COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE PHARMACY ADVISORY COMMITTEE
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts 02114

June 20, 2019 9:00 AM

Advisory Committee Members Present
James Lavery, JD BHPL Director (chair)
Antoinette Lavino, RPh, BCOP (Expert in USP<797>)
Caryn D. Belisle, RPh, MBA (Expert in USP<71>)
John Walczyk, RPh, PharmD (Expert in USP<795>)
Sylvia B. Bartel, RPh (Expert in USP<797>)
Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)
David H. Farb, PhD (Expert in Clinical Pharmacology)
Francis McAteer (Expert in Microbiology)
LCDR John Mistler, PharmD, CPH, USPHS (Expert in cGMP)

Board of Pharmacy Member Present
Timothy D. Fensky, R.Ph, FACA

Advisory Committee Members Not Present
Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)
Judith Barr, MEd, ScD, FASHAP (Expert in Pharmacoeconomics)
Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)

Support Staff
Ed Taglieri, MSM, NHA, RPh PSUD Supervisor – moderated meeting
David Sencabaugh, RPh, Executive Director
Heather Engman, JD, MPH, Pharmacy Board Counsel
Michelle Chan, RPh. Quality Assurance Pharmacist
Nathan Van Allen, RPh. Pharmacy Investigator

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1. **CALL TO ORDER AND ATTENDANCE BY ROLL CALL**
9:05 AM

DISCUSSION: E. TAGLIERI, moderator of the meeting, called the meeting of the Pharmacy Advisory Committee to order. He stated that the meeting is a public meeting and is being recorded; no one in the audience stated they were recording.

NOTE: A quorum was present.

Voted unanimously by roll call for the call to order
J. LAVERY: yes, A. LAVINO: yes, C. BELISLE: yes, S. BARTEL: yes. K. BYERS: yes, F. MCATEER: yes, J. MISTLER: yes.

2. **APPROVAL OF AGENDA**
9:07 AM

DISCUSSION: E. TAGLIERI asked if there were any changes to the agenda.

ACTION: Motion by J. LAVERY, seconded by K. BYERS and voted unanimously by those present to approve the agenda with no changes.

3. **APPROVAL OF MINUTES from 11/29/18 Advisory Committee Meeting**
9:08 AM

DISCUSSION: E. TAGLIERI asked if there were any changes to the minutes and asked for a motion to approve.

ACTION: Motion by C. BELISLE, seconded by K. BYERS and voted unanimously by those present to approve the agenda with no changes.

4. **Policy on Pharmacy Response to Above Action Level Environmental Monitoring Results: Revised reporting and response requirements**
9:10 AM

PRESENTED BY: M. CHAN

DISCUSSION**:**
T. FENSKY asked the advisory committee to review changes on the policy. M. CHAN stated the Board is seeking input regarding this policy in terms of the reporting process for EM findings, the Above Action Level matrix, CFU ranges, what is considered gross contamination, and the immediate recall process. Once 247 CMR 20.00 is promulgated and the policy is approved by the full Board, the policy will replace the existing advisory.

Section I: Required Board Notification

A. LAVINO : Is 1 business day enough?

C. BELISLE: Coming from a large institution, it is easy for us to do so, but what about smaller practices?
T. FENSKY: Since this is 1 business day upon receipt of the microbiology report, and only involves sending an email, it should not be too
difficult.

Section II: Response to Above Action Level Environmental Monitoring Results
S. BARTEL: What if the affected area does not affect compounding (i.e. ante room vs. hood)? The policy should specify.

J. WALCZYK arrived to the meeting
9:16 AM

Section III (a): Proper Remediation - Root Cause Analysis

A. LAVINO: Is there an expectation that a pharmacy find a root cause during RCA? What about cases where there is no exact cause?
E. TAGLIERI: It is just necessary to investigate the root cause.
M. CHAN: A root cause does not specifically have to be identified, but there must be an investigation.

