

**COMMONWEALTH OF MASSACHUSETTS  
BOARD OF REGISTRATION IN PHARMACY**

**Pharmacy Advisory Committee  
Meeting held via remote WebEx.  
Boston, Massachusetts, 02114  
March 22, 2023**

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**Advisory Committee Members Present**

Ed Taglieri, MSM, NHA, RPh (chair designee by James Lavery)  
Antoinette Lavino, RPh, BCOP (Expert in USP<797>)  
John Walczyk, RPh, PharmD (Expert in USP<795>)  
Sylvia B. Bartel, RPh (Expert in USP<797>)  
David H. Farb, PhD (Expert in Clinical Pharmacology)  
Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)  
John P. Mistler, Pharm. D, RPh, MBA, BCSCP, CPH (Expert in cGMP)  
Patrick Gannon, RPh, MS, FABC additional expert member  
Timothy D Fensky, RPh, DPh, FACA (Expert in USP<71>)  
Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)

**Board of Pharmacy Member Present**

Sami Ahmed, PharmD, RPh, BCPS, BCSCP

**Advisory Committee Members Not Present**

Judith Barr, MEd, ScD, FASHAP (Expert in Pharmacoeconomics)  
Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)  
Francis McAteer (Expert in Microbiology)

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Monica Botto, Assistant Executive Director  
Jacqueline Petrillo, PharmD, RPh, JD General Counsel  
Michael Egan, JD, Board Counsel  
William Frisch, RPh Director of Pharmacy Compliance  
Michelle Chan, RPh Quality Assurance Pharmacist  
Sam Penta, RPh Senior Investigator  
Nathan Van Allen, PharmD, RPh Pharmacy Investigator  
Joanne Trifone, RPh, Director of Investigations

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**TOPIC I.** Attendance by roll call:

Call to Order, by Ed Taglieri at 10:03am and announces that the meeting is being recorded.

Roll call attendance: E. Taglieri, K. Thomasset, P. Gannon, S. Bartel, J. Walczyk, J. Mistler, A. Lavino  
T. Fensky, K. Byers, D. Farb joined the meeting at 10:08am.

Not Present: F. McAteer, M. Gonyeau, J. Barr, J. Lavery (E. Taglieri appointed chair by J. Lavery for this meeting)

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**TOPIC II.** **Approval of Agenda** **TIME: 10:05am**  
**Agenda: 3/1/23**  
**Changes: None**

Motion by K. Thomasset and seconded by P. Gannon, and voted unanimously by those present to approve the agenda with no noted change by roll call vote.

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**Topic III** **Approval of Board Minutes**  
**1. Minutes** **Time: 10:06am**  
**Draft 1/25/23**

**Changes:** Minor edit to credentials and to provide clarity.

Motion by S. Bartel, seconded by A. Lavino, and voted unanimously by those present to approve the minutes from the 1/25/2023 meeting with the noted changes provided by P. Gannon by roll call vote.

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**TOPIC IV:** Presentation of Recommendation Document 23-02, "Review of Draft Regulations, 247 CMR 2.0, DEFINITIONS AND SEVERABILITY  
**Time: 10:08am**

**S. Ahmed** – Requests Pharmacy Advisory Committee to review and provide expert input on and recommendations to 247 CMR 2.00 Definitions and Severability

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**TOPIC V:** Presentation of Recommendation Document 23-02, "Review of Draft Regulations, 247 CMR 2.0, DEFINITIONS AND SEVERABILITY

**Time: 10:09am**  
**Recused:**  
**Presented: Bill/Michelle**  
**Discussion:**

**W. Frisch** – Intent of document is to broadly support for all sections of 247 CMR.

**M. Chan** – Presented each definition within the document to the committee members. Comment requested for each definition.

**Authorized Personnel** – Member comment on unlicensed (cashier, delivery), employees are approved prior.

**M. Chan** – Noted that this definition includes those deemed authorized by pharmacy.

**Automated Dispensing Device** – Member asked if this definition would include secured units (i.e.- lockers) for picking up prescriptions after hours or in alternate location within no healthcare facilities. Is this part of this discussion or out of scope?

**M. Chan** – Noted that the locker style unit would not be included in this definition and do not carry the same capabilities.

