation review.

Central Fill Pharmacies and Central Processing Pharmacies: The Committee supports the adoption of the central fill pharmacy and central fill processing models and recommends that the Board move forward in both instances.

Telepharmacy: The Committee discussed the pros and cons of telepharmacy but needs additional time to explore its many facets before making a formal recommendation to the Board.

Outsourcing: The Committee was presented with the outsourcing issue but ultimately did not have to make a recommendation, as the FY16 state budget bill (St. 2015, c. 46) contained provisions which authorized the Board to register outsourcing facilities.

Abnormal Environmental Monitoring Results: The Committee formed a ‘Sub-Committee on Abnormal Results’ to investigate and make recommendations concerning, ‘when and what action to take when abnormal environmental monitoring results are reported.’ The Sub-Committee’s work is ongoing, but it has reported to the full Committee on ‘proper response for abnormal environmental monitoring results obtained within the ISO 5 and ISO 7 buffer compounding environments.’

Sterile compounding regulation review: The Committee was provided draft sterile compounding regulation 247 CMR 17.00 for overview and comment to be presented to the Board before final promulgation of the regulation. A meeting is scheduled for January 2016 to deliberate and collect comments to be presented to the Board for their consideration.

Introduction

Following the 2012 national fungal meningitis outbreak, Massachusetts enacted sweeping legislation to reform the oversight of pharmacy practice and to improve the quality and safety of sterile compounding. Chapter 159 of the acts of 2014, *An Act Relative to Pharmacy Practice in the Commonwealth* took several significant steps to improve the delivery and oversight of pharmacy services in the commonwealth. The legislation was based on the premise that patient safety is paramount, and addressed critical gaps in state oversight.

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

The Advisory Committee is a panel of experts assembled to advise the Pharmacy Board on various topics set by the Legislature or as requested by the Board. The establishment of the Advisory Committee was the Pharmacy Board's top priority in FY15 and created a unique opportunity for members to have direct input on the rapidly changing landscape of the pharmacy industry, all with the common goal of ensuring patient safety both inside and outside the Commonwealth's borders.

The Pharmacy Board identified expert candidates as required by M.G. L. c. 112, §42C and St. 2014 c. 159 §24, and these experts were appointed by the Commissioner of Public Health as the Chair of the Committee. The members include:

Advisory Committee Expert Members:

Rory Geyer, PhD	cGMP aseptic processing
Caryn D. Belisle, RPh, MBA	USP Chapter 71
Anthony M. Cundell, PhD	USP Chapter 71
John Walczyk, PharmD, RPh, FIACP, FACA	USP Chapter 795
Sylvia B. Bartel, RPh, MHP	USP Chapter 797
Eric S. Kastango, MBA, RPh, FASHP	USP Chapter 797
Antoinette Lavino, RPh, BCOP	USP Chapter 797
Judith T. Barr, MEd, ScD, FASHP	Pharmacoeconomics
Keith B. Thomasset, PharmD, MBA, BCPS	Pharmacoeconomics
David H. Farb, PhD	Clinical Pharmacology
Michael J. Gonyeau, PharmD, Med, BCPS, FNAP, FCCP, RPh	Clinical Pharmacology
Michael C. Thomas, PharmD, BCPS	Clinical Pharmacology
Karen Byers, MS, RBP, CBSP	Microbiologist
Francis McAteer	Microbiologist

The Committee is statutorily required to meet at least twice per year and more often as necessary. All members are committed to the substantial task before them, and, between the Committee and the Sub-Committee, they met eight (8) times in 2015.

