COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE BOARD OF REGISTRATION IN PHARMACY

December 6, 2018
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Beth Rabasco, Phone: 617-624-5291 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.

Agenda

Time	#	Item		Contact
8:30	**I**	**CALL TO ORDER**		M. Godek
	II	**APPROVAL OF AGENDA**		
8:40	**III**	**APPROVAL OF BOARD MINUTES** • Draft of November 1, 2018 Regular Session Minutes		
8:45	**IV**	**REPORTS** • Applications approved pursuant to Licensure Policy 13-01 • Monthly report from probation • Board Delegated Review pursuant to Licensure Policy 14-02 • Above Action Levels approved by Staff Action 16-04		
8:50	**V**	**POLICIES and ADVISORIES** • Policy 2018-05: Requirements and Procedures for Reporting Theft or Loss of Controlled Substances • Policy 2018-06: Retail Pharmacy Participation in Investigational Drug Studies • Staff Action Policy 18-02: Retail Pharmacy Participating in Investigational Drug Study		

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<tr><td>9:00</td><td>VI</td><td>APPLICATIONS
Christine Vaudo, PH236024 – Waiver of CDTM requirement
Benzer Pharmacy/Southwick Pharmacy, DS 90050– Transfer of Ownership
Community, A Walgreens Pharmacy, DS90060 – Change of Manager
Central Street Pharmacy, DS89950 - Renovation</td><td></td><td></td></tr>
<tr><td>9:45</td><td>VII</td><td>FLEX
Election of Board officers for 2019
Comments to USP regarding sections <797> and <825>
Penicillin skin test – CDTM Pharmacist</td><td></td><td></td></tr>
<tr><td>10:00</td><td>VIII</td><td>REGULATIONS
Advisory Committee Recommendations to 247 CMR 17.00: Sterile Compounding</td><td></td><td></td></tr>
<tr><td>11:30</td><td>IX</td><td>FILE REVIEW<table><tr><td>1</td><td>SA-INV-13572- CVS #1009- DS1592</td></tr><tr><td>2</td><td>SA-INV-13690- CVS #1010- DS21285</td></tr><tr><td>3</td><td>SA-INV-13856- Rite Aid #10051- DS90205</td></tr><tr><td>4</td><td>PHA-2018-0069- Rite Aid #10205- DS2573</td></tr></table></td><td></td><td></td></tr>
<tr><td colspan="5">LUNCH BREAK
12:30</td></tr>
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1:30	**X**	**EXECUTIVE SESSION** The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, to evaluate the Good Moral Character as required for registration for pending applicants.		CLOSED SESSION
2:30	**XI**	**ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)**		CLOSED SESSION
2:45	**XII**	**M.G.L. c. 112, § 65C SESSION**		CLOSED SESSION
5:00	**XIII**	**ADJOURNMENT**		CLOSED SESSION

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts, 02114

December 6, 2018

Board Members Present	**Board Members Not Present**
Michael Godek, RPh. President	Dawn Perry, JD
Andrew Stein, Pharm D, RPh. President Elect	Carly Jean-Francois, RN, NP
Kim Tanzer, PharmD, RPh. Secretary	Susan Cornacchio, JD, RN
Julie Lanza, CPhT	
Timothy Fensky, RPh (Leaving 12:30 PM)	
Sebastian Hamilton, Pharm D, RPh	
Leah Giambarresi, Pharm D, RPh	
Stephanie Hernandez, Pharm D, BCGP, RPh	
Patrick Gannon, RPh (Leaving 12:30 PM)	

Board Staff Present
David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Associate 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 Pharmacy Investigations
Kimberly Morton, CPhT, Compliance Officer
Greg Melton, JD, PharmD, BCPS, RPh, Investigator
Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist
Joseph Santoro, RPh Investigator
Christina Mogni, RPh investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:36 AM
A quorum of the Board was present, established by roll call. President M. Godek chaired the meeting and asked if anyone was recording hearing, no one responded. He explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; L. Giambarresi, yes;
M. Godek, yes; P. Gannon, yes; S. Hernandez (yes); T. Fensky, yes;

S. Hamilton joins meeting 8:50 AM

Topic II. **Approval of Agenda** **TIME 8:36 AM**

Agenda December 6, 2018

DISCUSSION:
Change to Agenda:
1. Defer Central Street Pharmacy, DS89950 Renovation. Completed by Staff Action.

ACTION:
Motion by L. Giambarresi, seconded by P. Gannon and voted unanimously by those present to approve the agenda with noted change.

Dave introduced the 1 intern Aaron Slyman MCPHS-Worcester. Mike asked all students in the audience to stand and introduce themselves.

Topic III **Approval of Board Minutes** **TIME: 8:39 AM**

Minutes
1. Draft, November 1, 2018 Regular Session Minutes

Changes:
1. Page 10; change vote noted as S. Fensky to T. Fensky

Action:
Motion by L. Giambarresi, seconded T. Fensky, and voted unanimously to approve the regular session minutes of November 1, 2018 with noted changes.

TOPIC IV **REPORTS**
Applications approved pursuant to Licensure Policy 13-01 **Time: 8:39 AM**

Discussion: M. BOTTO noted that during the past month there have been thirty-three (33) changes of manager on record (MOR) and one (1) renovation/ expansions.

So noted

TOPIC IV **REPORTS**
Monthly Report from Probation **Time: 8:39 AM**

Discussion: M. BOTTO provided the October 24, 2018 – November 28, 2018, Board of Pharmacy Statistics Report for the Probation monitor, which noted seven (7) licensees successfully completed their probation, and that there are currently forty-six (46) licensees on probation.

So noted

TOPIC IV **REPORTS**
Monthly Report from BDCR pursuant to Policy 14-02 **Time: 8:39 AM**

Discussion: M.BOTTO noted that there were nine (9) Board Delegated Review cases heard on December 3, 2018. Eight of the cases were CE deficiencies (SA-INV-14010, SA-INV-14013, SA-INV-14059, SA-INV-13886, SA-INV-13970, SA-INV-14066, SA-INV-14065, and SA-INV-14068) which were closed with no discipline warranted and remediation complete. There was one consumer grievance (SA-INV-13859) which was closed, insufficient evidence. The Board Delegated Review session was attended by M. GODEK as the Board Member, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

TOPIC IV **REPORTS**
Above Action Levels Approved by Staff Action 16-04 **Time: 8:40 AM**

Discussion: K.MORTON noted that during the past month there were two (2) above action level results, which were successfully remediated and closed pursuant to licensure Policy 16-04.

So noted

TOPIC V **POLICIES and ADVISORIES** **Time: 8:40 AM**

1. Policy 2018-05: Requirements and Procedures for Reporting Theft or Loss of Controlled Substances

Discussion: K. MORTON explained that the OPP staff participated in a lean six sigma project concerning the high amounts of loss reports that were non-complaint, including reports that were incomplete, untimely, or unnecessary.
As a result, the policy and a reporting form have been updated. The revised policy contains updated descriptions of types of losses, including those that are not considered "not-reportable", and further instructs pharmacies how to manage non-reportable losses.
Revisions of the reporting form include removal of Sections A and B, and now include an initial email notification containing specific information as outlined in the policy. Within the next 21 days, or upon completion of investigation, the pharmacy must report their findings on a new electronic fillable loss reporting form. The new form removes unnecessary fields and must be completed and filed electronically.

ACTION: Motion by L. GIAMBARRESI, seconded by K. TANZER and voted unanimously by all those present to approve the policy.

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2. Policy 2018-06:
Retail Pharmacy Participating in Investigational Drug Study **Time: 8:44am**

Discussion: J. TRAN explained the policy revisions that included changes to the procedure in order for Board licensees to participate in research studies. The policy outlines the process and required documents for a researcher to include a retail pharmacy in the study. The revisions streamline the process both internally and for the licensees.
T. FENSKY asked what happens if a retail pharmacy does not know that they are part of a research study. A regular prescription comes into the pharmacy and you don't know it's part of a study.
H. ENGMAN commented that the policy is designed for situations where pharmacy is actively participating in study rather than just filling a prescription.

ACTION: Motion by A. STEIN, seconded by P.GANNON and voted unanimously by all those present to approve the policy.

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3. Staff Action Policy 18-02: Retail Pharmacy Participating in Investigational Drug Study
Time: 8:47am

DISCUSSION: W. FRISCH requests the approval of a policy allowing Board staff to review and approve applications for pharmacies to participate in research studies if they are in accordance with Board policy 2018-06.

ACTION: Motion by A. STEIN, seconded by P.GANNON and voted unanimously by all those present to approve the policy.

TOPIC VI APPLICATIONS

1. **Christine Vaudo, PH236024 Petition Approval for CDTM requirements 8:48AM**

   Action: Motion by S. HERNANDEZ, seconded by S. HAMILTON, and voted by the majority of those present to approve the application approve the pharmacist's education as meeting the CDTM requirement. T. FENSKY opposed the motion.

2. **Benzer Pharmacy/Southwick Pharmacy DS90050 Transfer of Owner 8:54AM**
   Represented by: Harry Patel (Operations Manager and Pharmacy Technician)

   Discussion:
   - M. Botto indicated that the application was updated with the simple/moderate compounding.
   - MOR on the application is a temporary MOR and they are currently seeking a permanent MOR.
   - Business model with have delivery of prescription for 30-50 miles and blister-packaging.
   - The company has 66 other locations nationwide.
   - The permanent MOR will report to the corporate office but currently the temporary MOR will report to the Operations Manager.

- After hour requests for patients will be forwarded to the MOR. In other states where after hour requests are not required, there is a temp agency that will provide a pharmacist for questions.
- The owners of the company reside in Michigan and the other owner lives in Florida. The corporate office visits monthly until the pharmacy is operational and then a visit occurs quarterly.
- The initial MOR had CE deficiencies so they had to change the MOR. The company does not own any other pharmacies in the state.

Action: Motion by S. HAMILTON, seconded by L. GIAMBARESSI, and voted by the majority of those present to approve the application. T. FENSKY and M. GODEK opposed the motion.

3. Community, A Walgreens Pharmacy DS90060 Change of Manager 9:18AM
Represented: Catherine McCabe

Recusal: Godek
Discussion:

- She indicated that she has been a MOR at another Walgreens locations.
- She has been trained for specialty medications and the delivery of the medications.
- She feels like she has a supportive team.

Action: Motion by L. GIAMBARESSI, seconded by P. GANNON, and voted unanimously of those present to approve the application. M. Godek recused.

