COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

Pharmacy Advisory Committee
Meeting held via remote WebEx
Boston, Massachusetts, 02114
June 24, 2020

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>)
Francis McAteer (Expert in Microbiology)
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)

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

Advisory Committee Members Not Present
Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)
LCDR John Mistler, PharmD, CPH, USPHS (Expert in cGMP)
Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)

Board Staff Present
David Sencabaugh, RPh, Executive Director
Monica Botto, Assistant 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
Sam Penta, RPh Senior Investigator
Nathan Van Allen, PharmD, RPh Pharmacy Investigator
Leo McKenna, PharmD, RPh Pharmacy Investigator
Michael Brosnan, PharmD, RPh Pharmacy Investigator
Paul Seed, RPh, Pharmacy Investigator
John Murray, RPh Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor

TOPIC I. Attendance by roll call: **Time: 9:09 AM**

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

Roll Call attendance: James Lavery; Antoinette Lavino; Caryn D. Belisle; John Walczyk; Francis McAteer; Judith Barr; Sylvia B. Bartel; David H. Farb; Karen Byers

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TOPIC II. **Approval of Agenda** **Time: 9:11 AM**
Agenda: 6/24/20
Changes: none

Action:
Motion by A. Lavino, seconded by J. Lavery and voted unanimously by those present to approve the agenda no noted changes by roll call vote.

Topic III **Approval of Board Minutes**
1. Minutes **Time: 9:12 AM**
Draft 10/30/19

Changes: none

Action:
Motion by C. Belisle, seconded J. Lavery, and voted unanimously to approve the minutes of the 10/30/19 with no noted changes.

TOPIC IV **Discuss: Draft "Advisory on the Pharmacist's Scope of Practice** **Time: 9:14 AM**

E. TAGLIERI: Initiated discussion of "Advisory on the Pharmacist's Scope of Practice at 9:13am. Requested T. FENSKY to discuss Board request formally with Pharmacy Advisory Committee.

T. FENSKY: June 12th board meeting resulted in vote to bring "Advisory on the Pharmacist's Scope of Practice" to Pharmacy Advisory Committee to request input. Briefly discussed how different states are handling expansion. Requested B. FRISCH to present further information.

E. TAGLIERI: Notes that input will be brought back to Board for review.

B. FRISCH: Presented background to development of draft advisory which was partially a result of public comment for 247 CMR 9. He noted that comments were received related to individual practice, such as Pharmacist's working in home care settings such as repackaging patient medications into daily planners. Recommendation was to develop guidance document to capture Pharmacist's current role and scope of practice. He is requesting additional information be included into advisory and noted that Board action is required to expand the scope.

M.CHAN: Initiated review of draft "Advisory on the Scope of Pharmacist's Scope of Practice" document. She noted that each section would be read to group and opportunity for comments will be available to members.

B. FRISCH: Clarified that the Advisory would also include Pharmacy Technician's scope of practice. Title to be changed.

M.CHAN: Reviewed Section I. Requested comments.

M.CHAN: Reviewed CDTM section. Requested comments.

M.CHAN: Reviewed Independent practice section. Requested Comments.

B. FRISCH: Noted that this is the section that drove the guidance advisory document from public comment. Notes there are some Pharmacists who freelance in community. Looking to include their activities and provide guidance.

E. TAGLIERI: Sees this type of practice being utilized in Long Term Care arena with contractual care of individuals in assisted living facilities.

M.CHAN: Notes that the Independently Practicing Pharmacist cannot be within a CDTM agreement by statute

M.CHAN: Reviewed "***" section: Notes that this came from remote pharmacists in other states. New regulations require MA licensed pharmacy or pharmacist.

D.FARB: Interested of wording of "should" versus "must" in independent practice.

M.CHAN: Notes this is an advisory and not mandated. Requested comments.

M.CHAN: Reviewed Testing section.

J. WALCYZK: Asks if testing is statute or could it be changed.

M.CHAN: Notes it is in the CDTM statute that Pharmacist cannot interpret test results.

