COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

# MINUTES OF THE PHARMACY ADVISORY COMMITTEE

239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts 02114
Monday, October 5, 2015

---

**Advisory Committee Members Present**

Lindsey Tucker, DPH Associate Commissioner, Chair
Sylvia B. Bartel, RPh (Expert in USP<797>)
Caryn D. Belisle, RPh, MBA (Expert in USP<71>)
Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)
Rory K.Geyer, PhD (Expert in cGMP)
Eric Kastango, RPh, MBA, FASHP (Expert in USP<797>)
Judith Barr, MEd, ScD, FASHAP (Expert in Pharmacoeconomics**)**
Antoinette Lavino, RPh, BCOP (Expert in USP<797>)
Michael C. Thomas (Expert in Clinical Pharmacology)
John Walczyk, RPh, PharmD (Expert in USP<795>)
Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)

**Advisory Committee Members Not Present**

David H. Farb, PhD (Expert in Clinical Pharmacology)
Francis McAteer (Expert in Microbiology)
Anthony M. Cundell, PhD (Expert in USP<71>)
Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)

**Support Staff**

James Lavery, JD, Director, Divisions of Health Professions Licensure
David Sencabaugh, RPh, Executive Director, Board of Pharmacy
Heather Engman, JD, MPH, Board of Pharmacy Counsel
William E. Frisch, Jr., RPh, Director of Pharmacy Compliance
Kelly Ann Barnes, JD, RPh Director of Pharmacy Quality Assurance
Colleen K. Collins, PharmD, RPh, Pharmacy Investigator
Richard Harris, Project Analyst

**Board of Pharmacy Members**

Garrett Cavanaugh, RPh

---

TOPIC:

1. **WELCOME & CALL TO ORDER** **9:03 AM**

   DISCUSSION: At 9:03 AM, Divisions of Health Professions Licensure Director J. LAVERY called the meeting of Pharmacy Advisory Committee to order. He stated that this is a public meeting and was being recorded. He asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. He introduced L. TUCKER, Associate Commissioner at the Department of Public Health (DPH) and Chair of the meeting, on behalf of DPH Commissioner, Dr. Monica Bharel. Members of the Advisory Committee and Board staff

introduced themselves. There were not any members participating remotely.
NOTE: A quorum was present.

---

TOPIC:

2. **APPROVAL OF AGENDA** **9:05 AM**

DISCUSSION: L. TUCKER asked if there were any changes to the agenda. There were not.
ACTION: At 9:06 AM motion by J. WALCZYK seconded by S. BARTEL and voted unanimously to approve the agenda with no changes.

---

TOPIC:

3. **APPROVAL OF MINUTES FROM JUNE 26, 2015** **9:05 AM**

DISCUSSION: L. TUCKER asked if there were any changes to the minutes from June 26, 2015. There were not.
ACTION: At 9:06 AM motion by E. KASTANGO seconded by K. THOMASSET and voted unanimously to approve the minutes from the June 26, 2015 Pharmacy Advisory Committee Meeting.

---

TOPIC:

4. **ABNORMAL RESULTS SUB-COMMITTEE UPDATE** **9:06 AM**

DISCUSSION:
L. TUCKER turned the meeting over to Director of Pharmacy Compliance W. FRISCH and Director of Pharmacy Quality Assurance K. BARNES. K. BARNES indicated that the subcommittee completed a lot of work to date and presented slides to the group. She commented that originally, the focus was of the group was on the identification of the organism but instead, the group shifted their focus to the location of the abnormal results. She stated that the group has reached consensus on policy positions for ISO-5, which will be brought forward to the Board for consideration.

K. BARNES stated that the charge of the Sub-Committee was to:

- Define successful remediation for above action levels of environmental monitoring (EM), to include elements that must be met to demonstrate successful remediation and a return to a "state of control."
- Develop guidance for appropriate response, remediation and notification requirements for pharmacies in response to above action level EM.