4. Central Street Pharmacy, DS9950 Renovation/Expansion 9:25AM

Discussion:

DEFER

TOPIC VII FLEX Time 9:21 AM

1. Election of Officers for 2019
Presented by: D. SENCABAUGH

President Elect: K. TANZER
Motion by A. Stein to elect K. TANZER, seconded by S. HAMILTON voted unanimously by all that were presented via roll call.
M. GODEK yes, A. STEIN yes, K. TANZER yes, J. LANZA yes, S. HAMILTON yes, L. GIAMBARRESI yes, S. HERNANDEZ yes, P. GANNON yes, T. FENSKY yes

Secretary:
Nominee 1. J. LANZA
VOTE BY ROLL CALL: M. GODEK yes, J. LANZA yes, L. GIAMBARRESI yes, T. FENSKY yes

Secretary:
Nominee 2. S. HAMILTON
VOTE BY ROLL CALL: K. TANZER yes, S. HAMILTON yes,

Secretary:
Nominee 3. S. HERNANDEZ
VOTE BY ROLL CALL: A. STEIN yes, S. HERNANDEZ yes, P. GANNON yes

FINAL VOTE: LANZA: 4 **HERNANDEZ:** 3 **HAMILTON:** 2
Secretary elected for 2019: J. LANZA

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2. Penicillin Skin Testing- CDTM pharmacist **Time: 9:30am**
Presented by: M. CHAN

DISCUSSION: M. CHAN discussed that a pharmacist had reached out to K. TANZER regarding a penicillin skin testing, and if a pharmacist could perform it under a CDTM in accordance with Massachusetts law. The question is, is a skin test an interpretation of a diagnostic test? Penicillin is also a controlled substance, so would this be considered the administration of a drug?
M. GODEK suggested that this could allow other things like TB testing, so the answers need to be careful and consistent. M.GODEK says that with proper training a pharmacist should be able to do this, but there needs to be firm guidance on who give the training, and what training is required. P. GANNON thinks that there is no doubt that it is something that a pharmacist can do, but that it goes beyond Massachusetts law. K. TANZER said that this is being done throughout the country, and there is a lot of literature discussing the value of the pharmacist involvement in penicillin skin testing. So, this might be a movement that we want to get involved in. H. ENGMAN says that this would require a statutory change. The first step would be to make a list of things the Board would like to have included in CDTM, and then discuss how to change the statute. P.GANNON suggests that the Board to research to see what other states allow and what information NABP has regarding states that allow this. K. TANZER will research and begin a legislative list.

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3. Public Comment Submitted for Draft USP <797> & USP <825>
Presented by: W. FRISCH

DISCUSSION: W. FRISCH spoke of the comments that were submitted for the public hearings regarding USP<797> and <825>. He highlighted some of the main topics upon which comments were made. The USP <797> comments were to retain the current contamination risk levels instead of the suggested categories. Other changes discussed the SCA and suggested it be a dedicated room, instead of a room with an area, and asked to specify what kind of compounding may occur there. Comments also requested more frequent viable air monitoring and more frequent monitoring of gloved hands. Comments regarding BUD suggested sterility tests for any CSP exceeding any standard BUD. Finally, the sterility and endotoxin testing were requested to retain the current standards.

For the proposed chapter <825>, comments were limited. Since much of it mirrors <797>, the comment was to refer to those in regards to <797>.
P. GANNON asked if we expect to hear back, and if so how we hear back?
M. CHAN said a letter was received confirming receipt.
W. FRISCH said that last time we didn't hear back
H. ENGMAN said since USP is not a government entity there is no legal requirement for them to accept or publish public comments.

TOPIC VIII: **REGULATIONS**

1. 247 CMR 17.00 Sterile Compounding **Time:** 10:10 AM

Presented by: W. FRISCH, M. CHAN and H. ENGMAN

DISCUSSION:

W. Frisch reviewed the process up to this point and discussed the goal of finalizing review and update from public comment at today's meeting. Present was Caryn Belisle from the Pharmacy Advisory Committee (PAC) along with Antionette Lavino. Caryn and Antionette presented Recommendation Document 18-02 to the Board, bringing information from the PAC the on 247 CMR 17.00 Sterile Compounding for the Board to consider in final edits.

Please find Attachment A attached with draft regulations 247 CMR 17.00 and todays comments for final input. This is the results of Board Deliberation today after input received from the PAC.

After final review of draft 247 CMR 17.00 today, W. Frisch asked the Board if they had any further comments or input they'd like to re-visit. The Board responded they did not. Board and Board Staff agreed we have a good balance in draft 247 CMR 17.00 of statutory regulatory requirements, input from stakeholders and public comments that reflects the needs of all involved with this process.

Action:
Motion by T. Fensky, seconded P. Gannon, and voted unanimously by all present to approve draft 247 CMR 17.00 Sterile compounding for administrative review and promulgation.

TOPIC IX **FILE REVIEW**

1. SA-INV-13572 **CVS #1009, DS1592** **TIME:10:01am**
Presented by : J. SANTORO
RECUSAL: NONE

DISCUSSION:

- Failure to properly fill and dispense a prescription observed during a retail compliance inspection. Specifically, the Pharmacy dispensed 180 mls of Ketamine on 2/6/2018 which was in excess of a 30-day supply.
- The Verification Pharmacist, Nicholas Chiodi incorrectly calculated the day supply. Of note, it was the first time he filled a prescription for Ketamine. He believed the prescription for 180mls was for a 30-day supply because it was a controlled medication written with 5 refills.
- Dating back to 5/2017, there were four other pharmacists who verified ketamine RXs in excess of a 30-day supply on 5/5/17, 6/3/17, 7/2/17, 8/10/17, 9/19/17, and 10/19/17 each for 60 mls (~90-day supply).
- Additionally, after 2/6/18 dispensing of 180mls (~9-10-month supply) two other pharmacists refilled the prescription 3 more times for a quantity of 20ml/30-day supply on 4/29/18, 7/19/18, & 7/26/18.
- Policy and procedures were reviewed with all staff pharmacists regarding the proper dispensing, maintenance of records, and review required for all controlled substances. The pharmacy team will ensure that quantity and day supply are accurately calculated for every prescription to be thoroughly reviewed by the pharmacist to ensure they are always dispensed in compliance with applicable state and federal laws. Pharmacy staff members also understand that the prescriber must always be contacted if there is ever an uncertainty around how the medication should be taken. In addition, a quality alert message has been implemented in the pharmacy system for ketamine which requires pharmacist to credential that they confirmed product validation with the prescriber as it not routinely for outpatient dispensing.
- MOR Bannan and Pharmacist Chiodi completed an additional 3 CE credits of law related to controlled substance dispensing and attested to reading 247 CMR 15. Pharmacist Francesconi completed 1 CE on Pharmacy Law and 5 CE credits on Patient Safety and attested to reading 247 CMR 15, in its entirety. Pharmacist Henry Huynh, Pharmacist Nancy Nguyen, Pharmacist Fariza Rahim, and Pharmacist Anhthu Hoang all completed 2 CE of law related to controlled substances and attested to reading 247 CMR 15, in its entirety.

ACTION: A motion by P. GANNNON, seconded by S. HERNANDEZ, and voted unanimously by those present to CLOSE (SA-INV-13572), No discipline warranted, Remediation complete.

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2. SA-INV-13690 CVS #1010, DS21285 Time: 10:07 am

Presented by : C. MOGNI

RECUSAL: NONE

DISCUSSION:

- On 7/16/18 (ISP-10055)- two schedule II prescriptions with "Void" and "Copy" visible in the background were observed as having been filled on 6/28/18.
- "Void" imprinted on background of Patient A's prescription for #280 oxycodone 20mg tablets and "Copy" imprinted on background of Patient B's prescription for #60 oxycodone 5mg tablets from 2 different facilities with warnings indicating the tamper resistant security features on both prescriptions;
- 8/8/18- Amended POC from CVS Corporate to include both prescriptions contended MOR Bekelian contacted the prescribers who indicated it was a hospital wide printer issue and that the pharmacy would no longer accept prescriptions with "Void" or "Copy" in the background;

- In the response from CVS Corporate, Pharmacist Pourshadi, who was identified as the verification pharmacist for Patient A's prescription that included a high dose DUR, indicated she had contacted the prescriber (not documented), Patient A has been a customer of 3 years, and there were no red flags, no explanation was given for filling a prescription with the word "Void" visible.
- In the response from CVS Corporate, Pharmacist Thomas, who was identified as the verification pharmacist for Patient B's prescription, indicated the patient and prescriber were local, there were no red flags, and no reason to believe the prescription was not legitimate, no explanation was given for filling a prescription with "Copy" visible;
- The response for MOR Bekelian was the same response as the POC with verbatim responses provided for Pharmacist Pourshadi, Pharmacist Thomas, and MOR Bekelian related to their normal practice when filling controlled substance prescriptions;
- CA: MOR Bekelian contacted the prescriber's to inform them that the Pharmacy staff will not accept prescriptions with "Void" or "Copy" imprinted on the background; Pharmacist Pourshadi completed 1 CE entitled "The Pharmacist's Role in Combating the Opioid Crisis in Pain Management".

ACTION: A motion by P. GANNON, seconded by S. HAMILTON, voted unanimously by members present to CLOSE (SA-INV-13690), No discipline warranted, remediation complete.

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3. SA-INV-13856 Rite Aid #10051, DS90205
Time: 11:19 am
Presented by: C. MOGNI

RECUSAL: M. GODEK was recused and was not present for discussion or vote on this matter

DISCUSSION:

- During an inspection (ISP-10347) on 8/27/18, it was discovered that Pharmacist Booth had knowingly dispensed a 3-day supply of a recalled lot of Contrave on 8/19/18 at the request of Rite Aid Pharmacy #10058 in Southampton that did not have the medication for the patient
- Pharmacist Booth had been processing the recall when the request came;
- Pharmacist Booth stated he made a judgement call after determining the recall was due to potential punctures in the bottle and not due to defective medication and so as not to provoke withdrawal symptoms including seizure;
- Pharmacist Booth attempted to unsuccessfully call the patient so a consultation note was put in the prescription to notify the Patient of the situation and to advise her to contact her physician for alternatives;
- According to Pharmacy Technician Rivera, the Patient read the note at the point of sale and declined counseling;
- CA: MOR Costa verbally counseled Pharmacist Booth that recalled medication should never be dispensed and they discussed other ways he could have taken care of the Patient; Pharmacist Booth notified the Patient's physician, reviewed the corporate recall policy, filed a QRE report, completed 2 CE's in "Preventing Medication Errors" and attested to reading 247 CMR 15.