Advisory Committee Meetings

March 27, 2015
June 26, 2015
October 5, 2015
December 11, 2015

Advisory Sub-Committee Meetings

May 1, 2015
May 29, 2015
August 28, 2015
October 30, 2015

As the Committee is charged with multiple issues to address, prioritization was necessary. The Board directed the Committee to review emerging models of coordinated, remote and shared pharmacy services, including central fill pharmacies, central processing pharmacies, outsourcing facilities, telepharmacy, abnormal environmental monitoring results and sterile compounding regulation review.¹

Of these areas, one that was of particular importance to the Board was work on *abnormal environmental monitoring results*. This included making recommendations to the Board regarding the proper response and corrective measures to be taken when abnormal environmental monitoring results are reported by sterile compounding pharmacies. This guidance is not currently found in the United States Pharmacopeia (USP) or any other source, making this an area where expert analysis and recommendations was of great value to the Board.

This report outlines the issues addressed by the Committee during 2015 along with its investigation findings, support or opposition, favorable elements of each model, analysis and recommendations, all with the goal of improving state oversight of the compounding pharmacy industry in Massachusetts and ensuring patient safety.

¹ Appendix A, *Recommendation 15-03, Emerging Models of Coordinated Pharmacy Services*

Coordinated, Remote and Shared Pharmacy Services

I. *Central Fill*

i. Overview of the Model

Central fill was defined by the Board as: A process that allows prescriptions to be filled at a central location before the medications are routed to the relevant pharmacies for dispensing to the ultimate end user.²

The central fill model is best implemented for refill prescriptions, maintenance prescriptions and new non-acute prescriptions. Prescriptions that are not needed by the patient for several days are ideal candidates for the central fill model.

The model is largely implemented by chain retail pharmacies across the nation with common ownership, but third-party contracts have allowed the model to extend to independently owned retail pharmacies.

ii. Investigation of the Model

- Utilizing the central fill model, retail pharmacies are able to spend more of their time on patient-centered activities such as consulting physicians, counseling, medication therapy management (MTM) or high-level patient services, such as immunization.
- The central fill model relieves the retail pharmacy of the burdens of high prescription volumes. The central fill model removes refill, maintenance and non-acute care prescription volume from retail pharmacies, shifting the concentration at the retail pharmacy to the dispensing of acute care prescriptions. This model allows the pharmacist to focus on the verification of fewer prescriptions.
- Central fill pharmacies are often built around high-speed, high-efficiency automated dispensing machines. The use of these machines promotes cost savings and error reduction.
- Central fill pharmacies have the ability to build in work-flow redundancies focused on catching and correcting errors prior to reaching patient.
- Central fill inventory promotes greater efficiency of unit-of-use and low demand drugs, through aggregate purchasing and consumption. The reduction of inventory costs, such as disposal or reverse distribution of expired drugs, at the retail pharmacy correlate directly to patient savings on prescription drugs.

² See Appendix B, *Memorandum to the Advisory Committee from the Board*.

- Central fill inventory promotes the reduction of expired medication dispensing and inspectional violations for expired medications at retail pharmacies, by removing unit-of-use and low demand drugs from the retail pharmacy inventory.
- The central fill model also reduces the need to expand existing pharmacy footprints.

iii. Recommendations for Regulations and Standards of Practice

- All central fill activities must be performed in Massachusetts. Central fill for non-resident pharmacies should be considered after the implementation of central fill for resident pharmacies.
- The central fill model should be applied to both retail pharmacies and hospital pharmacies, but a central fill pharmacy should not be able to service both retail and hospital pharmacies.
- The central fill model must not apply to sterile compounding prescriptions. A central fill pharmacy that seeks to engage in such activities must register with the FDA and Board as an outsourcing facility.
- Every retail pharmacy patient must be informed and must consent to have their prescription filled at a central fill location. It would be acceptable to accomplish this through signage or auto-forms stating that the prescription will be filled in another location.
- Every pharmacist must always have the option to override the central fill selection, but must be able to determine if there is enough time for a central fill location to fill and ship the prescription.
- Central fill activities must be limited to pharmacies with common ownership, or pharmacies with compatible computer systems that allow for exchange of required information.
- A central fill pharmacy must have a Board-approved contract with each retail pharmacy serviced, specifying the exact responsibilities of the retail pharmacy and the central fill pharmacy.
- A central fill pharmacy must be required to utilize the Prescription Monitoring Program (PMP) for all controlled substance prescriptions, since the central fill pharmacy does not have a direct relationship with the patient.
- The Board should determine if any controlled substances should be excluded from central fill pharmacies.
- A central fill pharmacy must require all pharmacy technicians to be nationally certified.