K. BARNES stated that the committee has met 4 times and Process Flow Diagrams have been evaluated with a focus on patient safety and providing guidance for appropriate response to above action level EM. She outlined the progress to date:

- Consensus has been reached for ISO-5. Guidance for above action EM Results in the ISO-5 area has been drafted, to include appropriate response, remediation and notification requirements.
- Proposed policy standards regarding above action level EM in the ISO-5 area has been drafted.
- Guidance for response to above action level EM results in the ISO-7 and ISO-8 classified areas are under development. The group continues discussions on proper responses including remediation and notification requirements.

K. BARNES indicated that future considerations of the group include:

- Developing policy standards for above action level EM results in the ISO-7 and ISO-8 classified areas.
- Developing policy standards for appropriate response, remediation and notification requirements for:
    - Failed Media Fill Tests,
    - Failed Glove-Fingertip Test,
    - Failed ISO certification results,
    - Failed HEPA Filter leak test,
    - Failed Sterility Test,
    - Failed HVAC,
    - Failed Smoke Study.

K. BARNES turned the meeting over to expert in cGMP, R. GEYER. R. GEYER reviewed the work of the Sub-Committee to date. R. GEYER presented the following standards that were reviewed and voted on by the Advisory Subcommittee on Abnormal Results during the meeting held on Friday, August 28, 2015. He stated that consensus was reached on the following:

- Pharmacy maintains policy and procedures defining a remediation plan to address abnormal EM results according to "Board Policy 2015-xx: Response to Abnormal EM Results."
- A pharmacist Manager of Record (MOR) or pharmacist designee shall notify the Board via email notification within 24 hours of receiving notification of abnormal EM results from the microbiologist/laboratory.
- A pharmacist MOR or designee shall submit a *Disclosure of Abnormal Results* accompanied by the microbiology report associated with abnormal EM within 7 days of receiving the reports in accordance with 247 CMR 20.
- A pharmacy shall immediately assess abnormal EM results and may not prepare compounded sterile preparations (CSPs) until a remediation plan is developed and implemented in accordance with "Board Policy 2015-xx: Response to Abnormal EM Results."
- A pharmacy shall develop a remediation plan in accordance with "Board Policy 2015-xx: Response to Abnormal Environmental Monitoring Results."
- In accordance with USP <797>, a pharmacy shall engage the assistance of a microbiologist, infection control professional, or industrial hygienist to develop a remediation plan.
- A pharmacy shall properly remediate abnormal EM results in accordance with "Board Policy 2015-xx: Response to Abnormal EM Results."
- A pharmacy shall perform repeat EM of non-viable air and viable air and surface (bacterial and fungal) as part of remediation to abnormal EM results within the ISO-5 classified space.
- The pharmacy may limit the repeat EM to the affected ISO-5 classified space.
- A pharmacy may not resume compounding in an ISO-5 Primary Engineering Control (PEC) following an abnormal EM result until remediation is completed and proven by microbiology reports of repeat EM results within acceptable levels.
- A pharmacy may not resume compounding in an ISO-7 area following an abnormal EM – (under development).
- A pharmacy may not resume compounding in an ISO-8 area following an abnormal EM – (under development).
- Successful remediation of abnormal EM results shall be proven by repeat EM microbiology

reports demonstrating results within acceptable levels.

- A pharmacy shall submit the completed remediation plan including microbiology report(s) from repeat EM to the Board within 30 days of the pharmacy's initial notification of the results or a timeframe agreed upon the Executive Director or their designees.

