

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE PHARMACY ADVISORY COMMITTEE

239 Causeway Street, Fourth Floor ~ Room 417A

Boston, Massachusetts 02114

Friday December 11, 2015

Advisory Committee Members Present

Lindsey Tucker, DPH Associate Commissioner, Chair

Caryn D. Belisle, RPh, MBA (Expert in USP<71>)

John Walczyk, RPh, PharmD (Expert in USP<795>)

Antoinette Lavino, RPh, BCOP (Expert in USP<797>)

Judith Barr, MEd, ScD, FASHAP (Expert in Pharmacoeconomics)

Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)

Francis McAteer (Expert in Microbiology)

Michael C. Thomas (Expert in Clinical Pharmacology)

Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)

Anthony M. Cundell, PhD (Expert in USP <71>) – via remote participation

Eric Kastango, RPh, MBA, FASHP (Expert in USP <797>) – via remote participation

Advisory Committee Members Not Present

Sylvia B. Bartel, RPh (Expert in USP<797>)

David H. Farb, PhD (Expert in Clinical Pharmacology)

Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)

Rory K. Geyer, PhD (Expert in cGMP)

Support Staff

James Lavery, JD, Director, Divisions of Health Professions Licensure

Heather Engman, JD, MPH, Board of Pharmacy Counsel

Kelly Ann Barnes, JD, RPh Director of Pharmacy Quality Assurance

Colleen Kate Collins, PharmD, RPh, Pharmacy Investigator

Richard Harris, Project Analyst

Michelle Chan, Quality Assurance Pharmacist

David Dunn, RPh, Assistant Executive Director

Board of Pharmacy Members

Michael J. Godek, RPh

TOPIC:

1. WELCOME & CALL TO ORDER

10:05 AM

DISCUSSION: At 10:05 AM, Associate Commissioner at the Department of Public Health (DPH), Lindsey Tucker called the meeting of Pharmacy Advisory Committee to order. She stated that the meeting is a public meeting and is being recorded. She asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. Members of the Advisory Committee and Board staff introduced themselves. E. KASTANGO and A. CUNDELL were participating remotely.

NOTE: A quorum was present.

TOPIC:

2. APPROVAL OF AGENDA

10:08 AM

DISCUSSION: L. TUCKER asked if there were any changes to the agenda. J. LAVERY noted that #8 was a typo on the agenda and should be stricken.

ACTION: At 10:08 AM motion by M. THOMAS seconded by A. LAVINO and voted unanimously by roll call to approve the agenda with the noted change.

M. THOMAS: yes, F. MCATEER: yes, K. BYERS: yes, J. BARR: yes, A. LAVINO: yes, J.

WALCZYK: yes, C. BELISLE: yes, K. THOMASSET: yes, E. KASTANGO: yes, A. CUNDELL: yes.

TOPIC:

3. APPROVAL OF MINUTES FROM OCTOBER 5, 2015 MEETING

10:09 AM

DISCUSSION: The approval of minutes will be deferred. Minutes will be sent for the October 5, 2015 meeting with the minutes from this meeting.

TOPIC:

4. ABNORMAL RESULTS SUB-COMMITTEE UPDATE

10:09 AM

DISCUSSION:

L. TUCKER turned the meeting to Director of Pharmacy Quality Assurance, K. BARNES. K. BARNES addressed the group on behalf of Director of Compliance, W. FRISCH and herself. She noted that the last meeting of the Sub-Committee was October 30, 2015 and the group discussed recommendations and policy standards for remediation of above USP <797> action levels taken from an ISO 7 Buffer room. A memo was sent to from the Sub-Committee to the Full Committee detailing these steps. She stated that the Sub-Committee already voted on the matter and they are requesting a vote from the Advisory Committee to move forward with such recommendations to the Board.

K. BARNES went through line by line and read the memo titled "Proposed Policy Standards for Sterile Compounding (ISO 7 Buffer Room)" as noted below in italics.