ACTION: A motion by S. HAMILTON, seconded by S. HERNANDEZ , and voted unanimously by all members present to CLOSE (SA-INV-13690), no discipline warranted, remediation complete.

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4. PHA-2018-0069 Rite Aid #10205, DS2573
Time: 11:14

Presented by: K. MORTON

RECUSAL: M. GODEK was recused and was not present for discussion or vote on this matter

DISCUSSION:

- RLCS of #100 oxycodone HCL 10mg tablets and #100 oxycontin 80mg tablets, which was later amended to include #633 alprazolam 1mg tablets, #1204 alprazolam 2mg tablets, #338 clonazepam 1 mg tablets, #75 dextroamphetamine-amphetamine ER 20mg capsules, #65 morphine sulfate ER 200mg tablets, and #999 tramadol 50mg tablets.
- MOR indicated that on December 30,2017 the loss of #100 oxycodone HCL 10mg tablets and #100 oxycontin 80mg tablets was discovered. Asset Protection District Manager reviewed video footage of the day before and observed the pharmacy technician trainee turning the camera away from the CII safe and bench. The statement indicated that the technician trainee was interviewed and admitted to moving the camera but did not admit to taking any drugs.
- After terminating the technician, a full controlled substance inventory was taken, resulting in the additional reported losses.
- On October 4, 2018 BORP heard SA-INV-12803, and requested it be converted to a complaint and request additional information from the pharmacy about the handling of controlled substances.
- In response, the Pharmacy District Supervisor Brendan Rock indicated that only Pharmacists handle and count CII Medications. PTs and PTT do not have access to or count CII medications. It is expected for all pharmacy technician and technicians that all CIII-V should be hand-counted twice. The Pharmacist will do a final count on any CIII-V that is counted by a PT or PTT. It is expected that all pharmacy technicians and technicians in training use extreme caution when handling CIII-V medications during the filling process. Only a pharmacist can perform monthly controlled substance counts and the weekly CII counts. This is not a task that is delegated to a technician or intern. A retail compliance inspection was conducted on March 20, 2018 with no deficiencies noted.

ACTION: A motion by A. STEIN, seconded by L .GIAMBARRESI , voted unanimously by all members present to DISMISS (PHA-2018-0069), discipline not warranted.

Topic X EXECUTIVE SESSION Time: 11:26 AM
Read by M. Godek

DISCUSSION:
ACTION: At 11:26 PM President M. GODEK read the statement on reasons for Executive Session.

12:30 PM to 1:30 PM Lunch Break

Topic X: **Executive Session Call to Order:** **Time: 11:26 AM**
By: M. Godek

ACTION: Motion by P. Gannon, seconded by L Giambarresi, and voted unanimously by roll call to call the November 1, 2018 meeting of the Executive Session to order.

Roll call attendance: M. Godek, yes; A. Stein, yes; K. Tanzer, yes; P. Gannon, yes; J. Lanza, yes; T. Fensky, yes; S. Hamilton, yes; L. Giambarresi, yes; S. Hernandez, yes.

Topic XI: **Adjudicatory Session (M.G.L. ch 30A § 18)** **Time: 1:14 PM**

DISCUSSION: None
ACTION: President M. Godek request a motion to enter Adjudicatory Session.

At 1:14 PM L. Giambarresi, seconded by K. Tanzer and voted unanimously by all those present to enter Adjudicatory Session:

Topic XII: **M.G.L. 65 C** **Time: 11:32 AM**

DISCUSSION: None
ACTION: President M. Godek request a motion to enter M.G.L 65 c Session.

At 11:32 AM S. Hernandez, seconded by P. Gannon and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

Topic XIV: **ADJOURMENT OF MEETING** **TIME: 2:32 PM**

ACTION: Motion by S. Hamilton seconded by K. Tanzer, and voted unanimously by those present, to adjourn from General Session.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 12/6/18 General Session
2. Draft Minutes of the 11/1/18 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01

4. Report on probation
5. Report on Board Delegated Complaint Review to licensure policy 14-02
6. Report on Above Action Levels approved by Staff Action 16-04
7. Joint Policy 2018-01: Permitted Prescription Changes and Additions
8. Policy 2018-05: Requirements and Procedures for Reporting Theft or Loss of Controlled Substances
9. Policy 2018-06: Retail Pharmacy Participation in Investigational Drug Studies
10. Staff Action Policy 18-02: Retail Pharmacy Participating in Investigational Drug Study
11. Christine Vaudo, PH236024; Waiver of CDTM requirements
12. Benzer Pharmacy/Southwick Pharmacy, DS90050; Transfer of Ownership
13. Community, A Walgreens Pharmacy, D90060; Change of Manager
14. Comments to USP regarding Sections <797> and <825>
15. Penicillin skin test-CDTM Pharmacist
16. Advisory Committee Recommendations to 247 CMR 17.00 Sterile Compounding
17. SA-INV-13572 CVS #1009 DS1592
18. SA-INV-13690 CVS #1010 DS21285
19. SA-INV-13856 Rite Aid #10051 DS90205
20. PHA-2018-0069 Rite Aid #10205 DS2573

Respectfully Submitted,
Kim Tanzer, PharmD, RPh
Secretary

Attachment A

247 CMR 17.00: STERILE COMPOUNDING

Section

17.01: Authority and Purpose
17.02: Sterile Compounding Licensure
17.03: Commercially Available Single and Multiple Dose Vials and Containers
17.04: Immediate-Use CSPs
17.05: Low Risk Level 12 Hour BUD CSPs
17.06: High Risk Level CSPs
17.07: Implantable Infusion Pumps
17.08: CSPs as Stock Solutions
17.09: CSPs made with Blood-Derived or Biological Material
17.10: Allergen Extracts as CSPs
17.11: Sterile Compounding for Veterinary Patients
17.12: Sterile Compounding Facility; General
17.13: Sterile Compounding Facility; ISO Classified Areas
17.14: Sterile Compounding Facility; ISO Class 5 Primary Engineering Controls
17.15: Sterile Compounding Facility; Secondary Engineering Controls; Buffer Rooms; Ante Rooms; Segregated Compounding Areas; and Other Classified Areas
17.18: Sterile Compounding Facility; HVAC Systems
17.19: Sterile Compounding Facility; HEPA Filters
17.20: Sterile Compounding Facility; Airflows and Pressure Differential Monitoring
17.21: Sterile Compounding Facility; Temperature and Humidity Monitoring
17.22: Sterile Compounding Facility; Certification of Classified Areas
17.23: Sterile Compounding Facility; Smoke Studies
17.24: Environmental Monitoring
17.25: Environmental Monitoring; Non-Viable Particle and Viable Air Sampling
17.26: Environmental Monitoring; Surface Sampling
17.27: Environmental Monitoring; Action Levels
17.28: Environmental Monitoring; Remediation of Above Action Level Environmental Monitoring Results
17.29: Cleaning and Disinfecting
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17.45: Verification of Compounding Accuracy; Release Checks
17.46: Labeling

Comment [MAC1]: Title change to be consistent with USP

17.47: Inventory Storage and Handling; Delivery of CSPs
17.48: Drug Utilization Review and Patient Counseling
17.49: Quality Assurance ("QA") Program
17.50: Sterile Compounding Policies and Procedures
17.51: Defective Products

17.01: Authority and Purpose

247 CMR 17.00 is promulgated under the authority grated the Board by M.G.L. c. 112, §§ 39G, 39I, and 42A. The purpose of 247 CMR 17.00 is to establish minimum professional standards for sterile compounding in order to safeguard the public health and welfare. 247 CMR 17.00 applies to pharmacies that hold a sterile compounding pharmacy license, non-resident sterile compounding pharmacy license, or institutional sterile compounding pharmacy license.

17.02: Sterile Compounding Licensure

(1) A pharmacy licensed by the Board shall comply with 21 U.S.C. § 353a, M.G.L. c. 94C, §§ 17 & 22, and M.G.L. c. 112, § 39F.

(2) A pharmacy licensed by the Board may not simultaneously hold an outsourcing facility registration issued by the federal Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 353b.

(3) The Board or its designee(s) may visit each pharmacy licensed by the Board under M.G.L. c. 112, §§ 39G, 39I, or 39J at any time without prior notice and inspect the pharmacy, staff, activities, and records to determine compliance with 247 CMR 2.00 *et seq*. and inspectional criteria described in the Board's Sterile Compounding Audit Tools.

(4) A pharmacy shall train its employees annually in lean concepts, in accordance with M.G.L. c. 112, § 39G. Lean concepts are tools that assist in the identification and steady elimination of waste and promote continuous improvement in quality and efficiency.

17.03: Commercially Available Single and Multiple Dose Vials and Containers

(1) A licensee shall discard a commercially available single dose vial punctured within International Organization for Standards ("ISO") Class 5 air within 6 hours after puncture.

(2) A licensee shall discard a commercially available multiple dose vial within 28 days after initial puncture or as directed by the manufacturer.

17.04: Immediate-Use CSPs

A licensee may prepare a CSP outside of a classified area only if the CSP is intended for immediate use in an emergent or urgent situation in accordance with United States Pharmacopeia ("USP") <797>.

17.05: Low Risk Level 12 hour BUD CSPs

17.06: High Risk Level CSPs

(2) A pharmacy may not prepare high risk level CSPs identified as demonstrably difficult to compound by the federal Food and Drug Administration ("FDA") or the Board.

(4) A pharmacy may not utilize lyophilization equipment to prepare lyophilized drug substances or ingredients used in CSPs.

(5) A pharmacy may not compound a component of a CSP from Active Pharmaceutical Ingredient ("API") when a version of that component is commercially available.

(6) Pre-sterilization procedures for high risk level CSPs, such as weighing and mixing, shall be completed in an ISO Class 8 or cleaner environment.

(8) A pharmacy may not dispense a high risk level CSP without preservatives unless:
(a) the CSP is dispensed in a single use container and labeled as "single use only"; or
(b) the container has been validated to prevent contamination of the CSP.

17.07: Implantable Infusion Pumps

17.08: CSPs as Stock Solutions

A pharmacy that prepares high risk level intermediate or stock solutions shall perform sterilization procedures immediately upon compounding the intermediate or stock solution and may not store non-sterilized solutions for future sterilization.

17.09: CSPs made with a Patient's Own Blood-Derived or Biological Material

(1) A pharmacy shall maintain a policy and procedure pertaining to compounding that involves a patient's own blood-derived or other biological material.