- All prescription drugs filled by the central fill pharmacy must be packaged in the central fill-branded containers, labels and bags, so that the origin of the prescription is clear to the patient.
- All return to stock drugs must be returned to the pharmacy of origin. A prescription drug that is filled by central fill must be returned to the central fill pharmacy by the dispensing pharmacy. If the central fill pharmacy is unable to determine the lot number of the returned to stock drug, in the event of a recall, the central fill pharmacy must dispose of the returned to stock drug.

iv. Support or Opposition for Adoption of the Model

The Advisory Committee supports the adoption of the central fill model.

v. Necessary Legislation

The need for legislation to promulgate these regulations was not deliberated by the Committee.

II. Central Processing

i. Overview of the Model

Central processing was defined by the Board as: A pharmacy that conducts the data input and profile review (including tasks such as contacting a prescriber for drug interactions) off-site. The prescription is then physically filled at the pharmacy where the prescription originated.³

The central processing model allows labor intensive and time consuming tasks to be removed from the pharmacy. Pharmacy staff at the central processing pharmacy is able to perform these activities with little or no distractions, unlike retail pharmacy staff.

Many states have allowed the implementation of the central processing model. Some states only allow resident pharmacies to engage in these services (Georgia), some allow resident and non-resident facilities to perform this function (Alaska), and others require a specialty license to engage in this function for residents and non-residents (Oklahoma).

ii. Investigation of the Model

- Utilizing the central processing model, retail pharmacies are able to spend more of their time on patient-centered activities such as counseling, medication therapy management (MTM), high-level patient services, such as immunization, or verifying filled prescriptions.
- The central processing model relieves the retail pharmacy of the burdens of time consuming tasks. The central processing model removes drug utilization reviews,

³ See Appendix B, *Memorandum to the Advisory Committee from the Board*.

physician authorizations, and insurance approvals from the retail pharmacy, shifting the concentration at the retail pharmacy to the verification of filled prescriptions.

- Central processing pharmacies focus their attention on many of the activities that often result in delay of therapy to patients at retail pharmacies.
- Staff at a central processing pharmacy is able to devote undistracted attention to performing important patient-safety measures, such as drug utilization reviews.
- Central processing pharmacies have the ability to build in work-flow redundancies focused on catching and correcting errors prior to the prescription being filled at the retail pharmacy.
- A pharmacy that may have otherwise closed due to low volume can remain open and accessible to the community by taking advantage of central processing opportunities.

iii. Recommendations for Regulations and Standards of Practice

- All central processing activities must be performed in Massachusetts. Central processing for non-resident pharmacies should be considered only after the implementation of central processing for resident pharmacies.
- The central processing model should be applied to both retail pharmacies and hospital pharmacies, but a central processing pharmacy should not be able to service both retail and hospital pharmacies.
- The central processing model must not apply to sterile compounding prescriptions.
- Every retail pharmacy patient must be informed and must consent to have their prescription processed at a central processing location. It would be acceptable to accomplish this through signage or auto-forms stating that the prescription will be processed in another location.
- Every pharmacist must always have the option to override the central processing selection.
- Central processing activities must be limited to pharmacies with common ownership or pharmacies with compatible computer systems that allow for exchange of required information.
- A central processing pharmacy must have a Board-approved contract with each retail pharmacy serviced, specifying the exact responsibilities of the retail pharmacy and the central processing pharmacy.
- A central processing pharmacy must be required to utilize the PMP for all controlled substance prescriptions, since the central processing pharmacy does not have a direct relationship with the patient.