Pharmacy maintains policy and procedures defining a remediation plan to address abnormal environmental monitoring results in accordance with "Board Policy 2015-xx: Response to Abnormal Environmental Monitoring Results."

A pharmacist Manager of Record or pharmacist designee shall notify the Board via email notification within 24 hours of receiving notification of abnormal Environmental Monitoring results from the microbiologist.

A pharmacist Manager of Record or pharmacist designee shall submit Disclosure of Abnormal Results accompanied by the microbiology reports associated with abnormal environmental monitoring results within 7 days of receiving the reports in accordance with 247 CMR 20.

A Pharmacy shall immediately assess abnormal environmental monitoring results and may not prepare CSPs (Compounded Sterile Preparations) until a remediation plan is developed and implemented in accordance with "Board Policy 2015-xx: Response to Abnormal Environmental Monitoring Results."

A Pharmacy shall develop a remediation plan in accordance with “Board Policy 2015-xx: Response to Abnormal Environmental Monitoring Results.”

A pharmacy shall engage the assistance of qualified personnel, such as a microbiologist, infection control professional, or an industrial hygienist to develop a remediation plan.

A pharmacy shall properly remediate abnormal environmental monitoring results in accordance with “Board Policy 2015-xx: Response to Abnormal Environmental Monitoring Results.”

Successful remediation of abnormal environmental monitoring results shall be proven by repeat environmental monitoring microbiology reports demonstrating results within acceptable levels.

A pharmacy shall submit the completed remediation plan including microbiology report from repeat environmental monitoring to the Board within 30 days of the pharmacy’s initial notification of the results or a timeframe agreed upon by the Executive Director or their designee.

A pharmacy shall perform repeat environmental monitoring of non-viable air and viable air and surface (bacterial and fungal) as part of remediation to abnormal environmental monitoring results. The pharmacy may limit the repeat environmental monitoring to the affected ISO classified space based on the pharmacy’s environmental monitoring sampling plan unless otherwise directed by the Board.

K. BARNES noted that the standards she just read were standards that were already approved for the ISO 5 area and as discussed at the Sub-Committee level those standards apply to all areas. K. BARNES stated that the standards she is about to read are the standards specific to the ISO 7 Buffer Room.

ISO 7 Buffer Room:

Upon receipt of an abnormal environmental monitoring result in ISO 7 buffer room, a pharmacy may resume compounding for low and medium risk CSPs if:

- The environmental monitoring data does not indicate 3 or more consecutive sampling reports with above action level results within the last 6 months and*
- The pharmacy has immediately assessed abnormal environmental monitoring results, developed and implemented a remediation plan, and scheduled repeat monitoring.*

K. BARNES added that in the ISO 5 area, the standard was decided that the registrant does not resume compounding until they receive the follow up results. She stated that the Sub-Committee felt that in the ISO 7 Buffer Area, the pharmacy could assess the result, begin remediation and may not need to await the repeat monitoring report prior to compounding, but the pharmacy would need to consider the trending of previous results.

A pharmacy resuming compounding of low and medium risk CSPs during remediation of ISO 7 buffer room abnormal results shall limit the BUDs (Beyond Use Dates) for CSPs to 24 hours room temperature, 3 days refrigerated or a timeframe agreed upon by the Executive Director or their designee until the repeat environmental monitoring reports demonstrate results within acceptable levels.

K. BARNES noted that the Sub-Committee felt that although it might be safe to resume

compounding, the Pharmacy would want to limit BUD, until you got the report that you remediated the organism. The group discussed the time frame and it was said that the numbers came from high risk BUDs. It was noted that the term “abnormal results” will be clarified in the regulations to “above action level.” It was also noted that high risk would be already included in the dating noted above, since that is the standard BUD for high risk compounds. It was recommended that the Board include “high risk” language above as a technical change for clarification purposes.

A pharmacy may not resume compounding if the environmental monitoring data indicates 3 or more consecutive sampling reports with above action level results within the last 6 months.