B. FRISCH: Notes expansion of scope of practice brought on by COVID-19 and only item voted on at this time. Guidance would be forthcoming.

J. WALCYZK: Is this something that can be changed

M.CHAN: Notes it is statute and must be change in the legislature.

H. ENGMAN: Notes that purpose of discussion is to talk through questions and discuss statutory change requirement.

J. WALCYZK: Requests that interpretation of test result is within scope.

B. FRISCH: Notes that CDTM pharmacist cannot interpret results. Simple "yes" "no" is within scope.

H. ENGMAN: Notes that CDTM statute may not apply to COVID-19 testing.

J. WALCYZK: Requests to change guidance to not call out COVID-19 specific testing.

C.BELISLE: Agrees with J. WALCYZK regarding specification of COVID-19 testing versus advisory noting expansion of testing.

E. TAGLIERI: Notes he will make notes and bring back to BOP.

J. BARR: Is purpose of testing for specific for COVID-19 or general scope. Thinks more detail and separate statement works better for health promotion screening.

D. FARB: Does interpretation cause delay in treatment based on results? Due to reliability and time delay in reading such as true positive or true negative. Is there a level of complexity involved with interpretation?

M. CHAN: Interpretation brought new level of responsibility and Board of Pharmacy not ready to advance.

S. BARTEL: Definition of interpretation is different due to various type of test and the actual result. Example provided: symptomatic but not positive, positive but not symptomatic.

B. FRISCH: Notes that there are questions related to sensitivity and type of testing. Wants to align advisory with HHS statements and approach. To advance this current issue but additionally future processing.

S. BARTEL: Notes that this is currently conducted in hospitals but possibly should not be blanketed to all tests.

K. BYERS: Notes this happen in diabetes care in community health centers with dose adjustments.

S. BARTEL: Certain tests are appropriate but not all.

E. TAGLIERI: Asks if a definition of "interpret" would help.: Notes it may be appropriate in CDTM specific role.

M.CHAN: Statute says they can evaluate test based on medication therapy?

E. TAGLIERI: Thinks it may work to provide a parameter

S. BARTEL: Based around medication management: Thinks COVID 19 is fine but may not be appropriate with all other testing results.

J. BARR: Thinks that COVID-19 testing should be separated from alternative testing as they really don't go hand in hand. Separate paragraph will help delineate difference.

E. TAGLIERI: Provided summary: Consider defining interpret, if around medication management, it would be ok, if outside of Medication Management, expanding and specify the difference between.

J. WALCYZK: As pharmacy expands and roles expand, specific tests are not available or accessible. Since testing is not available to pharmacists, tests can't be ordered. This testing role should be expanded to help patients with. Be separate from COVID. Thinks it is worth the ask to expand role of Pharmacist and provider status. Make sure that the Board can easily make changes to policy/advisory if future situations arise.

B. FRISCH: Notes good points and explains during process received inquiries from stakeholder regarding other tests. COVID-19 is main priority that needed to be dealt with now. Then they can expand and review individual tests in future.

D. FARB: Concerned with interpretation piece as there is so much change and confusion in information on daily basis that having another individual review other than physician may cause more wrong information being provided.

C. BELISLE: ID specialists in BWH highly depend on pharmacists and under-utilized tool in practice setting to help support lab results and interpreting and provided accurate and updated information to patient. Should be a trained pharmacist to review and provide accurate and timely information.

D. FARB: Questions difference between big institutions versus community hospitals and they may not be getting the same type of care and scope of interpreting with lack of resources at these institutions. Would not feel comfortable without specialists and resources available.

E. TAGLIERI: Input provided and initial thought process on CDTM structure and if RPh is going to engage in testing interpretation and training should be able to be provided. Notes Pharmacists should only engage in activities that they feel comfortable with.