Section III (b): Proper Remediation - Repeat Environmental Monitoring

F.MCATEER: It may be important to include that licensees should consider increasing frequency of testing.
E. TAGLIERI: This can be an example of a remediation plan.
T. FENSKY: We can add that as an example remediation plan in the policy.

D. FARB arrived to the meeting
9:44 AM

Section IV: Requirements for Sterile Compounding During Remediation - Above Action Level Response Matrix

A. LAVINO: I am concerned with the grid and the CFU ranges, as there is no evidence for it.
F.MCATEER: Is the matrix even necessary? By providing a matrix, USP <797> loses its impact. The policy would not give pharmacies
the freedom to interpret their EM results and decide what to do based on that.
A. LAVINO: All these numbers are not really statistically significant. I do not favor the use of making up numbers to decide how to respond to CFU counts.

E. TAGLIERI: The people sitting at the table have in-depth knowledge and know what they are doing. However, we need to provide some
form of guidance for those who don't know about clean room functionality and CFU counts inside and out.
A. LAVINO: But you do not have a scientific basis for providing CFU counts. The only number given in USP <797> is that >15CFU is
when you really have a problem. That is a number that can be used in the policy because it is not made up.
C. BELISLE: How do you correlate something you found on the floor in the ante room with it being in compounded products? I agree with
A. LAVINO and F.MCATEER that USP standards should be used to create guidance.
M. CHAN: We'd like to determine what is considered gross contamination, as well as the actions to take for gross contamination as well as above action levels.
J. MISTLER: We don't want to trigger pharmacies to do less EM.
M. CHAN: I am okay with just going with Above Action Levels per USP, but how should we define what is gross contamination and
how to respond/remediate?
A. LAVINO: USP includes percentages instead of CFU counts.

K. BYERS: We can potentially use percentages as guidance.
C. BELISLE: Would it be helpful if we just walk through an example for ISO 5 on the matrix?
M. CHAN: Walked through example for ISO 5 viable air using the matrix.
A. LAVINO: It is reasonable to use this if it is going off USP, the only issue lies in the CFU count.
C. BELISLE: Having the matrix is helpful because it makes things easier to understand, the USP says in ISO 5 viable air with CFU >2, you should engage a microbiologist, reduce max BUD, etc. This part makes sense, but the range can't be made up. The first CFU count >2 on the matrix is the only one that is correct because it matches up with USP.
E. TAGLIERI Just to summarize, should we use the USP chapter evidence to make the chart?
J. WALCYZ: I think we should be aligning as best as possible with USP.
E. TAGLIERI: Nathan, as an investigator who sees a lot of cases, what do you think?
N. VAN ALLEN: In terms of the matrix and setting limits, I am more in agreement with the committee in that it doesn't
necessarily help. If you can clarify using trending and recommendations, it would better help guide decision making.
S. BARTEL: We want people to incorporate trending to educate and encourage EM often in order to have them identify trends vs.
findings at one point in time.
K. BYERS: A single positive sample doesn't indicate a problem in the product produced, so pharmacists must use some judgement.
E. TAGLIERI: So what I'm hearing is the policy is okay, but the problem is with the matrix in terms of what to do during remediation.
M. CHAN: Everyone needs to respond to each above action level, but we are looking to at least have some recommendations as to what people should do.
A. LAVINO: How do we go about giving guidance about when and when not to recall?
C. BELISLE: My experience is that if you give a BUD that is higher than the USP BUD, you are constantly testing for sterility.
You cannot correlate Above Action Level with a contaminated product that was made within that window. The recall column in the matrix, if we are trying to match up with USP, needs to be removed because nothing can be correlated.

M. CHAN: So if there was a gross contamination, you still wouldn't recall?
A. LAVINO: No because you can't correlate that the product was affected by that gross contamination. This would be determined by
individual practice policies and interpretations.
E. TAGLIERI: The struggle is in determining when we suspend compounding and when we recall. How could we make this less grey?
A. LAVINO: I will read something from USP <1116> to try to clarify.
E. TAGLIERI: Let's all take a break for 10 minutes to think about where we are.

