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

**Pharmacy Advisory Committee**
**Meeting held via remote WebEx.**
**Boston, Massachusetts, 02114**
**May 4, 2021**

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**Advisory Committee Members Present**
Antoinette Lavino, RPh, BCOP (Expert in USP<797>)
Sami Ahmed, PharmD, RPh, BCPS, BCSCP (Expert in USP<71>)
John Walczyk, RPh, PharmD (Expert in USP<795>)
Francis McAteer (Expert in Microbiology)
Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)
Judith Barr, MEd, ScD, FASHAP (Expert in Pharmacoeconomics)
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)
Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)
LCDR John Mistler, PharmD, CPH, USPHS (Expert in cGMP)
Patrick Gannon, RPh, MSM, FABC (additional expert member)

**Board of Pharmacy Member Present**
Timothy Fensky, RPh, Board of Pharmacy Member

**Advisory Committee Members Not Present**
James Lavery, JD BHPL Director (chair)

**Board Staff Present**
David Sencabaugh, RPh, Executive Director
Heather Engman, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Joanne Trifone, RPh, Director of Investigator
Nathan Van Allen, PharmD, RPh Pharmacy Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor

**TOPIC I**. Attendance by roll call: **Time: 9:08 AM**

Call to Order, by: Ed Taglieri and announces meeting is being recorded.

Roll call attendance: A. Lavino; S. Ahmed; J. Walczyk; M. Gonyeau; J. Barr; S. Bartel; K. Byers; K. Thomasset; J. Mistler; P. Gannon

Not Present: James Lavery

Join meeting once started: D. Farb; F. McAteer.

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**TOPIC II**. **Approval of Agenda** **TIME: 9:10 AM**
**Agenda: 5/4/21**
**Changes: None**

Motion by M. Gonyeau, seconded by P. Gannon and voted unanimously by those present to approve the agenda no noted changes by roll call vote.

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**Topic III** **Approval of Board Minutes**
**1. Minutes** **Time: 9:11 AM**
**Draft 11/10/20**

**Changes: None**

Motion by K. Thomasset, seconded by A. Lavino and voted unanimously by those present to approve the 11/10/20 minutes no noted changes by roll call vote.

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**TOPIC IV** **Introduction of Committee Newly appointed and re-appointed** **Time: 9:14 AM**

**E. Taglieri:** Caryn Belisle appointed to Board of Registration Pharmacy - Hospital Seat
Sami Ahmed – USP 71 Expert Seat
Patrick Gannon – Expert Additional Witness.
Committee members terms expired; all re-appointed new 3-year terms.
Introduced all members and their respective seats.
No term limit for PAC members

**D. Sencabaugh:** Presented certificate to Patrick Gannon.

**V: Review status of Regulations:** **Time: 9:20 AM**
**Recused:**
**Presented: Michelle Chan**
**Discussion:**

**M. Chan:**
- Sections 6, 9, 10, 15, 20
- Waiting for fees to go into effect in relation to new license types
- Sections 5, 12 – will be rescinded when gets promulgated as no longer relevant
- Section 2 and 13 are both revised and will undergo comment period.
- Section 13 was revised to be standalone document including USP <825>
- Section 2 and 13 will not go forward until Section 17 and 18 are completed.
- Section 22 monetary penalties and fining.
- Section 19 withdrawn. Incorporated in Section 17 and 18
- Section 17 sterile has gone for one comment, revisions made in response to new 797 and comments
- Section 18 public comment. Changes based on USP 800. Administrative review and second public comment.
- Section 3, 4, 8 being combined to one document

**M. Chan: Asked for questions; none asked.**

**T. Fensky:** Introduced each topic for discussion.
First: Pharmacy point of care testing and Scope of Practice
Second: Smoke Visualization studies for USP <797> cleanrooms

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**VI: Discussion Pharmacy Point of Care Testing and Scope of Practice** **Time: 9:29 AM**
**Presented: Bill and Michelle**
**Discussion:**

**W. Frisch:**
- Presented background to reasons for pharmacist point of care testing.
- Presented spreadsheet developed by pharmacy student describing types of tests being conducted by pharmacists in other states.
- Initial discussion to only include CLIA waved tests.

**Ed. Taglieri:**
- David Farb Joined 925
- D. Sencabaugh rejoined on phone.

**P. Gannon:**
- States he is in favor of expansion of scope.
- Asks if NABP has published standards.

**W. Frisch**
- Noted that NABP model act did not appear to have standards.

**P. Gannon:**
- Need to ensure that recommendations are aligned appropriately across all areas of practice.

**K. Thomasset:**
- State he is in full agreement with P. Gannon statements.
- Asks if pharmacies in community and health systems have bandwidth to provide services?