(2) The procedures for compounding CSPs using a patient's own blood-derived or other biological material shall require compounding to be separate from routine material-handling procedures and must describe cleaning of the PEC and other equipment used in CSP preparation in order to avoid cross-contamination.

(3) After compounding CSPs with a patient's own blood-derived or other biological material, compounding personnel shall:

(a) thoroughly clean the PEC, equipment, and materials according to the pharmacy's daily cleaning protocol;
(b) repeat all hand hygiene and garbing activities; and
(c) change garbing.

(4) A pharmacy shall immediately respond to and remediate any broken, damaged, or spilled container involving a patient's own blood-derived or other biological material.

(5) A pharmacy shall maintain a policy and procedure for the immediate and systematic response (i.e. spill kit) to broken, damaged, or spilled container involving a patient's own blood-derived or other biological material.

17.10: Allergen Extracts as CSPs

A pharmacy shall prepare allergen extracts in accordance with 247 CMR 17.00.

17.11: Sterile Compounding for Veterinary Patients

A licensee shall separate drugs, ingredients, and components intended for animal use only from drugs, ingredients, and components intended for human use. A licensee shall handle and clean compounding supplies and equipment in a manner that prevents cross contamination of animal use only and human drugs, ingredients, and components.

17.12: Sterile Compounding Facility; General

17.13: Sterile Compounding Facility; General

(2) Each newly constructed ISO Classified area, shall allow for visual observation of the classified space from outside the classified space through windows or technology.

(1) An ISO Class 7 buffer room and ante room shall maintain a minimum of 30 air changes per hour.

(2) An ISO Class 8 room shall maintain a minimum of 20 air changes per hour.

(3) The air changes shall come from the HEPA filtered air. HEPA filtered air shall be introduced at the ceiling. For newly constructed buffer rooms, any air exchanges supplied to buffer room from the PEC must be in addition to the 30 air changes per hour ("ACPH").

(4) A pharmacy may not utilize any non-hazardous ISO classified area for both sterile and non-sterile compounding.

(5) A pharmacy shall limit access to all ISO Classified areas to authorized individuals only.

(6) The doors to SCAs, ante rooms, and buffer rooms shall be:

(a) constructed of a nonporous, smooth, non-shedding, impermeable material such as acrylic, polycarbonate or similar fiberglass-reinforced plastic, glass, or stainless steel;

(b) free from cracks and crevices; and

(c) cleanable and resistant to degradation by cleaning agents.

(7) Beginning January 1, 2020, the doors to ante rooms and buffer rooms shall be constructed with an active or passive interlocking design to prevent or minimize the ante room door and buffer room door from opening at the same time.

(8) A SCA, buffer room, ante room, and other ISO Classified areas shall be well lit.

(9) Upon new construction, remodeling, or change in configuration or square footage, , a pass-through shall:

(a) be constructed of a nonporous, smooth, non-shedding, impermeable material such as acrylic, polycarbonate or similar fiberglass-reinforced plastic, glass, or stainless steel;

(b) have an interlocking door design;

(e) not be a refrigerator unit.

(10) A licensee shall operate each ISO Class 5 PEC 24 hours per day, 7 days per week.

(11) If there is an interruption in the operation of the ISO Class 5 PEC, a licensee may not resume compounding until the PEC operates for at least 30 minutes, in accordance with manufacturer specifications, or in accordance with the PEC's validated recovery time.

(12) A pharmacy shall respond to planned and unplanned interruptions of HVAC operations in accordance with Board policy.

(13) A pharmacy shall limit furniture, equipment, supplies, and activities in a SCA, ante room, and buffer room to those essential for sterile compounding related activities.

(14) A pharmacy may not locate a refrigerator, dishwasher, or incubator in an ISO Classified area.

Comment [HAE2]: Advisory Committee change.

(15) All equipment in a SCA, ante room, and buffer room shall be nonporous, non-shedding, impermeable, cleanable, and resistant to degradation by cleaning agents.

(16) All counter tops, work surfaces, and racks, shall be constructed of stainless steel or other non-porous, non-shedding material.

(17) A pharmacy may only utilize carts in ISO Classified areas that are:

(a) constructed of stainless steel, molded plastic, or other non-shedding, non-porous material; and

(b) cleanable and resistant to degradation by cleaning agents.

(18) An ISO Classified area and SCA constructed or renovated after January 1, 2020 may not contain dust-collecting overhangs or ledges.

(20) Upon new construction, remodeling, or change in configuration or square footage, but not later than January 1, 2020, a pharmacy shall utilize light fixtures designed for clean rooms in all ISO Classified areas and the exterior surface of ceiling lighting fixtures shall be smooth, mounted flush with the ceiling surface, and sealed.

Comment [MAC3]: 12/4/18: Board staff recommends requiring change upon promulgation.

Comment [HAE4]: Advisory Committee change.

Comment [5]: 12/6/18 Board: accept amended language

(21) Ceiling surfaces in ISO Classified areas shall be impervious and hydrophobic.

(22) Ceiling panels, fixtures, and other penetrations through the ceiling or walls shall be smooth and sealed around the perimeter.

(23) Beginning January 1, 2020, sprinkler heads in all ISO Classified areas shall be recessed, covered, and easily cleanable.

(24) Walls shall be made of solid surface, locking sealed panels, or epoxy-coated gypsum board and shall be impervious, cleanable, and non-shedding.

(25) Floors shall be cleanable and composed of wide sheet vinyl that is heat sealed at seams, or other solid, smooth surface. Floors shall be coved at the wall or appropriately sealed.

17.14: Sterile Compounding Facility; ISO Class 5 Primary Engineering Controls

(1) A pharmacy shall locate an ISO Class 5 PEC for non-hazardous drug compounding within a positive pressure ISO Class 7 buffer room or SCA.

(2) Any equipment in the PEC must be proven through smoke studies to have no impact on the direct compounding area.

(3) The supporting base of a PEC shall be constructed of stainless steel or other non-shedding, coated metal.

(4) Unless the pharmacy is utilizing an SCA with a CAI or LAFW in accordance with 247 CMR 17.00, a pharmacy shall prepare CSPs in an ISO Class 5 environment within an ISO Class 7 buffer room that is adjacent to an ISO Class 7 or 8 ante room.

(5) A pharmacy shall prepare CSPs in a commercially manufactured ISO Class 5 PEC. A pharmacy may not prepare CSPs in a vertically integrated ISO Class 5 workbench or ISO Class 5 open buffer room design.

(6) A pharmacy may not locate any equipment or supplies within an ISO Class 5 area unless it is essential to compounding.

(7) An ISO Class 5 PEC shall provide HEPA filtered unidirectional air over the direct compounding area.

17.15: Sterile Compounding Facility; Secondary Engineering Controls; Buffer Rooms; Ante Rooms; Segregated Compounding Areas; and Other Classified Areas

(1) Buffer Room

(a) A newly constructed buffer room shall be at least 100 square feet.

(b) A buffer room may not contain a sink, drain, or any other source of water.

(c) Buffer room doors shall be hands-free.

(d) A buffer room shall be supplied with HEPA filtered air.

(e) A buffer room shall be ISO Class 7.

(f) A buffer room shall be physically separated from the ante room by walls, doors, or pass-throughs.

(g) Unless prohibited by local building or fire code, a buffer room may not have more than one door.

(2) Ante Room

(a) An ante room shall be supplied with HEPA filtered air.

(b) An ante room shall be at least ISO Class 8. However, an ante room adjacent to a negative pressure buffer room shall be at least ISO Class 7.

(c) Unless prohibited by local building or fire code, an ante room may not have more than one door between the ante room and an unclassified space.

(d) A newly constructed ante room shall be at least 72 square feet.

(e) An ante room shall have a line of demarcation that separates the less clean area from the more clean area.

(f) An ante room shall have a stainless steel sink that:

1. is equipped with hands-free controls for water and soap dispensing;
2. has proper depth and capacity for hand washing up to the elbows;
3. is designed or installed to prevent standing water;
4. is located on the clean side of the line of demarcation away from the buffer room door; and
5. minimizes splashing and dripping of water on adjacent walls and floor.

(g) An ante room sink may not have an aerator mechanism on the nozzle.

(h) An ante room shall have low-lint, disposable towels located in proximity to sink to minimize water dripping and splashing.

(i) An ante room may not contain automatic hand dryers.

(j) An ante room's plumbing systems shall be maintained in a good state of repair and be free of defects that could create conditions favorable for microbial growth.

(k) Exposed plumbing system pipes within the ante room shall be constructed of cleanable, non-corrosive material such as copper, PVC, or stainless steel.

(l) A pharmacy may not place a contamination control mat, such as a "tacky" mat, inside an ISO Classified area. If using a contamination control mat outside of the ante room door, the pharmacy shall replace the mat at least once per day and when visibly soiled.

(m) A cart used in the ante room shall be dedicated to one side of the line of demarcation. Only carts dedicated to the cleaner side of the line of demarcation may enter the buffer room after proper cleaning and disinfecting.

(n) An ante room may not contain a floor drain.

(3) Segregated Compounding Area ("SCA")

Comment [HAE6]: Advisory Committee change.

Comment [7]: 12/4/18: Board Staff recommends no change to original verbiage. The spirit of the proposed standard was to prohibit pipes installed along the wall.

Comment [8]: 12/6/18 Board: accept PAC change

(a) A pharmacy may only prepare low risk level, non-hazardous, non-radiopharmaceutical CSPs in an unclassified SCA if it holds an institutional sterile compounding pharmacy license, issued under M.G.L. c. 112, § 39I.

(c) A pharmacy utilizing an SCA shall adhere to all sections of 247 CMR 17.00, unless otherwise provided.

(d) An SCA shall:

1. be a dedicated, closed room restricted to sterile compounding activities;
2. be located away from unsealed windows, doors that connect to the outdoors, traffic flow, and any environmental control challenges such as restrooms, warehouses, or food preparation areas;
3. be constructed with nonporous, smooth, non-shedding, impermeable material that is free from cracks and crevices, is cleanable, and resistant to degradation by cleaning agents;
4. limit furniture, equipment, and supplies to those essential for sterile compounding and that are easily cleaned and disinfected.
5. have a dedicated stainless steel sink within or immediately adjacent to the SCA that:
    A. is equipped with hands-free controls for water and soap dispensing;
    B. has proper depth and capacity for hand washing up to the elbows;
    C. minimizes splashing and dripping of water on adjacent walls and floor;
    D. does not have an aerator mechanism on the nozzle; and
    E. is located at least one meter away from the PEC; and
6. have low-lint, disposable towels located in proximity to sink to minimize water dripping and splashing.
7. not contain automatic hand dryers; and
8. not contain a floor drain.