K. BARNES and W. FRISCH answered questions and clarified statements as follows:

- The action is without regard to the microorganism in the ISO-5 area.
- With regards to repeat EM, this includes the affected PEC.
- There will be guidance for the registrants in the policy for how to notify the Board and how to respond.
- The remediation steps will be outlined for registrants.
- In response to any abnormal EM, the expectation is that CSP compounding will cease and the type of remediation will dictate the length of time that particular hood can be used.
- Policy position is that you stop compounding for an abnormal result, even a brief period while you assess the situation. Consensus is reached on ISO-5, other areas are under development.
- Registrants shall refer to the Board Policy for responses to the specific ISO areas.
- Guidance for assessing and remediation will be in the policy.
- Premise of immediately assessing the report and ceasing compounding is intended for all areas.
- A. LAVINO suggested clarification regarding the results – are they based on USP <797> standards or the Board policy? K. BARNES commented 247 CMR 17 will need to be paralleled to USP <797> changes and that they are following USP <797>. W. FRISCH commented that the Sub-Committee felt that the guidelines should be based on USP <797>. A. LAVINO suggested it be clarified. K. BARNES noted that it will be edited to the definition section of the regulations.
- E. KASTANGO commented that the Commonwealth may need to be more stringent with more granularity because it may not be well defined in USP <797>.

K. BARNES reviewed on the vote as a Recommendation to the Board. K. BARNES referred the group to the Memo to the Advisory Committee from the Sub-Committee on Abnormal Results. She stated that as ISO-7 and 8 are developed, it could dictate the language of the statements and the recommendations in the memo are the policy statements for the consensus to date. She stated that the "pause" could be brief or lengthy so that the compounder can assess the situation. For ISO-5, there needs to be repeat EM in order to continue compounding. K. BARNES noted that there should be a continuity of care plan for hospitals/pharmacies that only have one PEC. K. BARNES added that the policy positions will eventually be in a better format; these are just the proposed policy statements.

ACTION: At 10:12 AM, motion by E. KASTANGO and seconded by R. GEYER and voted unanimously to accept the recommendations of the Sub-Committee Recommendation Document 15-01 and the corresponding memo.
J. LAVERY asked for the members of the committee to sign the recommendation. D. SENCABAUGH asked for a volunteer to go to the Board Meeting in November to discuss these recommendations. C. BELISLE volunteered and A. LAVINO will be an alternate in case of scheduling conflicts. J. SULLIVAN will handle the scheduling.

TOPIC:

**5. OUTSOURCING FACILITIES AS PER RECOMMENDATION 15-02 10:20 AM**

DISCUSSION: This topic was deferred until the next meeting.

---

TOPIC:

6. **SHARED PHARMACY SERVICES: CENTRAL FILL, CENTRAL PROCESSING, REMOTE ORDER ENTRY/ VERIFICATIN OF PATIENT SPECIFIC PRESCRIPTIONS 10:20 AM**

DISCUSSION: D. SENCABAUGH referred the group to the documents regarding central fill (CF) and central processing (CP). He stated that there is a deadline for the report due to the legislature at the end of the year. D. SENCABAUGH recommended that the group consider if the Board should move forward with the concept of CF and/or CP and if there are any recommendations or parameters that need to be considered. He added that they would still need to review existing regulations. D. SENCABAUGH referred the group to the "NABP Model Act 2013 Shared Services" document where the framework had been laid out. D. SENCABAUGH turned the meeting over to Board Member G. CAVANAUGH. G. CAVANAUGH gave an overview to the group; he has specific experience with CP. G. CAVANAUGH informed the group that pharmacists are looking at technology to free up the pharmacist, improve safety and improve patient outcomes. G. CAVANAUGH stated that he has experience at his company with CP and shared services, which was reviewed as follows:

- Data entry review and clinical QA is conducted by a licensed pharmacist for new and refilled prescriptions,
- The local pharmacy (in his case) is another Rite Aid pharmacy using a common database,
- Final product review, verification and counseling are performed at the originating pharmacy.
- Benefits include: safety (2 quality assurance checks), confidential, paperless, secure, shared common data base and accountability (all steps identify the pharmacist responsible and the location).
- The District Manager can tailor the program to enhance safety and determine what pharmacies will be processing.
- Frustrations originally were lack of workflow related visibility (i.e. an order "appears" in the queue).
- If the prescription requires clarification, it can send back to the store. Prescription goes back to the originating pharmacy then it is communicated to the patient.
- Currently stores do not cross state lines.
- He believes that the process is not currently communicated to the patient (i.e. in Rite Aid stores that have this outside of Massachusetts).