S. BARTEL: Agrees that training should be measurable. Should be stated.

M. CHAN: Reviewed Telepharmacy section: Requested comments.

E. TAGLIERI/B. FRISCH/M. CHAN: Note that this section has been dissected numerous times and evolving.

M. CHAN: Reviewed Medication Management section: Requested comments.

J. BARR: Questions passive nature of statement, isn't it within the current CDTM guidelines to adjust as needed. Believes statement should be explicit.

M. CHAN: Notes that the advisory is more for the general pharmacist versus the CDTM guidelines that are more specific and explicit. Requests comments

J. BARR: Notes that this section may not apply to all if more clarity is provided in section 1. Requests explicit definition.

J. WALCYZK: Wonder why this needs to be explained as CDTM agreement explains the requirements.

B. FRISCH/M. CHAN: Notes that more detail can be provided and explained in CDTM.

T. FENSKY: Notes that these activities are being done right now and is current practice such as Med sync.

J. WALCYZK: Agrees.

J. BARR: Believes since it is current scope than it should be explicitly explained.

M.CHAN: Reviewed Compliance packaging. Requested comments.

B. FRISCH: Explains in more detail that daily dose planners it is not redispensing or repackaging. This is one of the main drivers of this section.

J. WALCYZK: Wonders why this is happening without being associated with pharmacy?

M. CHAN: Notes this is a business model for a specific Pharmacist who made inquiry.

T. FENSKY: Notes it is like a Consultant Pharmacist role.

B. FRISCH: Notes that the section may need to be expanded further.

C. BELISLE: Initiated thoughts around pharmacist not working for the dispensing pharmacy versus another section of the pharmacy. Provided example of inpatient pharmacist versus ambulatory care pharmacy.

J. WALCYZK: Asks question? When LTC pharmacy fills in blister packaging which is subsequently changed by next Pharmacist, do different standards apply, is there now a difference in regulations with this role?

M. CHAN: Notes that the standards would be the same.

E. TAGLIERI: Framing statements: if a pharmacy has already blister or multi dose packaged, can a pharmacist than reorganize the meds into a separate planner? Does this need to be defined.

T. FENSKY: Notes that Pharmacist would be safer while repackaging than family member or nurse, etc.:

B. FRISCH: Notes all prevailing standards need to be applied and followed.

J. BARR: Suggests checking with consultant pharmacist associates for role in American society of consultant pharmacist and include standards for their operation.

M. CHAN: Reviewed Immunizations and Injections section VI. Requests comments

C. BELISLE: Agrees with statements

J. WALCYZK: Likes the writing, believes Pharmacists should be able to conduct other testing and administering medications such as pre-term labor, and emergent issues? Notes there is a difference between refills versus new orders. Statutory change?

E. TAGLIERI/M. CHAN/B. FRISCH: Note it is a statutory change.

M. CHAN: Reviewed Veterinary Medicine section: Requested comments. Notes that they have reached out to veterinary specific pharmacists

M. CHAN: Reviewed Technician Scope of Practice section. Requested comments.

B. FRISCH: Notes that there is a review of certain medication to be administered by Technicians such as immunizations.

A. LAVINO: Questions clarity of technician section. Is it meant to be comprehensive?

M. CHAN: Notes they are not common practice and wanted to call them out.

T. FENSKY: Notes this is happening in other states and wants discussion to provide guidance

B. FRISCH: Notes language comes from section 8 of regulation. Waiver and pilot program.

C.BELISLE: Notes pilot project policy is already available.

T. FENSKY: Explains confusion with Tech Check Tech, Technician Check Technician and Technology Check Technician?

E. TAGLIERI: Reminder that individuals must request pilot program and waiver request.

J. WALCYZK: Opposes technician final check. Is there an actual technician scope of practice that could be included?

B. FRISCH/M. CHAN: Will add link to scope of practice for technician.

Break: 10:10 AM to 10:15 AM

TOPIC V Review: Advisory on Sterile Compounding Pharmacy Response to HVAC Excursions Time: 10:15 AM