(p) A pharmacy utilizing an SCA shall perform environmental monitoring (non-viable and viable) in accordance with 247 CMR 17.24 – 247 CMR 17.27.

(e) The maximum BUD for a CSP prepared in an SCA is 12 hours at room temperature or 24 hours refrigerated.

(f) An SCA shall be equipped with a commercially manufactured positive pressure PEC, such as a laminar airflow workbench ("LAFW") or compounding aseptic isolator ("CAI").

(g) A pharmacy may not use any compounding device in a PEC that is located in an SCA.

17.16: Sterile Compounding Facility; Compounding Aseptic Isolators ("CAI")

17.17: Sterile Compounding Facility; Laminar Air Flow Workbench ("LAFW")

17.18: Sterile Compounding Facility; HVAC Systems

(2) A pharmacy shall have available a detailed HVAC design plan for ISO Classified areas that includes air flow diagrams and pressure differential schematics.

(3) Newly constructed clean rooms shall utilize a closed loop ducted system, a sealed plenum system, or other similar contamination control system for HVAC systems supplying HEPA-filtered air to ISO Classified spaces.

(4) Supply air provided to classified area(s) shall be provided exclusively through ceiling HEPA filters.

(5) A pharmacy shall ensure all pre-filters and HVAC components are maintained in accordance with manufacturer specifications.

(8) A pharmacy shall ensure the HVAC systems that supply HEPA filtered air to ISO Classified areas are operated and monitored 24 hours per day, seven days per week.

(10) Each secondary engineering control shall have ducted air returns mounted low on the wall in order to create a general top-down dilution of room air with HEPA-filtered make-up air.

(11) If utilized, relief air vents shall be mounted low on the wall and designed to prevent the ingress of less clean air or contaminants from adjacent ISO Classified space or ambient air.

17.19: Sterile Compounding Facility; HEPA Filters

(1) A pharmacy shall utilize HEPA filters tested to achieve a minimum efficiency rating in accordance with USP <797>.

(2) Each HEPA filter shall be leak tested at the factory, after installation, upon recertification (every 6 months), and any time a HEPA filter is repaired.

(3) A pharmacy shall immediately remediate a failed HEPA filter by properly repairing or replacing the HEPA filter, recertifying the affected ISO Classified area, and performing environmental monitoring (air and surface, bacterial and fungal) in the affected classified areas.

(4) A pharmacy shall ensure that nothing comes in contact with the HEPA filters, including cleaning and sanitizing agents, aspirate from syringes or compounding equipment, or glass from ampules.

(5) A pharmacy shall have a policy and procedure requiring visual inspection of the external portion of PEC filters for signs of gross contamination and proper repair or replacement, as necessary.

17.20: Sterile Compounding Facility; Airflows and Pressure Differential Monitoring

(1) *Non-hazardous CSPs*: There shall be a minimum differential positive pressure of 0.02 inches water column between:

(a) the buffer room and ante room;
(b) the ante room and unclassified space; and
(c) ISO Class 8 area and unclassified space.

(3) A pharmacy shall measure the differential pressure between each ISO-classified area with a gauge and shall review and document the differential pressure at each location at least once daily or by a continuous recording device.

(5) A pharmacy shall respond to any unexpected or prolonged out of range differential pressure and document its response.

17.21: Sterile Compounding Facility; Temperature and Humidity Monitoring

(1) All ISO Classified areas shall maintain a temperature of 68 degrees Fahrenheit (20 degrees Celsius) or less.

(2) All ISO Classified areas shall maintain a relative humidity of 65% or less.

Comment [HAE9]: Advisory Committee change.

Comment [10]: Board Staff recommends to leave humidity at 65%.

Comment [11]: 12/6/18 Board: leave humidity at 65%

(4) A licensee shall document the temperature and humidity of each secondary engineering control at least daily or by a continuous recording device.

(5) Drugs shall be stored according to USP and package insert directions. A pharmacy shall document the controlled room temperature of drug storage areas at least once daily or by a continuous recording device.

(6) A pharmacy shall maintain procedures describing the manner in which it investigates and responds to out of limit temperature or humidity conditions.

Comment [HAE12]: Advisory Committee change.

17.22: Sterile Compounding Facility; Certification of Classified Areas

(1) Primary and secondary engineering controls shall be certified:

(a) once every 6 months;
(b) whenever a PEC is relocated, added, replaced, or removed;
(c) upon remodeling, change in configuration, or change in square footage; and

(d) immediately following any major repair or major servicing of the compounding facility or engineering controls.

(2) Certification testing shall be conducted in accordance with USP <797>. The certification shall be completed in its entirety within a 72 hour time period. A pharmacy shall use accredited certifiers.

(5) The manager of record or his or her pharmacist designee shall review and sign the certification report.

(6) A Manager of Record or his or her pharmacist designee shall notify the Board, in the manner and format determined by the Board, of a primary or secondary engineering control certification failure.

17.23: Sterile Compounding Facility; Smoke Studies

(1) A pharmacy shall conduct a smoke study:
(a) upon initial certification of each primary and secondary engineering control;
(c) upon recertification of each PEC;
(d) immediately following the remodeling or change in configuration or square footage of any secondary engineering control; and
(e) upon the addition, permanent relocation, or permanent removal of any equipment located within the PEC or SEC.

(4) A pharmacy shall conduct smoke studies during dynamic operating conditions that represent the most challenging compounding conditions encountered by compounding personnel in order to demonstrate that compounding personnel performing manipulations and/or equipment used in the direct compounding area inside of the ISO Class 5 environment are not disrupting the flow of first air (HEPA filtered air stream) over critical sites.

(6) A pharmacy shall ensure that a description and results of each smoke study are documented in the certification report.

17.24: Environmental Monitoring

(1) A pharmacy shall develop an environmental monitoring sampling plan in conjunction with a qualified professional such as a microbiologist, industrial hygienist, or infection control professional.

(2) A pharmacy shall conduct viable air and surface sampling for bacterial and fungal organisms.

(3) A pharmacy shall collect environmental monitoring samples from each primary and secondary engineering control at locations that are prone to contamination.

(25) A pharmacy shall trend routine environmental monitoring results in order to facilitate decision-making for requalification of a controlled environment, remediation efforts, and for maintenance and sanitization schedules.

Comment [HAE13]: Relocated, per advisory committee.

(5) A pharmacy shall maintain an environmental monitoring plan that clearly denotes the frequency and location of viable bacterial and fungal air and surface sampling and non-viable particulate sampling.

(6) A pharmacy shall maintain an environmental sampling log that states the of each sample, sampling time, sampling methodology, and activities taking place in the respective classified areas.

(7) A pharmacy shall conduct environmental monitoring of each primary and secondary engineering control:

(b) as part of the certification of new facilities and equipment;

(c) immediately following any construction, repairs, or servicing of facilities and equipment;

(e) immediately following the addition, removal, replacement, or relocation of a PEC;

(f) as part of the recertification of PECs and SECs; and

(h) in response to a contaminated CSP.

(8) Frequency of environmental monitoring

(a) A pharmacy engaged in low and medium risk level compounding shall conduct routine viable and non-viable air environmental monitoring of each PEC and SEC at least every 3 months.

(b) A pharmacy engaged in high risk level compounding shall conduct routine viable and non-viable air environmental monitoring of each PEC and SEC at least monthly.

(c) A pharmacy engaged in low, medium, or high risk level compounding shall conduct routine viable surface environmental monitoring of each PEC and SEC at least monthly.

(10) Personnel that perform environmental monitoring shall be properly trained and shall demonstrate competency and proficiency in all sampling techniques.

(12) Equipment used for environmental monitoring shall be maintained and calibrated for use at least annually or more frequently in accordance with manufacturer's specifications.

(17) A pharmacy shall incubate environmental monitoring samples in accordance with USP and manufacturer's guidelines.

(18) Environmental monitoring for viable organisms shall include negative controls.

(20) A pharmacy engaged in high risk level compounding shall utilize a two-plate method for collection of viable air and surface samples. One plate shall be a general growth medium and the other plate shall be a medium that specifically supports the growth of fungus.

(22) A pharmacy shall have documentation, such as a "Growth Promotion Certificate," for environmental monitoring plates to validate that the media is able to support microbial growth.

(24) Results of viable air and surface sampling shall be measured by counting the number of discrete colony forming units (CFUs) per plate. The results are expressed as CFU per cubic meter or 25 square centimeters.

Comment [HAE14]: Relocated, per Advisory Committee.

(26) A pharmacy shall ensure its environmental monitoring reports include at a minimum:

(a) date report prepared;
(b) sample collection date and time;
(c) type of sample;
(d) date sample received by lab;
(e) date sample read by the lab;
(f) sampling methodology:
(g) dates of incubation;
(h) identification of sampling locations;
(i) sampling conditions (i.e. dynamic);
(j) activities taking place in the respective classified areas when samples are taken;
(k) media type(s);
(l) media lot number, expiration date, and growth promotion confirmation;
(m) incubation time and temperatures;
(n) results of each sample (raw and calculated CFU count);
(o) the identity of each CFU to at least the genus level; and
(p) indication that the Manager of Record or his or her pharmacist designee reviewed the environmental monitoring sample collection.

(27) Microbiology reports shall be signed by a microbiologist, unless the environmental monitoring resulted in zero CFU.

Comment [HAE15]: Advisory committee change.

Comment [MAC16]: Board staff: change not necessary. Microbiology report would not be generated if no growth.

Comment [17]: 12/6/18 Board: accept PAC change

(28) A pharmacy shall immediately remediate highly pathogenic microorganisms, including gram-negative rods, coagulase positive staphylococcus, molds, and yeasts, regardless of CFU count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

17.25: Environmental Monitoring; Non-viable Particle and Viable Air Sampling

(1) A pharmacy shall collect air samples under dynamic operating conditions.

(2) A pharmacy shall collect viable air samples with a volumetric air sampling device.

(3) A pharmacy shall collect non-viable air samples with an electronic particle counting air sampling device.

(5) The minimum volume of a viable air sample at each sampling location is 1000 liters.

(6) The results of viable air samples shall be described as the number of CFU per cubic meter of air sampled. Viable air sample results shall be evaluated by a microbiologist.