**W. Frisch** – New technology will be addressed in upcoming policies.

**M. Chan** – Policy does exist regarding healthcare facility types and requirements for such devices.

**Auto Refill Program** – Member concern with automatic enrollment in such program attributing to overall increase cost in healthcare.

**M. Chan** – Noted that 247 CMR 9.0 will include requirements for such program include and record consent from the patient.

**Designated Pharmacist In Charge (PIC)** – Member asked if this is the same as Manager of record?

**M.Chan** – Noted that this will most commonly occur with non-resident pharmacies as one pharmacist must be licensed in Massachusetts and take responsibility for this portion of the prescription processing. Does not necessarily have to be the Manager of the non-resident pharmacy.

**Final Dispensing Process Validations** – Does this need to be defined? Or refer to policy?

**W. Frisch** – Shared services policy allows virtual verification of final product if specific requirements are met including one licensed pharmacist at location. Policy allows for updates to be made as technology evolves.

**T. Fensky** – Agrees that use of a policy will benefit making changes in future and expand requirements when necessary (i.e. technology check technician procedures, etc.)

Additional members expressed agreement with such approach and cited examples such as gravimetrics and barcode scanning.

**D. Farb** – Inquired about future development of technology and security of devices and if that should be discussed within this document?

**J. Walczyk** – Asked where liability would fall if error were to occur while utilizing a remote dispensing location? MOR or person loading the machine?

**W. Frisch** – Shared services policy describes requirements, but liability is not included. Noted that each individual situation would be investigated for regulatory compliance. A disclosure must be made to the patient that some portion of the prescription processing might occur at another location. The patient must be given option to opt out.

**Good Moral Character (GMC)** – Member asked if there is an already recognized definition?

**P. Gannon** – Definition may need to include language to capture instances when the licensee commits non pharmacy related character decisions that do not directly include patient care and pharmacy poor conduct. Will Board have information necessary to proceed with review?

**E. Taglieri** – General definition can help assist the Board in determining such virtues and not get boxed into one viewpoint.

**M. Chan** – Will review and make adjustments.

**M. Chan** – Continued review of definitions.

**A. Lavino** – Inquired reason for addition of Massachusetts “located” pharmacy.

**M. Chan** – Explained that when non-resident pharmacy’s are licensed, the pharmacist responsible for prescription filled for Massachusetts patients does not necessarily need to be the manager of the pharmacy.

**T. Fensky** – Most states utilize PIC “Pharmacist In Charge” rather than MOR.

**National Drug Code (NDC)** – Members agreed to remove from document.

**Pharmacy Processing Automation (PPA)** – Discussed broad use of container in institutional setting and dispensing/packaging units that print patient information on package and do not require a label to be affixed.

Members and Board Staff discussed current issues associated with packaging (strip packaging, blister cards, multi-dose cards, unit-of-use, etc.) and the amount of information that could fit on prescription label. Also discussed expansion of use to other areas of Pharmacy such as sterile compounding.

**D. Farb** – Noted that confusion may occur if personnel misinterpret minimum labeling requirements of PPA versus minimum labeling requirements by statute.

Board staff and members noted that statutory requirement denote the minimum labeling requirements of a prescription.

**M. Chan** – Reviewed more definitions.

**J. Mistler** – Offered consideration for SADE by removing “directly” and potential inclusion of “may require medical or surgical intervention to treat one of the outcomes above”.

**P. Gannon** – Does transfer of ownership requirement continue with non-resident pharmacies?

**M. Chan** – If the Pharmacy is licensed by the Board, yes.

**J. Walczyk** – Will there be a grace period for non-resident pharmacies for MA RPh licensure?

**M. Chan/W. Frisch** – There is a timeline for making managerial changes.

**P. Gannon** – Initiated discussion regarding transfer of ownership of hospital institutions and application of Transfer of Ownership definition.

**M. Chan/W. Frisch** – Most instances are case by case review. Will review with legal to ensure complete.

Completed review of definitions.

K. Thomasset left meeting at 11:00am.

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**VI: Closing remarks and Adjournment of Meeting**

**Time: 11:02am**

**Comments:**

Yearly requirement is completed. Additional meetings will be offered if necessary.

**Adjournment:**

Motion by T. Fensky, seconded by P. Gannon, and voted unanimously by those present to close the meeting by roll call vote.