**P. Gannon:**
- Concern with duplication of services with providers.
- Concerned with ensuring information gets conveyed to provider effectively.
- Technology will be important.
- Concern with crossing lines between MD and RPh services.

**S. Bartel:**
- Agree with conducting PCOT and alignment.
- Looks to be a broad range across each state.
- Question – under health promotion screening, who generates order for lab test?

**W. Frisch:** - There are some organizations that have medical director for organization that can order.
**S. Bartel:** - Pharmacist, if involved, would need to be able to determine what test to be conducted. Info should be available for them.
**W. Frisch:** - Noted some example tests as cholesterol, fecal, hemoglobin, pregnancy, limited list.
**S. Bartel:** - Need to ensure there is an algorithm to ensure test results get evaluated and acted upon. Resident access is important.
**M. Chan:** - Restricted to statute. MGL is RPh can only order tests based on drug therapy. Statutory change required.
**J. Barr:** - Described past experience with total testing process. CLIA 76 was based on this.
**M. Gonyeau:** - Noted that critical piece of process is getting the results of testing to the provider for follow up.
**J. Barr:** - POCT standards are available.
**Walczyk:** - Agrees expansion is needed in POCT.
- Most important to get POCT up and running with broad open policy.
**P. Gannon:** - Should we only focus on drug therapy-based testing while we simultaneously work on expanding. statute?
**M. Gonyeau:** - Agree that statutory changes are needed as limitations exist as written.
**S.Bartel:** - Limited to CLIA waived tests only?
**W. Frisch:** - POCT is limited to easy to perform with low chance of inaccurate results.
**J. Barr:** - Need to look at total testing process. Differences between ordering, interpreting, performing tests.
- Complexity of testing methodology may determine types of tests to be conducted.
**W.Frisch:** - Currently reviewing other states allowances.
**P. Gannon:** - Discussed ease of conducting HbA1c at pharmacy when picking up diabetes meds. Pharmacy would need to be credentialed with payers to be paid for claim. May be one test to start and focus on.
**A.Lavino:** - Questioned HbA1c as a CLIA waived test? Will this prevent adding to list?
**J.Barr:** - May be because POCT is too new for A1c.
**D.Farb:** - Should addictive substances be included in POCT? May benefit everyone?
**P.Gannon:** - Not sure of how long for a result to be reported.
**D.Farb:** - Convenience may be important to this population.
**M.Chan:** - Should drawing blood be included in this discussion?
**D.Farb:** - State advancements have been made with technology and could be acquired.
- Public health benefits may be achieved.
- Pharmacies may be best equipped to initiate this type of testing.
**J. Walcyzk:** - Great idea. Should be pushing to be able to write for that test. Should come back to expansion of testing.
**S.Bartel:** - Important still to be able to answer how the info gets acted upon. So info does not get missed.
**W.Frisch:** - Discussed community pharmacy POCT article.
**J.Barr:** - Should there be a subcommittee?
**E.Taglieri:** - That would be requested by BORP.
**W.Frisch:** - May be a good step.
**S.Bartel:** - Agrees a deeper dive would be important.
**W.Frisch:** - May be worth NABP to look at?
**M.Gonyeau:** - I agree. If we can move short term items forward while working on changing the long term statutory changes.
**E.Taglieri:** - Break for 5 mins at 10:10am. Resume 10:15.

**VII: Discussion Board Advisory on Smoke Visualization Studies n ISO-Classified Spaces Time: 10:17 AM**
**Presented: Ed Taglieri**
**Discussion:**