(7) A pharmacy may not utilize passive air sampling procedures (i.e. settling media) to meet environmental monitoring requirements of 247 CMR 17.25**.**

17.26: Environmental Monitoring; Surface Sampling

(1) A pharmacy shall collect surface samples following compounding prior to cleaning.

(2) A pharmacy shall utilize the contact plate method to collect surface samples.

(3) Media used for surface sampling shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g., tryptic soy agar ("TSA") with lecithin and polysorbate 80).

(5) A pharmacy shall clean and disinfect surfaces following collection of a surface sample.

17.27: Environmental Monitoring; Action Levels

(1) A pharmacy shall take immediate remedial action upon notification of above action level environmental monitoring results.

(2) A pharmacy shall conduct a root cause analysis in response to any above action level environmental monitoring result or adverse trend in environmental monitoring.

(3) Non-Viable Air Sample Action Levels:

ISO Class 5	> 3520 particles 0.5 µm or larger per cubic meter of air
ISO Class 7	> 352,000 particles 0.5 µm or larger per cubic meter of air
ISO Class 8	> 3,520,000 particles 0.5 µm or larger per cubic meter of air

(4) Viable Air Sample Action Levels (cumulative count):

ISO Class 5	> 1 CFU
ISO Class 7	> 10 CFU
ISO Class 8	> 100 CFU
Highly pathogenic microorganisms, as defined by the Board	≥ 1 CFU

(5) Surface Sample Action Levels (cumulative count):

ISO Class 5	> 3 CFU
ISO Class 7	> 5 CFU
ISO Class 8	> 50 CFU
Highly pathogenic microorganisms, as defined by the Board	≥ 1 CFU

17.28: Environmental Monitoring; Remediation of Above Action Level Environmental Monitoring Results

(1) A pharmacy shall maintain a policy and procedure for remediation of above action level environmental monitoring results.

(2) A Manager of Record or his or her pharmacist designee shall notify the Board, in the manner and format determined by the Board, of above action level environmental monitoring results.

(7) A pharmacy shall respond to and properly remediate above action level environmental monitoring results in accordance with Board Policy: Response to Above Action Level Environmental Monitoring Results.

(8) A pharmacy shall document its response to each above action level environmental monitoring result.

17.29: Cleaning and Disinfecting

(1) A pharmacy shall document each cleaning in a cleaning log. The log shall include the date, time, cleaning agents utilized, and personnel who performed the cleaning.

(2) Mops, wipes, and other cleaning equipment shall be non-shedding. If a mop or other cleaning equipment is re-usable, it shall be dedicated to the classified area(s).

(3) Cleaning equipment used in hazardous drug compounding environments may not be utilized in non-hazardous drug compounding environments.

(4) Non-compounding personnel who perform cleaning shall be trained and successfully pass initial and annual competency assessments conducted by trained and qualified compounding personnel in both of the following areas:

(a) hand hygiene and garbing; and

(b) cleaning and disinfecting.

(5) Only trained compounding personnel may clean inside an ISO Class 5 work area.

(6) A licensee shall clean and disinfect the critical areas where compounding occurs inside an ISO Class 5 environment:

Comment [HAE18]: Advisory Committee change.

Comment [MAC19]: Board staff: consider moving this section to training section 17.33

Comment [20]: 12/6/18 Board: move to 17.33

Comment [MAC21]: Moved to 17.33(7)

(a) at the beginning of each work shift;
(b) between each batch;
(c) immediately following any spill; and
(d) in the event of, or suspicion of, a breach in compounding procedures or aseptic technique.

(7) A licensee shall follow manufacturer's directions or published data for the minimum contact time for cleaning, disinfecting, and sporicidal agents used in classified areas.

(8) A licensee shall disinfect all rubber stoppers of vials and bottles, the necks of ampules and other items by wiping with sterile 70% IPA and waiting for at least 10 seconds before they are used to prepare CSPs.

(9) A pharmacy shall clean horizontal work surfaces daily.

(10) A pharmacy shall clean floors daily.

(12) A pharmacy shall clean walls, ceilings, storage areas, and supply bins at least once per month.

17.30: Sterile Compounding Process; Hand Hygiene and Garbing

(1) Compounding personnel shall remove personal outer garments, jewelry, piercings, cosmetics, artificial nails, and nail polish before entering the ante room. Natural nails shall be trimmed to ¼ inch or less.
(2) Compounding personnel shall wear clean, laundered scrubs only worn within the facility. A pharmacy shall have a changing area for sterile compounding personnel.

Comment [HAE22]: Advisory Committee change.

(3) Compounding personnel shall use dedicated shoes or shoe covers while in classified areas or segregated compounding areas.

(4) Prior to entering an ante room, compounding personnel shall don scrubs and either dedicated shoes or shoe covers.

(5) Once inside the ante room, but prior to crossing the line of demarcation, compounding personnel shall perform the following tasks in the following order: don a head cover, facial hair cover if applicable, and face mask. While crossing line of demarcation, don shoe covers.

(6) Once on the clean side of the line of demarcation, but prior to entering the buffer room, compounding personnel shall perform the following tasks in the following order:
(a) wash hands and forearms to the elbows for at least 30 seconds with antimicrobial soap and water. The hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under warm running water followed by vigorous hand washing.
(b) dry with lint-free disposable towels.

(c) don:

1. a non-shedding clean coverall for low and medium risk level compounding; or
2. a non-shedding sterile coverall for high risk level compounding.

(7) Once garbing and hand hygiene procedures are completed, compounding personnel shall access the buffer room without touching hands on any surface.

(8) Once inside the buffer room, compounding personnel shall perform antiseptic hand cleansing using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations and hands shall be allowed to dry thoroughly before donning sterile powder-free gloves.

(9) Compounding personnel shall routinely disinfect gloves with sterile 70% IPA after contacting non-sterile objects and after exposure to less than ISO Class 5 air.

(11) Compounding personnel shall repeat all hand hygiene and garbing activities if personnel cross line of demarcation from the clean to the less clean side of ante-room or if exposed to less than ISO Class 8 air.

(12) The non-shedding coverall may be removed and retained in the compounding area if not visibly soiled to be re-donned by the same personnel during that shift only. All other garb must be discarded and replaced with new garb before entering the compounding area.

(13) Sterile compounding personnel shall doff garb in the following order:

(a) Remove gloves;
(b) Remove mask, goggles, or face shield;
(c) Remove coveralls;
(d) Remove dedicated shoes or shoe covers.

17.31: Sterile Compounding Process; Aseptic Technique

(1) Food and drinks are not allowed in any ISO Classified area.

(2) A pharmacy may not store corrugated cardboard boxes or other particulate producing materials in any ISO Classified area.

(4) Compounding personnel shall remove supplies, equipment, and other materials from shipping cartons and cardboard boxes in an unclassified area and shall wipe said supplies, equipment, and other materials with residue free disinfectant before transporting said items into an SCA, ante area, or buffer area.

(5) Compounding personnel shall disinfect all supplies and drug components with an appropriate agent prior to moving said supplies and drug components into the ISO Class 5 compounding area.

(6) Syringes, needles, and tubing are only removed from outer wrapper packaging in the ISO Class 5 area.

(7) A licensee shall don sterile gloves for all sterile compounding, regardless of the type of PEC.

(8) Compounding personnel shall inspect sterile-gloved hands and gauntlet sleeves prior to compounding for wear and tear and replace gloves as needed.

(9) Compounding personnel shall routinely disinfect sterile-gloved hands with sterile 70% IPA prior to entering/re-entering an ISO Class 5 area and after contacting non sterile objects.

(10) Compounding personnel shall perform manipulations in the direct compounding area inside of the ISO Class 5 environment in such a way as to not disrupt the flow of first air (HEPA filtered air stream) over critical sites.

(11) Compounding personnel shall inspect each component for visible particulate matter, tampering, breaks in packaging, water damage or moisture and other changes which would render the item unacceptable for use in sterile compounding.

17.32: Sterile Compounding Process; Miscellaneous

(1) A pharmacy shall use filtered needles or straws for any compounding involving the use of glass ampules.

(3) A pharmacy shall immediately respond to and remediate any broken, damaged, or spilled CSP.

(4) A pharmacy shall ensure all classified areas allow for the orderly placement of equipment and materials to prevent confusion among ingredients, containers, labels, in-process materials, and finished preparations and shall be designed, arranged, and used to prevent cross-contamination.

(5) A pharmacy shall maintain a written continuity of care plan that describes how patient needs will be met in the event the pharmacy is unexpectedly unable to compound or dispense CSPs.

17.33: Sterile Compounding Personnel Training; General

(1) Compounding personnel shall be free from active infection and skin areas shall be intact without any burns, sunburns, lesions, abrasions, or cuts.

(2) A pharmacy shall ensure all compounding personnel are properly trained in sterile compounding, have successfully completed gloved fingertip/thumb sampling, and have been media-fill qualified for the risk level and type of compounding conducted.

(3) A pharmacy shall maintain documentation of all training activities, competency assessments, and compounding qualifications. The documentation shall be readily retrievable and retained for at least two years.

(4) A pharmacy shall maintain a written or electronic file for all sterile compounding personnel, which includes for each individual: a job description, roles and responsibilities, documentation of initial and ongoing competency assessments, and documentation of initial and ongoing compounding qualification activities.

(5) All personnel who physically compound or directly supervise compounding shall pass didactic coursework, practical skill assessment, media fill testing, and gloved fingertip/thumb sampling before being allowed to compound sterile preparations.

Comment [MAC23]: Moved to below (8)

(8) A pharmacy shall, at least annually, assess and document core competencies for all personnel who physically compound or directly supervise compounding.

Comment [MAC24]: Moved from below.

(7) In addition to the annual assessment of core competencies, a pharmacy shall ensure all personnel who physically compound or directly supervise compounding are evaluated by visual observation on hand hygiene and garbing, cleaning and disinfecting, and aseptic technique initially and at least every six months.

Comment [MAC25]: Moved to below (6)

(6) Compounding personnel shall be requalified in all core competencies if a pause in compounding practice exceeds six months.

Comment [MAC26]: Moved from above.

(9) In the event a compounding individual fails a written sterile compounding assessment exam, gloved fingertip/thumb sampling, or media-fill test, he/she may not compound until he/she is requalified and successfully retested.

(10) Sterile compounding pharmacies shall maintain accurate, comprehensive, and organized records and reports, immediately retrievable for inspection, related to environmental monitoring, certification, product testing, validation, personnel glove fingertip sampling, media fills, certificates of analysis, compounding records, and master formulation records.

(12) A pharmacy shall review and document actions in response to repeated failed gloved fingertip tests or media fills, including the potential impact on CSPs.