- A central processing pharmacy must require all pharmacy technicians to be nationally certified.

iv. Support or Opposition for Adoption of the Model

The Advisory Committee supports the adoption of the central processing model.

v. Necessary Legislation

The need for legislation to promulgate these regulations was not deliberated by the Committee.

III. *Telepharmacy*

i. Overview of the Model

Telepharmacy is the delivery of pharmaceutical care via telecommunications to patients or practitioners in locations where such patients or practitioners may not have direct pharmacist contact.

Telepharmacy began in the early 2000s and was introduced with the hope of expanding access to quality health care to communities nationwide, primarily in rural, medically-underserved areas.

ii. Investigation of the Model

- Telepharmacy allows pharmacists to provide high-level pharmaceutical care services in rural environments that have limited access to health care services.
- Telepharmacy offers the potential for cost savings, as one pharmacist can be utilized for multiple sites.
- Telepharmacy offers enhanced inventory control and record keeping.

iii. Recommendations for Regulations and Standards of Practice

After preliminary conversation on this topic, the Committee noted that Telepharmacy could encompass an entire spectrum of pharmacy services, and it requested further research on Telepharmacy before making any recommendations.

The Committee is actively researching the topic and will start by defining the terms and outlining where Telepharmacy should apply with regard to pharmacy practice in the Massachusetts. The Committee plans to address the issue in a progressive fashion, focusing on supplementing, not replacing, pharmacy services. The Committee is further exploring the concepts of Telepharmacy by researching the specific issues around the safety and service capabilities of Telepharmacy (to include counseling), hospitals and rural environments and self-contained pharmacy dispensing machines (also known as “Pharmacy in a Box”).

The Committee will review the National Association of Boards of Pharmacy (NABP) Report of the Task Force on Telepharmacy, the American Association of Health-System Pharmacists (ASHP) Statement on Telepharmacy, other state regulations (to include North Dakota and Illinois), and current applicable Massachusetts regulations and recommendations from the DPH State Office of Rural Health. The Committee will also consider accessibility, cultural competence, and linguistic issues to best serve patients and practitioners through this model.

The Committee plans to answer the following questions related to Telepharmacy:

1. Does the Committee agree that Telepharmacy is a topic that the Board should consider for the development of guidance or regulation?
2. Should limitations to population exist or any geographical concerns where implementation of Telepharmacy would or would not be in the best interest of the public?
3. What type of licensing should be required, if any?
4. What type of security safeguards should be considered (pharmacy system database concerns, controlled substance security, HIPAA)?
5. What are the roles, registration and certification recommendations of support staff?
6. What other public safety concerns should the Board of Pharmacy consider?

iv. Necessary Legislation

The need for legislation to promulgate these regulations was not deliberated by the Committee.

IV. Outsourcing

The Federal Food, Drug and Cosmetic Act was amended in November 2013 to recognize and register outsourcing facilities as a third alternative to traditional pharmacies and manufacturers. However, since the Massachusetts pharmacy reform legislation, St. 2014, c. 159, made no mention of outsourcing facilities, there was a lack of clarity on whether, and when, outsourcing facilities registered with the FDA may operate in Massachusetts, or ship into Massachusetts. New statutory provisions included in the FY16 General Appropriation Act (chapter 46 of the acts of 2015) address this issue by establishing a state registration requirement for outsourcing facilities.

The FY16 GAA contains provisions in its outside sections that add a new statute, M.G.L. c. 112, § 36E, which authorizes the Board to register outsourcing facilities and specifies the requirements for registration. In addition, the outside sections amended relevant sections of M.G.L. c. 94C to authorize the Board to issue controlled substances registrations to outsourcing facilities.

M.G.L. c.112, § 36E requires the Board to promulgate regulations implementing the outsourcing facility provisions. The Board voted to approve the proposed amendments to 247 CMR 11.00 and the proposed new regulation 247 CMR 21.00 on November 3, 2015 and to proceed with the public comment period. The Board held a public hearing on December 10, 2015.