The group discussed CF systems. Some Advisory Committee Members felt that the process appeared inefficient in that the stores did not appear to be utilizing technology to the fullest capacity in the process of filling prescriptions. D. SENCABAUGH suggested counseling would be improved. However, there was the thought that not all patients want counseling so you may not be able to use that as a data metric to measure how well a retail pharmacy is doing. L. TUCKER suggested that they request data from other states including the types of metrics they are using. D. SENCABAUGH suggested that NABP would be a good resource for that.

When asked about existing CF and/or CP activity in the state, D. SENCABAUGH indicated that he knew of a Walgreens Pharmacy pilot program but added that he was unsure if it still exists.

D. SENCABAUGH reviewed the questions from the minutes that were approved and the thoughts were that:

- Both retail and hospital would be involved.
- There is an "opt in" at retail pharmacies, and patients would be informed (especially with CF).
- This would occur in state only.
- Central pharmacy and dispensing pharmacies had the same operating pharmacies and a contract in place.
- PMP would be required for any controlled substances.
- Only certified technicians should be utilized [with regards to support staff] at the central location.

D. SENCABAUGH read The NABP Model Act 2013. The following items were discussed, clarified and/or decided by the group:

- Section (a6) - "….compounding for specific patients, …" under a CF, are we stating it is patient specific only? What about preparing medications in advance (i.e. bags of cefazolin)? It appears this will be patient specific for now. This may be addressed in the future with 503A and 504Bs and what hospitals are allowed to do. Currently, CF relates to patient specific only, pursuant to a prescription.
- Section (1) (i) - Strike "non-resident" as this would not apply out-of state.
- Section (1) (ii) (A) – The definition of same owner should be clarified to same parent company or organization.
- Section (1) (ii) (C) - An interface between 2 systems that share information would apply in this situation.
- Section (1) (iv) – Verify that this aligns with Massachusetts Law. D. SENCABAUGH mentioned that the plan would be to crosswalk all of these details with regards to existing laws and regulations.
- Section (2) (i) – Regarding pharmacists acting independently of a Pharmacy, it could be an independent pharmacist working remotely (i.e. from home). Both parties need to have the information and be able to audit an issue and will also have a contract. The Board should ask for the contract. To clarify, the actual remote work will be physically done in-state and the workers will be licensed in the Commonwealth. The group felt that this work will be kept in state for now and they will consider border states/contiguous states in the future.
- Section (2) (i) (C) – If medications are being shipped out of state and there is disciplinary action then we would need to know this.
- Section (3) (ii) (A) – Unclear why it needs to be separate. Might apply for a patient bringing in own medications, as it will be stored separately. Could also apply if they are only doing certain medications. There was a suggestion to make a sub-committee on this topic as a whole but there is no timing or resources for that. Another idea was to separate out CF and CP and handle separately. Next, there was a suggestion to look at the states that rolled out since 2013 (when the model act came out) to see how they were handled the suggestions with regards to the act. NABP might give some ideas of where states need to deviate from the model. D. SENCABAUGH will ask for that from NABP and will ask for that when he asks for the data.
- Section (3) (iii) (A) – Verbiage states that "Pharmacists, technicians, interns, etc "employed

by" the shared pharmacy services …" M. THOMAS stated that interns may not be considered employees if they are on rotation. Board staff noted that they treat interns as employees, so it should then apply to interns. Board staff will look into this wording further. Also, the group had questions regarding the scope of practice and if it is expanding. D. SENCABAUGH noted that the Board needs to cross-walk this with existing regulations to see if the scope is expanding and will contemplate whether all techs need to be nationally certified in central locations.

- Section (3) (iii) (A) – The Coordinating Pharmacy is the pharmacy where the prescription will be dispensed.
- Section (4) (i) (C) – Regarding policies and procedures, verbiage may need to be adjusted for retail versus hospital, regarding notifying patients. The group already discussed exempting hospital pharmacists from that requirement.
- Regarding abnormal results if that happens at CF, then site would be required to alert other pharmacies and to the Board for traceability, etc.
- The group agreed with moving forward with the concepts of CP and CF in Massachusetts.
- Conceptually, the Pharmacy Advisory Committee agreed with the recommendation that the Board of Pharmacy should move forward with developing regulations for Shared Pharmacy Services.

