COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

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

October 30, 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>)
Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)
Francis McAteer (Expert in Microbiology)
LCDR John Mistler, PharmD, CPH, USPHS (Expert in cGMP)
Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)

Board of Pharmacy Member Present
Julie Lanza, CPhT, Secretary

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)
Sylvia B. Bartel, RPh (Expert in USP<797>)
David H. Farb, PhD (Expert in Clinical Pharmacology)

Support Staff
Ed Taglieri, MSM, NHA, RPh PSUD Supervisor – moderated meeting
David Sencabaugh, RPh, Executive Director
Heather Engman, JD, MPH, Pharmacy Board Counsel
William Frisch, RPh, Director of Pharmacy Compliance
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 TIME: 9:03 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.
Roll call for the call to order:

C. BELISLE: yes, F. MCATEER: yes, J. MISTLER: yes, K. THOMASSET: yes, J. WALCZYK: yes, A. LAVINO: yes, J. LAVERY: yes.

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2. APPROVAL OF AGENDA **TIME: 9:04 AM**

DISCUSSION: E. TAGLIERI asked if there were any changes to the agenda. There were none.

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

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3. APPROVAL OF MINUTES from 06/20/19 Advisory Committee Meeting **TIME: 9:04 AM**

DISCUSSION: E. TAGLIERI asked if there were any changes to the minutes and, if none, asked for a motion to approve.

ACTION: Motion by J. WALCYZK seconded by A. LAVINO and voted unanimously by those present to approve the agenda with no changes.

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4. Advisory on Sterile Compounding Pharmacy Response to HVAC Excursions **TIME: 9:05 AM**

PRESENTED BY: W. FRISCH

DISCUSSION**:** W. FRISCH stated the Board is seeking input regarding this advisory in terms of how facilities should respond to HVAC system excursions, specifically temperature and humidity, in sterile compounding environments.

Section I: General Recommendations

W. FRISCH: States that the Advisory Committee's input is needed to develop this advisory and suggests we go through the document section by section.
F. MCATEER: Suggests developing standard operating procedures (SOP) for power outages that requires employees to be trained and notes that implementation of SOP will help pharmacies produce a proactive response that may also help facilitate communication with the Board.
K. THOMASSET: Notes that Section A does not contain enough detail directed towards compounding pharmacies and needs more clarification regarding whether or not pharmacies "should" or "must" have policies and procedures.
W. FRISCH: Clarifies and states that because this draft document is an advisory, it will be treated as "should".
A.LAVINO: Suggests the rewording of Section A in order to provide more clarity.
W. FRISCH: States that this is an initial draft and the language will be clarified later. Proceeds to explain Section B of the draft advisory.
F. MCATEER: Raises a question regarding the meaning of "building management representative" and asks if this includes CDER certification.
K. THOMASSET: Asks for clarification regarding excursions limits
C. BELISLE: Suggests that the first and second subsections do not need to be included as they are already in the regulations but subsection three can remain in order to address HVAC.

W. FRISCH: Proceeds to explain Section C of the draft advisory which has been included to ensure that there is a HVAC maintenance plan implemented in order to maintain proper operations, constant monitoring and assessment.
E. TAGLIERI: Does uninterrupted power sources mean having a generator? Notes that not all facilities are capable of having a generator.
W. FRISCH: Reinforces that there needs to be a plan in place and highlights the importance of engaging the right individuals when necessary for additional consultation.

K. BYERS arrived to the meeting **TIME: 9:23 AM**

W. FRISCH: Reviews Section D which is included in the draft advisory in order to help individuals during excursions and provide general guidelines on when it is safe to resume compounding and other activities.
J. WALCZYK: Recommends removing "uninterrupted power source" due to the fact that not every pharmacy will be able to comply, especially smaller compounders. The inclusion of such language may cause confusion.
E. TAGLIERI: Suggests that institutions should have some sort of back-up plan should they experience a power outage.
J. MISTLER: Recommends that if "uninterrupted power source" remains in the advisory, then a testing plan should be implemented in order to ensure that the back-up generator or power source is well maintained.

Section II: Sterile Compounding Pharmacy Response to Temperature and Humidity Excursions
W. FRISCH: Began by going through the relevant standards that address how pharmacies should respond to temperature and humidity excursions.
C. BELISE: Asks if the definition of excursion should be explicitly stated before determining how pharmacies should respond to such excursions.
A. LAVINO: Agrees and raises a question as to whether an excursion should be defined as the time an HVAC system is out of range.
F. MCATEER: Notes that the language used in this advisory should be "will," instead of "should," as pharmacies are required to maintain temperature within limits.
C. BELISE: Disagrees with changing the language to "will," stating that there are many variations as to what institutions consider an "excursion," which changes what procedures respective institutions are required to take when experiencing excursions.
J. WALCZYK: Suggests that we default to the language of USP <797>, which is "should".
J. MISTLER: Notes that important to assess the duration of excursion to determine best practice procedures.
J. LAVERY: Agrees, and suggests a more general approach when detailing what constitutes as an excursion.
H. ENGMAN: Agrees, as taking a general approach places more responsibility on facilities to think about facility-specific excursions. Notes that this advisory should be viewed as general guidance for all facilities.