PRESENTED BY: M. CHAN

DISCUSSION**:** M. Chan presents the next document for review and states that with your great assistance and input from the October 30th meeting, we were able to develop this new advisory that that recommends response and remediation steps in the event of an excursion in temperature, humidity or differential pressure resulting from HVAC system malfunction or interruption in HVAC system operations. Your feedback centered around creating general guidance for facilities to prepare for and respond to excursions based on facility specific excursion limits. The final version of this document includes general recommendations and a general response plan for all excursions, as well as compounding during remediation. The Board approved this final version of the advisory on March 5th, 2020.
M. CHAN: asks if anyone have any comments about this?
C. Belisle: stated that she thinks it came out great, and that she likes how it reads. She thinks it's comprehensive and, hopefully folks will find this helpful if they have and when they have excursions.
E.TAGLIERI, M.CHAN, and W. FRISCH thanked C. Belisle

From closing comments section (continuation of discussion on Response to HVAC excursions): 10:21 AM

A. LAVINO: wanted to go back to the response HVAC excursions. She states that in section 3, its asterisked that in response to temperature and humidity excursions that last longer than 60 minutes, it is recommended that sterile compounding be suspended until remediated and asks Did everyone see that?
A. LAVINO: notes that in the asterisked section that if temp excursions greater than 25 degrees or relative humidity excursions greater than 65% that last longer than 60 minutes, it is recommended that sterile compounding be suspended.
M. CHAN: agrees.
A. LAVINO: comments that she doesn't recall that being discussed previously.
A. LAVINO: notes that she knows that very often especially in hospital environments, humidity greater than 65% can last longer than that depending on the day.
W. FRISCH: responds that he doesn't think this came up, and that this is something that was added in after the fact.
W. Frisch: continues and states that we really didn't want to get into defining what a prolonged excursion was and this is just a recommendation for temperature or humidity excursions longer than 60 minutes, that it may be an indication that something has gone awry with the HVAC system.
A. LAVINO: questions when we've asked organizations to develop their own determination of what the excursion issues are, wouldn't it still apply that way?
W. FRISCH: answers that this is just a guidance document, so if the facility wanted to have a different protocol, that's up to them. But we just wanted to put something in there for people to think about if its longer than an hour, then they may have a problem.
A. LAVINO: comments I don't recall us having that kind of conversation and that with some HVAC system designs the humidity will be above 65 percent for longer than an hour on hot, humid days and we have policy in place for that.
A. LAVINO: provides an example; you triple clean or something like that but not to suspend compounding. That recommendation seemed to be significant.
W. FRISCH: responds with we were having a lot of back and forth, I think there was some discussion at the prior advisory committee about the word prolonged excursions. He goes on to say it's hard to define. Is that an hour? Is that 2 hours? Is that 4 hours? Is that a day? I think we just want to put some type of a recommendation in there.
W. Frisch: continues with we can take another look at that, but you are not going to find anything out there in the literature about what that is.
A. LAVINO: agrees and states that she thinks maybe some commentary should be added about investigating as to why an HVAC system can't support keeping the temp and humidity in range and then looking at other mitigation strategies whether it be cleaning or even testing if temp and humidity are out of range for over an hour.
A. LAVINO: continues that there's a lot of HVAC systems where there's nothing wrong with them, but they just can't support it. But she doesn't think it's possible for people to suspend compounding and is not sure if it's necessary either. Maybe they don't have dehumidification built in and they need to add that, or they would do a CAPA that addresses the fact they know that they have to add that type of equipment.
W. FRISCH: responds that he thinks that if the temperature is 78 or 80 degrees for half an hour there is probably a problem, but adds that they will take a look at that again and try to make some improvements to that for future revision.
J. WALCZYK: comments that he would agree with that too. He didn't know things got added in or changed and he didn't see that either.
J. WALCZYK: adds that Even cleaning can set you off on your humidity. He notes that is not usually an hour on something like that but if you have contact time with cleaners and you are doing a deep clean your humidity can be out just from the cleaners themselves.
W. FRISCH: acknowledges that statement.
J. WALCZYK: notes that they shouldn't put a timeframe in because even with the guidance document, that time frame can be interpreted by inspectors and if you're continuously recording you can show that.
J. WALCZYK: continues every day we do our cleaning, every week we do our intensive clean, and there are different cleaning strategies so you're always going to have those excursions, so he'd be very cautious of having a time frame in there specifically for that and he thinks that's why it isn't easy to find a time frame in other regs.
J. WALCZYK suggests maybe we should put something in that if it goes over an hour the situation needs to be assessed.