ACTION: At 11:20 AM motion by J. BARR seconded by M. THOMAS and voted unanimously that conceptually, the Pharmacy Advisory Board agreed with the recommendation that the Board of Pharmacy shall move forward with developing regulations for Shared Pharmacy Services.

---

TOPIC:

**7. PROCESS OF ADDING NEW ITEMS TO THE AGENDA 11:22 PM**

DISCUSSION:

The process of adding new items to the agenda was discussed by the committee. D. SENCABAUGH stated that in the past the Board makes a recommendation to the committee and the committee votes to approve the agenda and chapter 159 allows the advisory committee to discuss other items. D. SENCABAUGH suggested that the group be cautious of emails and recommendations with regards to "BCC" and reminded the group to comply with Open Meeting Law. H. ENGMAN reminded the group that pursuant to the Open Meeting Law, the agenda needs to be posted on website within 48 business hours.

It was suggested that an item on the agenda could be a proposal for new business as a standing item but H. ENGMAN stated that the topic must be on the agenda that was posted prior. C. BELISLE recommended that there was a standing item on the agenda such as item "proposed items for the next meeting" that could be voted on and added to the next subsequent meeting without substantive discussion. H. ENGMAN suggested for efficiency that a committee member send in the suggested topic, and then it is added to the agenda and approved at the meeting by the committee if the agenda topic(s) is (are) felt to be suitable.

L.TUCKER mentioned that they will try this process for next month and adjust if needed.

---

TOPIC:

**8. CLOSING REMARKS/ADJOURNMENT 11:33 AM**

DISCUSSION: L. TUCKER noted that the next full advisory committee date needs to be determined by the committee and the next Abnormal Results Sub Committee meeting is scheduled for October 30, 3015 from 10:00 AM to 1:00 PM.

ACTION: At 11:33 AM Motion by J. WALCZYK seconded by C. BELISLE and voted unanimously to adjourn.

---

LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the October 5, 2015, Pharmacy Advisory Committee Meeting
2. Draft Minutes of the Pharmacy Advisory Committee, June 26, 2015.
3. Advisory Committee Update: Abnormal Results Sub-Committee (power point slides) by Kelly Ann Barnes and William E. Frisch, October 5, 2015.
4. Proposed Policy Standards for Sterile Compounding (power point slides), presented by Rory K. Geyer, October 5, 2015.
5. Email correspondence to the Advisory Committee from the Sub-Committee on Abnormal results, Proposed Policy Standards for Sterile Compounding, October 5, 2015.
6. Recommendation Document. Recommendation 15-01 - Abnormal Results.
7. Recommendation Document: Advisory Committee R 15-03, Emerging Models of Coordinated Pharmacy Services.
8. NABP Model Act 2013. Shared Services.
9. *States, NABP Create Model Regulations Addressing Shared Remote Pharmacy Services Across Jurisdictions*, NABP Newsletter, 2013.
10. *Best of Both Worlds; McKesson Begins Offering Central Fill Benefits to Independent Pharmacies,* Pharmacy Today, October, 2010, 56- 57.
11. *Central Fill Promises to Make Pharmacies More Efficient*, Chain Drug Review, July 19, 2010.
12. Rhode Island Section 22.0, *Central Fill Operations*, p. 62-63.
13. New Hampshire Chapter Ph 1200 *Central Prescription Processing*, Ph 1201.01 – 1203.
14. Pennsylvania § 27.203. *Centralized Prescription Processing.*
15. Oregon Processing Drug Outlets 855-041-3100. *General Requirements, Policies and Procedures, Records, Prescription or Drug Order Processing, Prohibited Practices.*

Respectfully submitted,

Colleen K. Collins, PharmD, RPh
Pharmacy Investigator