A pharmacy may not engage in high risk compounding upon receipt of an abnormal environmental monitoring result in ISO 7 buffer room if the environmental monitoring data indicates 2 or more consecutive sampling reports with above action level results.

A pharmacy may not freeze any CSP upon receipt of an abnormal environmental monitoring result in ISO 7 buffer room until repeat monitoring reports demonstrate results within acceptable levels unless otherwise approved by the Executive Director or their designee.

K. BARNES clarified that the freezing standard would apply to all levels of compounding: low, medium and high risk.

ACTION: At 10:26 AM motion by A. LAVINO seconded by J. WALCZYK and voted unanimously by roll call to accept the vote and recommendation taken by the Sub Committee concerning response to an action level in the ISO 7 Buffer Room with the technical correction as noted.

M. THOMAS: yes, F. MCATEER: yes, K. BYERS: yes, J. BARR: yes, A. LAVINO: yes, J. WALCZYK: yes, C. BELISLE: yes, K. THOMASSET: yes, E. KASTANGO: yes, A. CUNDELL: yes.

K. BARNES asked for a representative from the Advisory Committee to bring the ISO 7 policy standard recommendations forward to the January 5th, 2016 Board meeting. A. LAVINO volunteered but noted she would need to check her schedule.

TOPIC:

5. SHARED PHARMACY SERVICES/TELEPHARMACY

10:28 AM

DISCUSSION: Assistant Executive Director, D. DUNN discussed the topic of Telepharmacy and noted he was presenting it with Board member, M. GODEK. D. DUNN noted the Committee was sent documents to review on this topic. He stated that Telepharmacy is an emerging model of Shared Pharmacy Services where through video conferencing pharmacists can connect with patients or physicians to deliver pharmaceutical care. He stated they are looking to see if the Advisory Committee believes that this is an approach that should be considered by the Board for regulation.

A. LAVINO stated that many of these services have been serving rural areas and the underserved, and asked how the Board plans on wording regulations because this could affect pharmacy positions.

D. DUNN stated that there are some draft questions for the Committee that are outlined in a memo

titled “Telepharmacy.” He noted that the second question asks a similar question, in that, should this be limited to certain populations or geographic areas? He noted that North Dakota is one of the lead states with this service. He noted that urban areas may also benefit from these services. D. DUNN read the questions from the memo as follows:

1. Does the Committee agree that Telepharmacy is a topic that the Board should consider for the development of guidance or regulation?
2. Are there limitations to population, geographical concerns where implementation of Telepharmacy would or would not be in the best interest of the public?
3. What type of licensing should we require if any?
4. What type of security safeguards should be considered (pharmacy system database concerns, controlled substance security, HIPPA)?
5. Define roles, registration and certification of support staff.
6. What other public safety concerns should the Board of Pharmacy consider regarding Telepharmacy?

M. GODEK stated that Illinois is starting to implement Telepharmacy. He stated that it is geared to stores when they are closed, so there is still access for the public to get their prescriptions. He stated that the unit itself has an individual store and DEA number, so it is registered as a separate entity and the unit can store up to 2000 medications and it only stores unit dosed products. He added that locations that have been considered include college campuses and airports.

J. LAVERY noted that the legislature is asking the Advisory Committee to look at this issue and note the concerns.

M. GODEK noted and clarified that:

- The machines typically takes 7-10 minutes to process, a pharmacist is there for questions/comments. The number of pharmacists is based on volume. Illinois is in the infancy stages of the process.
- The unit is large, like a very large ATM with a headset with a large monitor. The patient puts the prescription into the unit, scans a driver’s license and insurance card. No controls are filled in Illinois but providers can send electronically prescribed prescriptions. If the machine does not have enough product, pharmacist or support staff will route to the pharmacy or to an off-site location.
- All medications are unit dose products, typically dispensed for a 30 day supply, with no reconstitutables.