The Committee was presented with the outsourcing issue at its first meeting along with some educational materials. Subsequently, the FY16 GAA passed, authorizing the Board to register outsourcing facilities, and thereby negating the need for a Committee recommendation.

V. Shared Pharmacy Services Regulations:

The “shared services” concept language is recommended by NABP to be used by regulatory bodies in the promulgation of regulations surrounding the above-referenced models of pharmacy, excluding outsourcing. The use of such language replaces technology-specific provisions, which may later become antiquated, and places an emphasis on the responsibilities of the pharmacy and pharmacist for resulting outcomes from the use of any technology system. The shared services system allows for broad categorization of systems and overarching regulations that can account for operational and cognitive technology-supported functions.

The Committee utilized the NABP Model Act on Shared Services as a guideline. Below is a general outline of the Shared Service regulations to be reviewed and considered by the Board.

1) General Requirements:

- i. The Pharmacy must possess a resident license issued by the Board prior to engaging in Shared Pharmacy Services. This activity would not be allowed out-of state. The actual remote work shall be done in-state, and the workers will be licensed in the Commonwealth.
- ii. A Pharmacy may provide or utilize Shared Pharmacy Services only if the Pharmacies involved:
 - a) have the same parent company or organization; or
 - b) have a written contract or agreement that outlines the services provided and the shared responsibilities of each party in complying with federal and state pharmacy laws and rules; and
 - c) submit the contract to the Board; and
 - d) keep the contract on file at all Shared Pharmacy locations; and
 - e) share a common electronic file or technology that allows access to information necessary or required to perform Shared Pharmacy Services in conformance with the pharmacy act and the Board’s rules. An interface between 2 systems that share information can apply.
- iii. A Pharmacy engaged in Shared Pharmacy Services shall comply with appropriate federal and state controlled substances registrations for each Pharmacy if controlled substances are maintained.
- iv. A Pharmacy engaged in Shared Pharmacy Services shall notify the Board in writing within 10 days of a change of location, discontinuance of service or closure of a Pharmacy.

2) Operations:

- i. Pharmacies engaging in Shared Pharmacy Services, or a Pharmacist acting

independently of a Pharmacy and participating in Shared Pharmacy Services shall:

- a) maintain records identifying, individually, for each prescription drug order processed, the name of Pharmacist or Pharmacy Intern who took part in the drug utilization review, refill authorization or therapeutic intervention functions performed at that pharmacy and any Certified Pharmacy Technician if they assisted in any of those functions;
 - b) maintain records identifying, individually, for each prescription drug order filled or dispensed, the name of each Pharmacist or Pharmacy Intern who took part in the filling, dispensing, and counseling functions performed at that pharmacy and any Certified Pharmacy Technician or Pharmacy Technician if they assisted in any of those functions;
 - c) report to the Board as soon as practical the results of any disciplinary action taken by another state's Board of Pharmacy;
 - d) maintain a mechanism for tracking the prescription drug order during each step of the processing and filling procedures performed at the Pharmacy;
 - e) maintain a mechanism for the patient to identify all pharmacies involved in filling the prescription drug order and;
 - f) be able to obtain for inspection any required record or information within 72 hours of any request by the Board or its designee.
- ii. Notification to Patients
- a) Retail Pharmacies engaging in Shared Pharmacy Services shall notify patients that their prescription drug orders may be processed or filled by another pharmacy unless the prescription drug is delivered to patient in institutional facilities where a licensed health care professional is responsible for administering the prescription drug to the patient.