**W.Frisch:** **- Goal is to develop guidance document to help improve compounding process and environment.**
**- Rough draft to be reviewed.**
**M.Chan:** - Reviewed each section.
- Purpose is where majority of input is requested.
- Should additional items be included?
**F.McAteer:** - Well written
- One item to add is to inform staff that smoke studies can be used in CAPA situations
- Trace potential contamination issues.
**W.Frisch:** - Stated that visualization in ISO 7 area is also important and wanted included. Documents have high focus on ISO 5.
- Noted that FDA focuses on these items as well.
**J.Mistler:** - Agrees that they should be used in CAPA situations and investigational purposes as well.
**K.Byers:** - Questions value of routinely conducting smoke studies in every piece of equipment once properly installed and integrated.
**J. Walcyzk:** - Agrees
**K.Thommaset:** - Do we want to add prescriptive information regarding smoke volume?
**W.Frisch:** - Unsure is expansion of information is required in this document?
**J.Mistler:** - Agrees that adequate amount of air is important.
**A.Lavino:** - Unsure that high level of detail is needed.
**W.Frisch:** - Less focus on how to conduct versus why they are done and value.
**A.Lavino:** - Believes licensee will have trouble determining and may not be helpful.
- Does believe that smoke studies are important and knowledge.
**P.Gannon:** - Are certifiers credentialed? Oversight?
**W.Frisch:** - Unsure if all certifiers are CETA certified?
**P.Gannon:** - May be a start in narrowing the scope and focus of guidance document?
- Is there any language for smoke studies from USP?
**W.Frisch:** - Yes. Incorporated as much as possible.
**P.Gannon:** - Too many details may have negative effect.
**F.McAteer:** - Qualitative test. Pass/Fail. No quantification.
**M.Chan:** - What types of items are being looked for?
**F.McAteer:** - Want to see unidirectional flow. Is different for each type of PEC and SEC.
**W.Frisch:** - May be important training tool.
**M.Chan:** - Additional
**J.Walcyzk:** - May not all be CETA certified?
**F.McAteer:** - May go hand in hand with NSF certification.
**K.Byers:** - All may not have NSF certification.
**J.Mistler:** - Described reasons for failures. May be worth expansion.
**M.Chan:** - Described frequencies
**J.Mistler:** - Significant maintenance? Block airflow? Perform another study.
**K.Byers:** - Dynamic testing of each PEC will cause operational issues in pharmacy.
**A.Lavino:** - I think that is currently what is done?
**S.Bartel:** - Agree.
**K.Byers:** - Described that simulation may not always be done in every PEC. Available staff may be challenged.
**A.Lavino:** - How are we describing significant maintenance?
**J.Mistler:** - Described situations for significant maintenance.
**K.Thomasset:** - Is this too much detail?

**A.Lavino:** - Agree. Details will leave registrant to question what significant maintenance is.
**J.Mistler:** - Agree. Not the intent. Should be left up to the RPh to make final decision. Justification necessary.
**W.Frisch:** - Will take comments under advisement.
**P.Gannon:** - Catch all statement at end to contact BORP for guidance?
**A.Lavino:** - Is that where the BORP want to be?
**W.Frisch:** - We have provided help to licensees in past.
**A.Lavino:** - Believes this level of detail will result in problems. Need to be informative but not overreaching.
**J.Mistler:** - Agree. Provided examples.
**K.Byers:** - Noted there is other information to determine proper functioning of cleanroom.
**E.Taglieri:** - Noted time of meeting.
**M.Chan:** - Described procedure and video recordings.
**W.Frisch:** - Info is straight from USP document and CETA.
**J.Mistler:** - May want to include protocol to give RPh tools for adequate completion.
**F.McAteer:** - Agree. May want to define dynamic conditions?
**J.Walcyzk:** - Clarify that it would be either RPh or PT, not both?
**F.McAteer:** - Smoke studies carry their own risks.
**J.Mistler:** - Agree.
**J.Walcyzk:** - Just PEC, not SEC for total cleaning?
**F.McAteer:** - Yes. Depending on extent of exposure to smoke contaminants.

**E.Taglieri:** - Time check. 7 Mins until 11am.

**M.Chan:** - Comments?
- Any additional items?
**J.Walcyzk:** - Does FDA have training documents?
**J.Mistler:** - Not specifically but focused on Aseptic Guide.
**F.McAteer:** - May want to add aseptic technique information?
**J.Mistler:** - Agree.
**W.Frisch:** - Believe there is a good number of considerations generated from meeting.
**A.Lavino:** - Considerations will be beneficial.
**W.Frisch:** - Documentation section reviewed.
**A.Lavino:** - Is narrated video satisfactory?
**W.Frisch:** - Yes. Written description can support the video procedures.
**J.Walcyzk:** - Should narration be mandated?

**Ed Taglieri:** - Time check.

**W.Frisch:** - Will take comments and include where necessary.

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**V: Closing:** **Time: 11:02 AM**

**Comments:** - PAC meets twice yearly. Next meeting will be scheduled.
- Unsure of in person or virtual meeting

**Adjournment:**

ACTION: Motion by P. Gannon seconded by K. Byers, and voted unanimously by those present, to adjourn from meeting by roll call vote.