E. TAGLIERI: expresses that that's all good input for when we update.
W. FRISCH: adds that we do take all the expert input and we try to synthesize what we heard at the advisory committee meetings. But from time to time, we do have to put in certain guardrails and certain other things that may have not been discussed at the advisory committee. Sometimes the documents come out with things are added after the advisory committee meeting and we have to take all the expert input and shape a document the best we can.
E. TAGLIERI: explains that we send your input back to the board, and then the board can deliberate it and change it to what they are comfortable with, so that's sometimes how something you may have discussed changes when it comes out.
W. FRISCH: expresses his appreciation.

TOPIC VI Advisory on Implementation of USP <800> in Community Pharmacy Time: 10:17 AM

PRESENTED BY: M. CHAN

DISCUSSION**:** M. CHAN presents the final document for review today which is the advisory on Implementation of USP 800 in community pharmacies. As we discussed at our last meeting, the need was identified to provide practical guidance for retail pharmacies in order to comply with the requirements of USP 800. Though the document is not meant to be all inclusive, it states the need for a documented formal hazardous drug program to include such topics as identifying hazardous drugs, assessing risk, determining PPE usage and the development of policies and procedures. Going forward this will help pharmacy inspectors guide community pharmacies towards a path to compliance. The final version of this advisory was approved by the Board on December 5th, 2019
M. Chan asks if anyone has any comments on this?
W. FRISCH states that he wants to thank the advisory committee again, for both of these documents , but especially the HVAC excursion document. We really took a lot of valuable expert input, and it really helped to shape that document in terms the facility setting their facility specific parameters

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VII: Closing Comments and Adjournment of Meeting Time: 10:19 AM

Comments: Ed thanked everyone for their patience with the Web X meeting and appreciate everything that has been done in the last three months and on the front lines how everyone has responded. We are required to have advisory meetings twice a year. The next meeting will be in the Fall and would anticipate the meeting would be a Web X meeting at lease to the end of the year and then be evaluated at that time. Are there any questions or comments before I ask for adjournment?

John asked: what the status of 247 CMR 6 and 9.

Ed responded: The Board is waiting for 247 CMR 6 and 9 to be promulgated into law so they can be implemented.

Antoinette asked: Regarding the HVAC excursions in Pg.4. section 3 asterisk section response to temperature and humidity excursions if greater than sixty minutes that it is recommended that compounding would need to be suspended until the excursion is remediated.

Antoinette noted that in Hospitals the excursion can last longer than the time stated depending on the day.

Bill responded: This was added after the fact and that it was a recommendation that if temperature and humidity was out of specs for greater than 60 minutes may indicate something has gone wrong with the HVAC system.

Antoinette: When we ask our physicians develop our own determinations of what excursions we can define it that way.

Bill responded: This was a recommendation that can be reviewed again or based on protocols developed within individual facilities. Currently there is limited specific data on responding to temperature and humidity excursions but it does occur longer than hour it may indicate that there is a problem with the HVAC system.

Antoinette: noted that temperature and humidity excursions can be related to various issues and that recommending suspending compounding may not be the right response it could mean mitigating in other ways testing or triple cleaning the room or something like that. I don't know if suspending compounding is the right answer.

Bill responded: That we can take another look at the proposed regulation and make some improvements based on your discussion.

VIII **ADJOURMENT OF MEETING** **TIME: 10:31 AM**

ACTION: Motion by J. Walczyk seconded by C. Belisle, and voted unanimously by those present, to adjourn from General Session by roll call vote.