Discussion of Telepharmacy from the Committee included:

- J. BARR noted that Telepharmacy is an entire spectrum of pharmacy services, 23 states already have it. It was noted to have been around for a while and was historically noted to be a “Pharmacy in a Box,” but has not fully evolved. She suggested that the group start small and evolve over time. She noted that caution should be exercised and regulations are needed, but in a progressive fashion (i.e. focus on partnering, not replacing of, pharmacy services).
- K. THOMASSET stated that telehealth is evolving in other professions and from a convenience standpoint, ATM type machines dispense in areas for overnight services. He added that if we are going to provide product, we would need to have regulations. He noted that there may be tactile issues with counseling, in that it might be difficult to have a pharmacist counseling on how to use an inhaler via video.

- High definition capability would be required.
- Worried about “tech check techs” processes, as it opens up for the number of pharmacists manning each machine. In Illinois, only the Manager of Record has access to that machine and is only available in about a dozen locations in that state.
- Pharmacy records of counseling and accountability have to be considered.
- Mass DPH has a state office of rural health that could be used by the Board to guide their decision on geographic location(s).
- J. WALCZYK noted that Telepharmacy has a role in counseling, and the dispensing application may be unclear. He stated that it could be potentially be helpful for a prescription that has already been processed and is ready for pick up.
- M. THOMAS stated that we need to be careful of where we are on the spectrum, and agreed with Keith and Judy.
- L. TUCKER suggested that perhaps the concerns (prevent/limit) and research (what is the need and where it should be) should be delineated. She stated that we need to learn the guardrails required (economic, job, safety).
- Group should build next agendas by defining the area of Telepharmacy and then move forward to the newer models.
- May want to consider what the workforce is going to look like and the availability of the profession, as there may not be accessibility issues in Massachusetts.
- What is defined as access - pharmacies in rural areas or patients unable to get to a pharmacy? Also, the group should consider linguistic issues and other accessibility issues.
- Counseling could be the first bucket of information that the Committee looks at.
- The Advisory Committee is not ready to endorse Telepharmacy until there is further information.
- There is an ASHP report, it was suggested that the Committee should reach out to ASHP to see what led them to that report (2013 draft document). K. BARNES suggested the interns could assist with this work.
- Compare to the 23 states (and 17 proposed) and see what the states are doing.
- The three buckets of information were defined as: service, safety and “Pharmacy in a Box”. We have access to the NABP model language, the state languages and ASHP draft language.
- Group noted that we have a matrix of 3 levels: safety, service, but then there is hospital/hospital, rural and then “Pharmacy in a Box” which may overlay the 3. Also, it was noted they need follow up with DPH.
- Recommend that we look at South Dakota’s regulations.
- M. THOMAS asked if the practice is currently prohibited.
- K. THOMASSET noted that there are hospitals (currently governed more by DPH than the Board of Pharmacy) in the Commonwealth now that use Telepharmacy (e.g. a large 24 hour hospital that is filling orders for a satellite hospital that is available via phone for nursing staff), but not to the extent that is being discussed here.
- K. BARNES noted there are some regulations for prescriptions that are filled and ready, for picking up prescriptions in off hours.
- At Lahey, the service is limited to non controls and refills for employees only from a machine (Script Center, made by Asteres). The pick up is with a prescription number.

It was noted that the Advisory Committee should learn what is happening here in Massachusetts and elsewhere, to include the DPH office of rural health. D. DUNN will compile this information

and present it at the next meeting.