Break

9:57 AM - 10:10 AM

E. TAGLIERI: Upon discussion, we thought about not including the grid as part of the policy. But we want to do

something with the grid in order to make things easier for practice. We can talk about each of the categories and have you all give
guidance towards recommendations for the remediation plan.
A. LAVINO: We need to take out “in accordance with the matrix” from the policy. I agree it could be helpful to use the matrix as a
guidance document and not a policy.
E. TAGLIERI Now we can go through each category on the matrix. [ISO 5]
M. CHAN: After discussing with T. FENSKY, we decided we should either go with BUD 12hrs/24hrs or 1dy/4dys, since remembering several sets of numbers could be confusing.

J. WALCYZ I agree. I would go with 1dy/4dys because pharmacies need time to get the medication to the patient.

S. BARTEL: I agree.

T. FENSKSY: 1dy/4dys is probably more reasonable.

E. TAGLIERI: So we can change the recommendation to 1dy/4dys for air and surface, and for highly pathogenic, compounding should stop completely?

M. CHAN: When will we suspend compounding for ISO 5?

A. LAVINO: For highly pathogenic.

M. CHAN: So we will only suspend compounding for any highly pathogenic organisms in ISO 5?

K. BYERS: Yes, the pharmacist should remediate immediately and suspend compounding.

C. BELISLE: Only that part of the pharmacy affected should be suspended.

E. TAGLIERI: The disadvantage of having a 1 room operation is that they would have to find out how to deal with this type of issue and have a continuity of care plan (i.e. transfer).

D. SENCABAUGH: We wouldn’t want having only 1 room to be an excuse to continue compounding in these situations.

M. CHAN: Would there be no batching and freezing?

J. WALCYZ: I’m not sure if this is necessary to include because there is already a reduced BUD.

E. TAGLIERI: If we are deferring to the 1dy/4dys BUD, it is not necessary because batching and freezing is allowed within the
parameters of 1dy/4dys.

E. TAGLIERI: Engaging a microbiologist is a given. What about recalling CSPs?

A. LAVINO: I think this should be removed altogether.

D. SENCABAUGH: We can change this to recommending pharmacies consider a recall and asking them to submit why or why they did not recall the products. The decision would lie with the registrant.

A. LAVINO: I think that is fine to say.

E. TAGLIERI: So we could change the column to “consider recall.”

J. WALCYZ: Or we could just remove it altogether and add that in the advisory

E. TAGLIERI: I would be concerned that the licensee would just go through the guidance matrix and rely on that instead on referring to the whole policy.

A. LAVINO: This can be added to the bottom of the matrix.

D. SENCABAUGH: We can also suggest conducting adverse event surveillance so it becomes a recommendation. We want registrants to consider doing something. The guidance should help registrants go through the process.

M. CHAN: We can remove the last 3 columns and add them to the policy as "additional items to consider" in the form of a
checklist to make it easier for registrants to use.
E. TAGLIERI: Let's move onto ISO 7.

M. CHAN: Should we keep the 1dy/4dys? - several members agree-

E. TAGLIERI: To confirm, ISO 7 is the only place 1dy/4dys would happen is with highly pathogenic organisms and there is

no specific guidance to air and surface growth?

K. BYERS: A single positive environmental sample in the air and surface should not indicate a 1dy/4dys BUD, but should

definitely be remediated. The decision should be deferred to the pharmacists to decide if they want to do a 1dy/4dys BUD.

E. TAGLIERI: Ok, so the only place to draw the line to 1dy/4dys is with highly pathogenic organisms. Should compounding be

suspended in any of these cases?

A. LAVINO: There would be no suspending in ISO 7. If pharmacies keep testing and still have problems, then that's a problem.

E. TAGLIERI: A microbiologist would definitely be engaged. What about batching and freezing?

A. LAVINO: Pharmacies should be able to batch outside of highly pathogenic organisms.

C. BELISLE: This would not be much of a concern in air and surface.

E. TAGLIERI: Moving on to ISO 8. I assume it would be quite similar to ISO 7.

C. BELISLE: Nothing would be done other than remediating,

A. LAVINO: We would remediate even with highly pathogenic organisms

E. TAGLIERI: If no one has any other things to discuss, let's vote on the edits and recommendations to send to the Board for
consideration.