3) Security:

- i. Drugs shall be stored in compliance with state and federal laws and in accordance with these rules, including those addressing temperature, proper containers and the handling of outdated drugs.
- ii. Drugs stored at Shared Pharmacy Services Pharmacies shall be stored in an area that is:
 - a) separate from any other drugs used by the health care facility; and
 - b) secured, so as to prevent access by unauthorized personnel.
- iii. Access to the area where drugs are stored at the Shared Pharmacy Services Pharmacy must be limited to:
 - a) Pharmacists, Certified Pharmacy Technicians, Pharmacy Technicians or Pharmacy Interns who are employed by the Shared Pharmacy Services Pharmacy; or
 - b) Personnel employed at the Institutional Facility or clinic where the Shared Pharmacy Services is located who:
 1. are licensed health care providers;
 2. are designated in writing by the Pharmacist in Charge or the person responsible for the supervision and on-site operation of the facility where the automated pharmacy system is located; and
 3. have completed documented training concerning their duties

associated with the Shared Pharmacy Services Pharmacy

- iv. Shared Pharmacy Services Pharmacies shall have adequate security to:
 - a) Comply with federal and state laws and regulations; and
 - b) Protect the confidentiality and integrity of Protected Health Information.
- v. The Coordinating Pharmacy (i.e. where the prescription will be dispensed) shall have procedures that specify that drugs may only be delivered to the remote pharmacy or remote dispensing site in accordance with the policies and procedures of the Coordinating Pharmacy.
- vi. PMP is required for the processing of any controlled substances.

4) Policies and Procedures:

- i. Each participant in Shared Pharmacy Services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for Shared Pharmacy Services. Each participant is required to maintain this portion of the joint policies and procedures that related to that participant's operations. The polices and procedures shall:
 - a) Outline the responsibilities of each of the pharmacies;
 - b) Include a list of the name, address, telephone numbers, and all license and permit numbers of the pharmacies involved in Shared Pharmacy Services; and
 - c) Include policies and procedures for;
 - 1. notifying patients that their prescription drug orders my be processed or filled by another pharmacy and providing the name of the pharmacy;
 - 2. protecting the confidentiality and integrity of protected health information;
 - 3. dispensing prescription drug orders when the filled prescription drug order is not received or the patient comes in before the prescription drug order is received;
 - 4. maintaining required manual or electronic records to identify the name, initials, or identification code and specific activity or activities of each pharmacist, certified Pharmacy Technician, Pharmacy Technician or Pharmacy Intern who performed any Shared Pharmacy Services;
 - 5. complying with federal and state laws; and
 - 6. operating a Continuous Quality Improvement Program for Shared Pharmacy Services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

5) Individual Practice:

- i. Nothing in this Section shall prohibit an individual Pharmacist licensed in the State, who is an employee of or under contract with a Pharmacy, or a licensed Certified Pharmacy Technician, or Pharmacy intern, working under the supervision of the

Pharmacy, from accessing that Pharmacy's electronic database from inside or outside the Pharmacy and performing the Prescription Drug order processing functions permitted by the Pharmacy Act, if both of the following conditions are met;

- a) The Pharmacy establishes controls to protect the confidentiality and integrity of Protected Health information; and
- b) No part of the database is duplicated, downloaded, or removed from the Pharmacy's electronic database.

VI. Other Accomplishments of the Advisory Committee

Abnormal Results

The Subcommittee on Abnormal Results was convened to provide expertise in the development of sterile compounding standards in the Commonwealth. The Subcommittee worked to develop standards for the appropriate response to above action level environmental monitoring results in the cleanroom environment, based on the location of the identified organism(s).

This work was and is critical for the Board and its staff. The guidance is not currently found in the United States Pharmacopeia (USP) or any other source, making this an area where the Committee and Sub-Committee's expert analysis and recommendations is of great value to the Board. The Board expects hundreds of new licenses to be issued in 2016. With that come potentially hundreds of reports of above action level hits on environmental monitoring conducted by the pharmacies. Developing standards for the appropriate response to an above action level hit in various areas of the cleanroom environment will allow pharmacies to follow a set standard regarding reporting, remediation, and notification requirements. These standards do not currently exist and will put Massachusetts in the forefront of sterile compounding safety and innovation.

On October 5, 2015, the Sub-Committee reported their conclusions for policy standards on the appropriate response, remediation and notification requirements for above action level environmental monitoring results in the ISO-5 classified area. The Advisory Committee unanimously approved the Sub-Committee's recommendation, the corresponding memorandum, and formal recommendation to the Board.