Break **TIME: 9:56-10:06 AM**

J. MISTLER: Suggests that the Board have guidance that identifies the following: type of compounding, facility, duration, amplitude, trending, and overall product quality impact.
F. MCATEER: Notes adding in "risk assessment" to the above recommendation.

Section III: Compounding Pharmacy Response to Planned and Unplanned Interruptions to HVAC System Operation

W. FRISCH: Introduces Section III of the draft advisory with no questions or comments from the Pharmacy Advisory Committee.

Section IV: Sterile Compounding Pharmacy Response to Differential Pressure Excursions

W. FRISCH: Introduces Section IV of the draft advisory which covers remediation steps on how to proceed when differential pressure excursions occur.
C. BELISLE: Notes that within her facility, a temperature alert is set every 30 minutes and if the temperature were to exceed the range for over 1 hour, this would warrant an assessment of why this event occurred and what the next steps should be (12 hour BUD, re-cleaning etc.)
C. BELISLE: Suggests having individual institutions define "anomaly" as each facility varies widely.
J. WALCZYK: Suggests adding "prolonged" in front of the word excursion for further clarity.

Section V: Recommended Conditions for Resuming Sterile Compounding for Prolonged Drop or Loss of Differential Pressure Loss in ISO Classified Environments

W. FRISCH: Introduces Section V of the draft advisory which entails recommendations for resuming sterile compounding after a prolonged drop or loss of differential pressure loss in ISO classified environments. Notes that the language used in this section be more general.
K. THOMASSET: Suggests that the Board hold an education session or CE on cGMP, as pharmacists would need more guidance due to the general language used in this section.
F. MCATEER: Suggests that there should be various testing done such as smoke study, HEPA leak testing etc. and documented on file.

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5. **Policy 2019-01: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing and Telepharmacy** **TIME: 10:30 AM**

PRESENTED BY: M. CHAN

DISCUSSION**:** M. CHAN presents an update regarding Policy 2019-01 and states that the policy has been before the Board and has been finalized in October. The updated version of the policy contains sections for all shared services requirements as well as specific requirements for central fill, central processing and most recently, telepharmacy. There were no comments or questions from the Pharmacy Advisory Committee.

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6. **Discuss Implementation of USP Chapters** **TIME: 10:37 AM**

PRESENTED BY: W. FRISCH

DISCUSSION**:** W. FRISCH presents an update regarding the Board's decision to provide a soft implementation of the delayed USP chapters <795> and <797> and asks for an open discussion regarding the development of a guidance document for community pharmacies to help shape their practical adoption of the USP <800>.

A.LAVINO Notes the type of drugs that community pharmacies dispense that may be considered HDs as well as distinguish between high risk and low risk drugs. Ex: cyclophosphamide, tamoxifen etc. States that there should be procedures in place for the segregation and receiving of these products.
C. BELISE states that the Board should develop such a guidance, but poses a question as to whether the guidance includes retail and ambulatory pharmacies as well. Notes that USP <800> can cause confusion in regards to storage and handling particularly when it comes to finished products vs. unfinished drugs. Suggests that different risk assessments should be performed with respective drugs on the NIOSH list.
W. FRISCH clarifies that the guidance is aimed for all community pharmacies and the initial thought was for the pharmacies to develop and implement programs and policies for USP <800> regarding non-compounding HDs.
J. MISTLER recommends adding in a requirement for cleaning procedures for equipment that comes in contact with hazardous drugs (designated trays and spatulas) along with deactivating solutions.
K. BYERS notes that the use of baby wipes, which contain surfactants, in cleaning up HDs is a useful practice. Recommends educating patients as well as employees to engage in the method of pouring HD tablets into the vial lid to avoid clouds of HD powder.
J. MISTLER suggests that practice or procedures should be implemented to ensure that the pharmacy can identify table 1 NIOSH drugs and recommends required CEs on HDs for the rest of the pharmacy staff.
J. WALCZYK notes that the Board include a guidance for even “simple” compounding. Ex: Clonazepam suspension.

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8. **Closing remarks Adjournment of Meeting:** **TIME: 10:55 AM**

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