TOPIC:

6. OUTSOURCING FACILITY REGULATIONS

11:10 AM

DISCUSSION: H. ENGMAN referred the group to the memo regarding Outsourcing Facility regulations with attachments and gave a status report on Outsourcing Facility Regulations. It was noted that:

- The Federal Food Drug and Cosmetic Act was amended in 2013 to recognize and register outsourcing facilities as a third alternative to traditional pharmacy compounding and manufacturing.
- The Massachusetts pharmacy reform legislation did not mention outsourcing facilities, so the legislature assigned the topic of outsourcing facilities to the Advisory Committee and wanted the advisory committee to report its recommendation for registration and oversight of these facilities.
- In the meantime, MGL c. 112 § 36E was added to address the outsourcing issue and authorizes the Board of Pharmacy to register resident and non-resident outsourcing facilities.
- The Statute requires the Board to promulgate regulations to implement the licensure requirements. The legislation gave very little discretion to the Board. The Statute specifies the requirement for registration as well as the grounds for discipline and denial of outsourcing facilities.
- There were also amendments to the Controlled Substances Act (Chapter 94C).
- MGL Chapter 112 § 36 E sets forth the requirement for outsourcing facilities to obtain licensure, the facility must register with the FDA. The facility must have been inspected by the FDA within 2 years, must be eligible for a MCSR and there is also a provision that if a resident outsourcing facility has not been inspected within 2 years, the Board is authorized to issue a provisional registration, which allows a facility to compound drugs but the facility could not distribute the drugs until after it was inspected. She noted that this language was in the Statute and the Board does not have the ability to change it. The Statute also states the grounds for discipline or denial of an outsourcing facility to include an FDA warning letter from an inspection, misrepresentation or fraud, failure to report, failure to comply with cGMP, lack of suitability and failure to obtain an MCSR.
- 247 CMR 11 – added outsourcing facilities can receive a MCSR.
- 247 CMR 21 sets the outsourcing registration requirements for residents and non-residents and other suitability requirements and transfer of ownership.
- The Board approved the regulations on November 3, 2015. Public hearing was held yesterday and they received comment from 2 entities. They will go back to the Board in January and then will be in effect.
- There are no open questions left for the Board.
- The FDA needs to inspect on the initial registration, and after that it is up to the FDA's routine inspection schedule.
- Outsourcing facilities will not be pharmacies and will have to comply with section 11, 21 and 10. The Board will not be inspecting them but will issue a registration.
- The FDA does not prohibit compounding and shipping until inspected. In Massachusetts, the Statute states that the facility needs to be inspected prior to registration.
- FDA has a list of registered outsourcing facilities on its website and the Board will as well.

TOPIC:

7. DISCUSSION OF REPORT

11:35 PM

DISCUSSION:

J. LAVERY updated the group regarding the report that is being drafted for the legislature. Chapter 159 of the Acts of 2014 established the Advisory Committee and requires that the DPH, in consultation with the Board and Advisory Committee report to the Legislature recommendations on Central Fill, Central Processing, Outsourcing Facilities and Telepharmacy.

He stated that the Committee was also asked to advise the Board on:

1. The establishment of specialty pharmacies licensure categories,
2. The development of quality assurance, inspection and testing procedures with regards to compounding,
3. The application of accountability documentation requirements in licensed sterile pharmacies and complex non-sterile pharmacies, and
4. The development of regulations to supplement USP, all chapters and any other area as requested by the Board.

J. LAVERY stated that the group will be voting on the proposed policy standards for a pharmacy's response to abnormal environmental monitoring results and they are intended to be incorporated into the current draft of 247 CMR 17. He applauded the work of the Board and Advisory Committee as this above action remediation guidance does not currently exist in other parts of the country.

J. LAVERY stated that the report is due December 31, 2015 and the final product will be shared with the group.

TOPIC:

8. 247 CMR 17

11:42PM

DISCUSSION:

K. BARNES referred the group to the proposed 247 CMR 17 language. She stated, *"The proposed 247 CMR 17 accepted by unanimous vote at a special Board meeting on November 24, 2015 is largely based on the requirements of USP <797>. The proposed regulations are the result of many months of work. The Board reviewed various sections of the proposed regulations at its regularly scheduled meeting in May, June, August, September, October and November as well as two special meetings in July and November."*

The proposed regulations provide practice standards related to compounding facilities, compounding personnel (as related to aseptic technique, hand hygiene and garbing, and media fills) and monitoring related to the products prepared (validation of the Master Formulation Record, as well as product sterility, endotoxin testing).