On December 11, 2015, the Sub-Committee reported their conclusions for policy standards on response to above action level environmental monitoring results in the ISO 7 buffer space/room. The Advisory Committee unanimously approved the Sub-Committee's recommendation, the corresponding memorandum, and formal recommendation to the Board.

The work of the Sub-Committee remains ongoing, with future topics to include standards for the appropriate response to above action level environmental monitoring results in the ISO-7 and ISO-8 classified areas.

VII. 247 CMR 17.00 -Sterile Compounding Review

On December 11, 2015, the Committee was provided draft sterile compounding regulation 247 CMR 17.00 for overview and comment to be presented to the Board before final promulgation of the regulation. A meeting is scheduled for January 2016 where the Committee will deliberate and collect comments to be presented to the Board for their consideration.

Conclusion

Massachusetts was at the epicenter of the sterile compounding crisis. Since that time, the Commonwealth has been a leader in sterile compounding reform. The Advisory Committee has aided in this endeavor and has provided well-reasoned and analytic recommendations to the Board concerning abnormal environmental monitoring results. It has also offered recommendations on emerging models of coordinated, remote and shared pharmacy services that will ensure that the Board is moving forward with technological advances in the ever-changing landscape of the pharmacy industry.

The subjects that the Committee considered were complex and multifaceted. Meeting eight times over the course of the year allowed them to tackle many of the mandated tasks. A central fill model will allow pharmacies to spend more of their time on patient-centered activities such as consulting physicians, counseling, medication therapy management, or high-level patient services, such as immunization. This model allows the pharmacist to focus on the verification of fewer prescriptions and to build in work-flow redundancies focused on catching and correcting errors prior to reaching patient. The potential reduction of inventory costs, such as disposal or reverse distribution of expired drugs at the retail pharmacy, correlate directly to patient savings on prescription drugs.

A central processing model will allow labor intensive and time-consuming tasks to be removed from the pharmacy. Pharmacy staff at the central processing pharmacy is able to perform these activities with little or no distractions, unlike retail pharmacy staff. Central processing pharmacies focus their attention on many of the activities that often result in delay of therapy to patients at retail pharmacies. Staff at a central processing pharmacy is able to devote undistracted attention to performing important patient-safety measures, such as drug utilization reviews. A pharmacy that may have otherwise closed due to low volume can remain open and accessible to the community by taking advantage of central processing opportunities.

The Committee began a discussion of telepharmacy and noted that it could encompass an entire spectrum of pharmacy services. The Committee is further exploring the concepts of Telepharmacy by researching the specific issues around the safety and service capabilities of Telepharmacy including its viability in hospitals, rural environments, and self-contained Pharmacy dispensing machines also known as “Pharmacy in a Box”. They will explore its many facets before making a formal recommendation to the Board.

The Committee was presented with the outsourcing issue but ultimately did not have to make a recommendation, as the FY16 General Appropriation Act contains provisions authorizing the Board to register outsourcing facilities.

The Committee and Sub-Committee’s work to develop standards for the appropriate response to above action level environmental monitoring results in the cleanroom environment has been critical as the Board moves forward with regulations to expand oversight of sterile compounding in Massachusetts. The guidance from the Committee will be integrated into regulations and sub-regulatory guidance as the Board moves forward with pharmacy reform in Massachusetts. The Committee and Sub-Committee’s expert analysis and recommendations has been

instrumental in this process. These standards do not currently exist and will put Massachusetts in the forefront of sterile compounding safety and innovation.

The work of the Committee remains ongoing with regard to additional areas of the cleanroom environment, telepharmacy, sterile compounding regulation review and comment, and other legislatively mandated topics. The expertise, guidance and commitment of the Committee has aided the Board as it moves forward with pharmacy reform and the primary goals of patient safety, cost savings and greater access to pharmacy services.