ACTION: Motioned by A. LAVINO, seconded by C. BELISLE and voted unanimously by those present to approve the edits and recommendations noted for the "Policy on Pharmacy Response to Above Action Level Environmental Monitoring Results" to be sent to the Board for consideration.

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5. **Telepharmacy additions to Policy 2019-01 Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing**

10:43 AM

PRESENTED BY: M. CHAN

DISCUSSION**:**

M. CHAN: Began by going through the policy line by line and no questions or comments were discussed in the definition section.

E. TAGLIERI: Gave examples of what the policy is meant to accomplish (i.e. sterile compounding pharmacy with camera looking at technician performing functions and a pharmacist verifying technique or in a retail setting with pharmacist verification on site but not in the same space as filling)

J. WALCYZ: Discusses potential issues with language and seeks clarification on what defines "on-site"

D. SENCABAUGH: Ensures advisory members that each clean room has a separate permit so pharmacists can only perform verification checks on site for that particular permit
J. WALCYZ: Asks if pharmacists still have to comply with ratios and D. SENCABAUGH confirms that ratio requirements would have to be followed.
MEMBERS: Discuss defining and spelling out the language for geographical space to limit confusion
J. LAVERY: Questions what the "industry standards" are in terms of cameras and monitoring
M. CHAN: Refers to the NABP model act in order to define the standards
E. TAGLIERI: States that Massachusetts does not have a need for a pharmacy without a pharmacist, however if someone reaches out to the board they may be considered through a potential pilot program and regulations and policies can be discussed after the project
J. MISTLER: Notes considerations of the camera, view, failure, durability and if there is an obstruction to the view
D. SENCABAUGH: Suggests adding "board approved standards" in addition to industry standards and members agree
E. TAGLIERI: Notes the purpose of having telepharmacy done by a Massachusetts licensed facility/pharmacy is to ensure accountability if an error occurs
J. WALCYZ Makes final comment that he does not want this policy to create "vending machine" pharmacies

ACTION: Motioned by C. BELISLE, seconded by J. LAVERY and voted unanimously by all those present to approve input from today's meeting of the Pharmacy Advisory Committee on Telepharmacy additions to Policy 2019-01 Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing to be sent to the board for consideration

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6. **Update on Advisory: Use of Technology to Check Inventory Management Activities Performed by Certified Pharmacy Technician**

11:10 AM

Presented by: C. BELISLE

DISCUSSION**:**

C. BELISLE conducted a pilot using automatic dispensing using technology and technicians to limit errors. The pilot excluded federally controlled substances, gabapentin and products that were compounded in the clean room. The project also excluded medication in the operating room and ambulatory care setting. It evaluated inpatient settings and looked at a variety of settings, people and times of day in the hospital. The project utilized barcodes to track medications being stored in medicine cabinets all the way to the point of administration to patients. The project eliminated the check of the pharmacist by using barcodes and found approximately a 1.8% margin of error. C. BELISLE concluded that the pilot was very successful and encourages other institutions to utilize this practice if they can implement it appropriately. The pilot lead to this Board approved advisory. She thanked the Board for their support.

So Noted

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7. **Discuss Date for fall meeting as well as topics** **11:17 AM**

DISCUSSION**:**

Discussed potential dates for the fall meeting and members agreed that E.TAGLERI sending an email was the most convenient. E. TAGLERI also noted that members can email him potential topics for discussion in order to be placed on the agenda for the next meeting. The next meeting will most likely be held in October or November 2019.

So Noted

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8. **Closing remarks Adjournment of Meeting:** **11:21 AM**

ACTION: Motioned by J. WALCYZ, seconded by C. BELISLE and voted unanimously by those present to adjourn the Pharmacy Advisory Committee.