Additionally, the proposed regulations provide guidance on documentation requirements for this area of pharmacy practice and establish standards to protect public safety by clarifying ambiguity in USP <797> which is written as a guidance document as opposed to a compliance document (an example here is the use of should versus shall, or 'remediate immediately' and 'periodically').

The proposed regulations do exceed USP <797> by requiring increased monitoring of sterile compounding personnel as well as the sterile compounding environment. Moreover, the proposed

regulations seek to increase public safety by establishing maximum BUD and stricter sterility and endotoxin testing of high risk level CSPs.

An example: the proposed regulations establish standards for public safety for the area in which a compounder steps outside the establish standards of USP <797> when the compounder is not applying the standard USP <797> BUD but rather utilizing peer-reviewed literature or direct testing to support the BUD. Although this practice is acceptable by USP <797> standards, USP is silent on additional monitoring requirements for this practice. The proposed regulations establish standards of increased monitoring for personnel, facility and product when the compounder extends BUDs beyond the guidance of USP. Our contention for these stricter standards is that this is an area that potentially increases risk and therefore requires additional stricter oversight.

The development of the proposed regulations by the Board staff has included research, attendance at specialized training programs such as HVAC and microbiology seminars as well as working closely with NABP and various stakeholders with subject matter expertise in various areas covered in the proposed regulations.

Throughout the development of the proposed regulations, Board staff communicated with many stakeholders including numerous Massachusetts pharmacists. Meetings were held with various pharmacy organizations and their membership (examples included Mass Hospital Association, Mass Society of Health System Pharmacists, Mass Independent Pharmacist Association, and the Mass Chain Pharmacy Council).

Board staff have also presented the proposed regulations at several pharmacist continuing education programs across the state, including Mass Health Council, MCPHS University Stoklosa Symposium, Northeastern University, Parenteral Drug Association, Mass Health Providers, and PharmEd continuing education. Board staff also worked with various Directors of Pharmacy. We conducted site-visits to understand the challenges faced by smaller hospitals were held with various hospitals or to review ongoing / upcoming construction projects.

Through the various outreach valuable feedback was received and in some areas changes to Board staff recommendations were made and in others new recommendations were drafted."

K. BARNES stated that the language that was distributed to the group on 247 CMR 17 was the draft product that was the result of this feedback and was approved by Board staff on November 24, 2015 and is ready to go to the executive office and be released for public comment. She stated that the request was that the Advisory Committee wanted a chance to review the draft regulations (which were noted to be available on the Board's website).

H. ENGMAN clarified that the Board voted to proceed with the administrative review process with a public comment period and public hearing process and it is very likely that changes will still occur with the document. She noted that all are welcome to comment individually or as a group during the public comment period, then it would go back to the Board for review.

Discussion points included:

- The Advisory Committee is set up to provide advice to the Board and the Committee can give recommendations to the Board.
- The group can meet again before public comment as there is time for that. Feedback can

- occur during the public comment period as an individual or as a member of this group.
- The document that has been provided to the Advisory Committee is an updated draft with incorporations of feedback made from the public, to include stakeholders.
- Stakeholder feedback that was incorporated also included MHA, MSHP, HVAC engineers, and microbiologists and was very vast.
- NABP will likely be the entity that will be conducting non-resident pharmacies inspections. The standards Massachusetts is holding their pharmacies will be applied to non-resident pharmacies as well. So for cases where we asked to exceed USP 797, Board staff looked closely at each standard audit tool with NABP, and even if NABP may not include a Massachusetts standard exactly on their audit tool, they would ask a registrant for their standard (e.g. how often they are performing environmental monitoring would be an open ended question instead of a yes/no question).
- The group agreed that all members of the Advisory Committee need to look at the document and comment on the draft collectively to the Board.
- K. BYERS volunteered to be the scribe to collate the comments and will collate the Advisory Committee's feedback and present it to the Board as a group memo.
- It was recommended that the feedback be structured specific to each section so that the review could be easily organized.
- J. SULLIVAN will send out the document as a word document so members can use track changes in the document.
- Members can give typewritten copies to K. BYERS at the next meeting and she can collate into the feedback. It was noted that these documents are all public record.
- The Advisory Committee will send out the draft electronically and will craft an email that will have clarity regarding the process. Comments can be sent to Janet so that during the next meeting it can be cut and pasted into the document.