(13) A pharmacy shall verify that each lot of media for personnel monitoring is able to support microbial growth.

17.34: Sterile Compounding Personnel Training; Gloved Fingertip/Thumb Sampling

(1) The action level for a gloved fingertip/thumb sample for hand hygiene and gloving is 1 CFU for both gloves.

(2) The action level for a gloved fingertip/thumb sample for aseptic technique performed after each media fill is 3 CFU for both gloves.

(3) All compounding personnel shall successfully complete at least 3 gloved fingertip/thumb sampling procedures before initially being allowed to prepare CSPs and following any gloved fingertip/thumb sampling failure or media fill failure. The action level for this gloved fingertip/thumb sample is 1 CFU for both gloves.

(4) During the initial gloved fingertip/thumb sampling, fingertip/thumb samples shall be taken of both gloved hands onto media plates immediately after compounders perform hand hygiene and garbing but *before* their gloves are cleaned with sterile 70% IPA.

(5) All gloved fingertip/thumb sampling performed after the initial qualification shall be performed after each media fill.

(6) Frequency of gloved fingertip/thumb sampling

(a) After initial qualification, compounding personnel who prepare low or medium risk level CSPs shall perform gloved fingertip/thumb sampling at least every 6 months after each media fill.

(b) After initial qualification, compounding personnel who prepare high risk level CSPs, CSPs with extended BUDs, or CSPs prepared in batches that will be stored in the freezer shall perform gloved fingertip/thumb sample at least every 3 months after each media fill.

(8) Gloved fingertip/thumb sampling media shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80).

(10) A pharmacy shall incubate gloved fingertip/thumb samples in accordance with USP or manufacturer specifications.

17.35: Sterile Compounding Personnel Training; Media Fill Challenge Testing

(1) Compounding personnel who prepare low and medium risk level CSPs shall complete a media fill before initially being allowed to prepare CSPs. Following initial qualification, compounding personnel shall complete one media fill at least once every six months.

(2) Compounding personnel who prepare high risk level CSPs shall complete a media fill before initially being allowed to prepare CSPs. Following the initial qualification, compounding personnel who prepare high risk level CSPs, CSPs with extended BUDs, or CSPs prepared in batches that will be stored in the freezer shall complete a media fill at least every 3 months.

(2) The high risk level media fill procedure must simulate a high risk level CSP by producing the sterile growth media from non-sterile powder.

(4) Media fill challenge testing shall be performed under conditions closely simulating the most challenging or stressful conditions encountered during compounding.

(5) A pharmacy shall utilize general microbial growth promotion media, such as Soybean-Casein Digest.

(6) A pharmacy shall incubate media fill units utilizing general microbial growth promotion media in accordance with USP and manufacturer guidelines.

17.36: Sterile Compounding Equipment

(1) A pharmacy shall clean, maintain, calibrate, and service equipment associated with compounding or used to monitor controlled environments in accordance with manufacturer's specifications.

(2) A pharmacy shall ensure personnel who use equipment received training, demonstrated the ability to use the equipment properly, and are able to appropriately respond to an equipment malfunction. Competency assessments shall be performed and documented at least one time per year.

(3) A pharmacy shall test Automated Compounding Devices ("ACD") for volumetric and gravimetric accuracy at least daily or more frequently in accordance with manufacturer specifications.

(4) A pharmacy shall ensure balances and scales used to prepare CSPs are calibrated and qualified for performance and tolerances at least annually or more frequently in accordance with manufacturer specifications.

(5) A pharmacy shall ensure microbiological incubators are calibrated and certified to National Institute of Standards and Technology ("NIST") standards at least annually or more frequently in accordance with manufacturer specifications.

Comment [MAC27]: Updated abbreviation

(7) While incubating samples, a pharmacy shall document temperatures of incubator(s) at least once each business day, or by continuous monitoring device.

Comment [HAE28]: Advisory Committee change.

17.37: Sterile Compounding Robotics

(1) Robotic compounding equipment shall be constructed with a hard solid cleanable surface that is resistant to degradation by cleaning agents and disinfectants.

(2) A sterile compounding robot utilized to prepare CSPs shall be considered a PEC and shall maintain unidirectional airflow at the critical site and ISO Class 5 conditions during dynamic operating conditions.

(3) A sterile compounding robot shall be located in an ISO Class 7 buffer area.

(4) A pharmacy shall perform routine maintenance and calibration of the aseptic filling robot at least twice per year or more often if required by the device manufacturer.

(5) A pharmacy shall maintain a daily record of the accuracy of the sterile compounding robot. The Manager of Record shall ensure the precision of the sterile compounding robot is maintained, all records are reviewed, and all out of specifications are responded to immediately.

(6) A sterile compounding robot shall utilize two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID), or another similar process, to identify ingredients and components during set up and replacement of components.

(7) A sterile compounding robot shall be equipped with the capability to identify all ingredients, components, and volumes to ensure CSPs are accurately prepared and labeled.

(8) A pharmacy shall validate the sterile compounding robot maintains sterility of final CSPs through media fill challenges, in accordance with 247 CMR 17.35, Personnel Media-Fill Challenge Testing.

(9) A pharmacy shall assure that tubing set(s) used for the sterile compounding robot are traced from the source container to the port where it is attached during the initial daily set up and with each change in the source container.

(10) Compounding personnel shall be trained and shall demonstrate competency in the use of the aseptic filling robot. A pharmacy shall document initial training, as well as annual competency assessments.

(11) The pharmacist in charge or his or her designee shall validate changes to the sterile compounding robot product database.

(12) A pharmacist must review and document any overrides to alerts from the sterile compounding robot upon final verification.

(13) A pharmacy shall adhere to manufacturer recommendations pertaining to the maximum time ingredients or components may be stored in the sterile compounding robot. Documentation shall occur each instance an ingredient or component is added or replaced.

(14) A licensee shall clean and disinfect the critical areas where compounding occurs inside the ISO Class 5 environment of the aseptic filling robot:

(a) at the beginning of each work shift;

(b) immediately following any spill;

(c) in the event of, or suspicion of, a breach in compounding procedures or aseptic process; and

(d) in accordance with manufacturer's specifications.

(15) A pharmacy shall properly disinfect all ingredients and components prior to placement in the sterile compounding robot.

17.38: Sterile Compounding Ingredient and Component Selection

(1) A pharmacy shall store compounding ingredients and components according to manufacturer specifications or USP storage conditions.

(2) A pharmacy may not obtain components from a facility that is not registered by the FDA unless said components are not available from any FDA registered facility. In the event a pharmacy obtains components from a facility that is not registered by the FDA, the pharmacist shall evaluate the Certificate of Analysis, manufacturer reputation, and the reliability of the source.

(3) A pharmacy that performs high risk level sterile compounding shall confirm that APIs meet the requirements of the federal Food, Drug & Cosmetics Act, § 503a(b)(1)(B).

(4) A pharmacy shall utilize API intended for human-use in compounding CSPs for human patients.

(5) A pharmacy shall obtain components utilized in high risk level sterile compounding, including buffers, diluents, excipients, preservatives, and vehicles from commercially available sources if available in the marketplace. A pharmacy may not compound or produce high risk level sterile compounding components, including buffers, diluents, excipients, preservatives, and vehicles, if said products are commercially available.

(6) A pharmacy shall use commercially available sterile containers and sterile container closure systems if available in the marketplace.

17.39: Sterilization and Depyrogenation

(1) A pharmacy may not utilize ethylene oxide gas or irradiation to sterilize components, equipment, ingredients, or CSPs.

(3) A pharmacy shall sterilize the final preparation of a high risk level CSP in accordance with USP <797>, even if intermediate or stock solutions were previously sterilized. In the event a component of a CSP cannot be sterilized, a pharmacy shall confirm the sterility of the final patient CSP in accordance with USP <71>.

(4) A pharmacy shall ensure that all glassware and containers utilized for sterile compounding are depyrogenated.

(5) Sterilization by filtration

(a) A pharmacy shall perform sterilization by filtration in an ISO Class 5 environment using pharmaceutical grade, pyrogen-free, 0.2 micron sterile filters that are suitable for the intended use.

(b) A pharmacy shall perform and document a filter integrity test (such as bubble point) at the conclusion of the compounding procedure.

(6) Sterilization by Dry Heat and Steam

(b) A pharmacy shall pass CSPs through a filter with a nominal pore size not larger than 1.2 µm immediately prior to filling containers that will undergo terminal sterilization unless said CSP cannot be filtered.

(7) Dry Heat Ovens and Steam Sterilizers

(a) A pharmacy may not locate a dry heat oven or steam sterilizer in a buffer room.

(b) A pharmacy shall ensure each dry heat oven and steam sterilizer operates properly and in accordance with manufacturer specifications pertaining to required temperatures, sterilizing cycle time, depyrogenation cycle time, loading patterns, loading capacity, temperature monitoring, placement of thermocouplers or other temperature sensing device, use of biological indicators and endotoxin challenge vials, and filter integrity testing, as applicable.

(c) A pharmacy shall verify the effectiveness of each dry heat sterilization, dry heat depyrogenation, and steam sterilization process using appropriate Biologic Indicators or Endotoxin Challenge Vials in accordance with USP Chapter <1035>.

(d) A pharmacy shall ensure dry heat ovens and steam sterilizers are equipped with a system for controlling and recording temperature and exposure time.

(e) A pharmacy shall maintain a log of temperature and exposure time for each use of the dry heat oven or steam sterilizer. The log shall be readily retrievable and maintained for at least 2 years.

17.40: Sterility and Endotoxin Testing

(1) A pharmacy shall conduct sterility testing on the following types of CSPs:

(a) CSPs with extended BUDs, regardless of risk level;

(b) high risk level CSPs that are prepared in groups of 25 identical individual single dose packages (i.e., ampules, bags, syringes, vials) for administration to multiple patients;

(c) high risk intermediate or stock solutions;

(d) high risk level CSPs exposed longer than 12 hours at refrigerated temperature 2-8 ºC (36-46 ºF) before being sterilized; and

(e) high risk level CSPs exposed longer than 6 hours at room temperature 8 ºC (46 ºF) before being sterilized.

(2) A pharmacy may not dispense a CSP that requires sterility testing until and unless it receives negative sterility testing results.

(3) A pharmacy shall utilize both a general growth media for bacteria and a fungal specific media for all high risk level CSP sterility tests.

(4) A pharmacy shall conduct sterility testing and test the proper number of articles in accordance with USP.

(5) A pharmacy shall send each failed sterility test specimen for microbial identification to at least the genus level. All Staphylococcus organisms must be identified as coagulase positive or negative.

(6) Except for inhalation and topical ophthalmic preparations, a pharmacy shall conduct bacterial endotoxin assay testing according to USP <85> on the following types of CSPs:

(a) high risk level CSPs with extended BUDs;

(b) high risk level CSPs that are prepared in groups of 25 identical single dose packages (i.e., ampules, bags, syringes, vials) for administration to multiple patients;

(c) high risk intermediate or stock solutions;

(d) high risk level CSPs exposed longer than 12 hours at refrigerated temperature 2-8 ºC (36-46 ºF) before being sterilized; and

(e) high risk level CSPs exposed longer than 6 hours at 8 ºC (46 ºF) before being sterilized.

(7) A pharmacy may not dispense a CSP that requires endotoxin testing until it receives endotoxin testing results within limits in accordance with USP <85>.

(8) A pharmacy may conduct sterility and endotoxin testing internally, provided that personnel are trained through an accredited certificate program and the pharmacy utilizes an accredited laboratory to conduct sterility and endotoxin testing at least once every 3 months.

(9) A pharmacy shall initiate an investigation and document a CAPA for any out of specification product testing results.

17.41: Storage and Beyond-Use-Dating ("BUD")

(1) In the absence of sterility testing, a pharmacy may not exceed the following BUDs:

Aseptically Prepared CSPs	Controlled Room Temp (20°C to 25°C)	Refrigerated (2°C to 8°C)	Freezer (-25°C to -10°C)
Prepared from one or more non-sterile starting components	1 day	4 days	45 days
Prepared from only sterile, commercially available starting components	4 days	9 days	45 days

(3) The BUD assignment shall begin on the date the pharmacy prepared the CSP.

(4) A pharmacy may not extend BUDs beyond those described in 247 CMR 17.41(1) unless it has scientific evidence that the CSP remains potent, stable, and sterile under specified storage conditions for the duration of the BUD. Such evidence may be from relevant and reliable sources or direct testing.

(5) A pharmacy may not assign a BUD to any CSP that exceeds 90 days from the date of

compounding.

(7) In the event the storage condition of a CSP is changed, a pharmacy shall assign a new BUD that does not exceed the original BUD or the maximum BUD for the new storage temperature, whichever period is shorter.

(8) A pharmacy may not assign a BUD to a CSP that exceeds the expiration date of any component or BUD of any intermediate or stock solution CSP used to produce the final patient CSP.

(9) A pharmacy shall utilize freezer units that freeze CSPs to a frozen state.

17.42: Packaging and Preparation Containers

A pharmacy shall verify and document the impact on product sterility, stability, potency, container/vial membrane, and container closure systems when freezing and thawing CSPs initially before compounding and whenever there is a change to the container closure system, components, or process.

17.43: Master Formulation Records

(1) A licensee shall maintain and follow a master formulation record for the following types of CSPs:

(a) high risk level CSPs;
(b) low or medium risk level CSPs with extended BUDs;
(c) low or medium risk level CSPs compounded in anticipation of a patient specific prescription or order;
(d) allergen extracts as CSPs; and
(f) CSPs prepared by a sterile compounding robot.

(2) A pharmacy shall validate that the CSPs produced according to a master formulation record are sterile, stable, and have the correct potency for the assigned BUD in the following circumstances:

(a) high risk level intermediate or stock solutions;
(b) CSPs with extended BUDs; and
(c) CSPs prepared in batches that will be stored in the freezer.

A pharmacy shall conduct this validation initially and any time there is a change to the master formulation record.

(3) A pharmacy shall utilize a qualified professional to conduct the stability, sterility, and potency tests.

(4) A master formulation record shall include:

(a) the risk level of compounding;
(b) all ingredients;
(c) detailed compounding processes;
(d) BUD assignment;

(e) all equipment;
(f) the primary and secondary engineering controls utilized;
(g) product testing including sterility, stability, and potency, as applicable;
(h) quality control procedures including final release checks;
(i) depyrogenation and sterilization procedures and validations, as applicable;
(j) compounding personnel;
(k) garbing protocol;
(m) storage conditions;
(n) container closure system; and
(o) required labeling information.

17.44: Compounding Record

(1) A compounding record shall comply with requirements of USP <797> and shall include at least the following:

(f) lot numbers and expiration dates of all ingredients and components;
(h) name of the person who prepared the preparation and name of the pharmacist who verified the preparation;
(i) identity of any automated compounding device, if applicable;
(k) batch lot number, prescription or order number, as applicable;
(m) assigned BUD;
.

(2) The compounding record shall serve as the accountability documentation described in M.G.L. c. 112, §§ 39D & 39F.

(3) A licensee shall complete a compounding record each time he or she prepares a CSP. The licensee shall review the compounding record for accuracy and completeness. A pharmacist shall verify the compounding record prior to releasing inventory or dispensing the CSP.

(4) A pharmacist shall verify the compounding record followed the master formulation record, if applicable, to ensure errors did not occur in the compounding process and the preparation is suitable for use.

17.45: Verification of Compounding Accuracy; Release Checks

(1) A pharmacist shall perform a release check and shall verify:
(a) correct fill volume and quantity;
(b) drug identity and strength;
(c) the CSP matches the compounding record, master formulation record, and prescription or order, as applicable;
(d) the ingredients measured during compounding;
(e) packaging;
(f) labeling; and
(g) expected physical appearance.

Comment [29]: 12/4/18: Board staff recommendations- M.G.L. c. 112, §§ 39D & 39F: "Accountability documentation", physical documentation validating the lot numbers and expiration dates or beyond-use dates of drugs or drug preparations with a patient drug prescription order from a practitioner listed in section 9 of chapter 94C; provided, that "accountability documentation" shall include evidence of receipt of patient-specific prescriptions prior to dispensing in accordance with section 17 of said chapter 94C. The purpose of accountability documentation shall be: to facilitate tracing of a complex non-sterile drug preparation or sterile drug preparation back to the pharmacy where it was compounded; identify the individual, pharmacy technician or automated compounding device that compounded the complex non-sterile drug preparation or sterile drug preparation; and identify the prescription order that generated the compounding of the complex non-sterile drug preparation or sterile drug preparation.

Comment [HAE30]: I need the language for the practice standard. This requirement does not apply to n=1.

Comment [MAC31]: See above for changes. Draft USP requires compounding record for all CSPs.

(2) After compounding is completed, a pharmacist shall visually examine each CSP for the presence of particulate matter or other defects.
(3) A pharmacist shall visually inspect CSPs for container closure integrity and any other potential defect.
(4) If CSPs are not distributed immediately after compounding and are stored in the pharmacy, a pharmacist shall perform a pre-release check prior to dispensing to ascertain container defects, damage, particulates, or other unexpected and undesirable circumstance.

(5) In the event a CSP does not pass a release check, the pharmacy shall:
(a) quarantine the CSP;
(b) perform a root cause analysis; and
(c) document the results of the root cause analysis and remediation plan.

17.46: Labeling

(1) In addition to standard prescription labeling requirements, a pharmacy shall include the following information on the label or container of each CSP:
(a) BUD;
(b) batch or lot number of anticipatorily prepared CSPs;
(c) storage and handling information; and
(d) a statement indicating the product is a sterile compounded drug preparation.

Comment [HAE32]: This is slightly different than the statute.

(2) A sterile compounding pharmacy and a non-resident sterile compounding pharmacy shall also include a telephone number on the label or container of each CSP to foster communication between patients and a pharmacist who has access to the patient's records, in accordance with M.G.L. c. 94C, § 21. The phone shall be staffed during regular hours of operation every day and not less than 56 hours per week.

17.47: Inventory Storage and Handling; Delivery of CSPs

(1) A pharmacy shall ensure the methods used to transport CSPs from the pharmacy to the patient do not damage the CSP and maintain appropriate temperatures during transit.

(2) A pharmacy shall store finished CSPs and drug components separate from food or specimens.

(3) A pharmacy shall verify that packaging, containers, and materials maintain physical integrity, sterility, stability, and purity of CSPs.

17.48: Drug Utilization Review and Patient Counseling

(1) A pharmacist or pharmacy intern shall perform a Drug Utilization Review in accordance with 247 CMR 9.07.

(2) In addition to the counseling described in M.G.L. c. 94C, § 21A, counseling on a CSP shall include the proper use, possible side effects, storage, handling, and disposal of the medication, as applicable.

(3) A pharmacist or pharmacy intern shall instruct the patient or the patient's agent to report any adverse event related to the CSP to the compounding pharmacy.

(4) A pharmacist or pharmacy intern shall instruct the patient or patient's agent to observe and report any changes in the physical characteristics of the CSP to the pharmacy.

(5) 247 CMR 17.48(2) through (4) do not apply to institutional sterile compounding pharmacies.

17.49: Quality Assurance ("QA") Program

A pharmacy shall maintain a formal, written Quality Assurance Program in accordance with USP <1163> and 247 CMR 15.00.

17.50: Sterile Compounding Policies and Procedures

A pharmacy shall maintain a written policy and procedure pertaining to the following:

(1) personnel monitoring, including gloved fingertip/thumb sampling and media fill challenge testing;

(2) environmental monitoring, including non-viable air and viable air and surface testing;

(3) ISO classified area monitoring, including airflows and pressure differential monitoring and temperature and humidity monitoring;

(4) proper storage, handling, shipping, packaging, transportation, and delivery of CSPs;

(5) final release checks and verification of all CSPs;

(6) Quality Assurance Program, including RCA and CAPA;

(8) hand hygiene and garbing processes;

(9) aseptic technique;

(10) patient monitoring and adverse event reporting;

(11) patient monitoring in response to suspected or identified problems with CSPs or reported adverse events;

(12) maintenance, calibration, and cleaning intervals for all pieces of equipment;

(13) response (i.e. spill kit) to broken, damaged, or spilled CSPs;

(14) compounding procedures specific to each risk level;

(15) sterilization and depyrogenation processes, as applicable;

(16) sterility and endotoxin testing, as applicable;

(17) assignment of BUD;

(18) proper waste handling and disposal;

(19) cleaning and disinfecting; and

(20) potency and stability testing, as applicable.

17.51: Defective Products

A pharmacy shall immediately recall any CSP that is contaminated or defective or suspected to be contaminated or defective.

REGULATORY AUTHORITY

247 CMR 17.00: M.G.L. c. 112, §§ 39G, 39I, and 42A