ACTION: At 12:12 PM motion by, J. BARR seconded by E. KASTANGO and voted unanimously by roll call to recommend that the Board not move forward with public comment of 247 CMR 17 until they receive comment from the Advisory Committee.
M. THOMAS: yes, F. MCATEER: yes, K. BYERS: yes, J. BARR: yes, A. LAVINO: yes, J. WALCZYK: yes, C. BELISLE: yes, K. THOMASSET: yes, E. KASTANGO: yes, A. CUNDELL: yes.

For the next meeting, J. SULIVAN will send out an email with potential dates as soon as possible, with an aim to meet in mid-January.

H. ENGMAN reminded the group that committee members should not discuss the regulations with other members of the Advisory Committee pursuant to open meeting law.

TOPIC:

9. CLOSING REMARKS/ADJOURNMENT

12:18 PM

ACTION: At 12:18 PM motion by J. BARR seconded by J. WALCZYK, and voted unanimously by roll call to adjourn.

M. THOMAS: yes, F. MCATEER: yes, K. BYERS: yes, J. BARR: yes, A. LAVINO: yes, J. WALCZYK: yes, C. BELISLE: yes, K. THOMASSET: yes, E. KASTANGO: yes, A. CUNDELL: yes.

LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the December 11, 2015, Pharmacy Advisory Committee Meeting
2. Memo from the Sub-Committee on Abnormal Results to the Advisory Committee dated October 30, 2015. "Proposed Policy Standards for Sterile Compounding (ISO 7 Buffer Room).
3. Telepharmacy, From Wikipedia. Available at: <https://en.wikipedia.org/wiki/Telepharmacy>
4. Report of the Task Force on Pharmacy Practice Technology Systems. NABP.
5. Telepharmacy. November 2, 2015. North Dakota State University.
6. Pros and Cons for Telepharmacy. Available at: <http://news-health.net/pros-and-cons-for-telepharmacy/>.
7. Draft ASHP Statement on Telepharmacy. ASHP.
8. Memo from David Sencabaugh and Michael Godek to the Members of the Pharmacy Advisory Committee dated December 11, 2015. "Telepharmacy."
9. Memo from Heather Engman to the Members of the Pharmacy Advisory Committee dated December 8, 2015. "Outsourcing Facility Regulations."
10. MGL Chapter 112 § 36E Outsourcing Facilities; Registration.
11. MGL Chapter 112 § 39D Definitions Applicable to Sections 39D – 42D; Reporting of Improper Dispensing of Prescription Drugs; Reporting of Serious Adverse Drug Events: Recall and Reporting of Defective Drug Preparation.
12. MGL Chapter 112 § 39F Compounding and Distribution of Sterile or Complex Non-Sterile Drug Preparation Prohibited Without License; Adherence to Current Standards Under cGMP.
13. MGL Chapter 112 § 39F Non-resident Pharmacies; Licensure; Designation of Pharmacist in Charge; Distribution of Drug Preparations Produced or Compounded by a Pharmacy not granted a Non-Resident License Prohibited.
14. MGL Chapter 112 § 42A Rules and Regulations; Participation in National Data Reporting Systems; Suspension or Revocation of License or Permit; Hearing; Summary Action Upon Belief of Threat to Public Health, Safety or Welfare.
15. MGL Chapter 94C § 1 Definitions.
16. MGL Chapter 94C § 6 Rules and Regulations.
17. MGL Chapter 94C § 7 Registration of Persons who Manufacture, Distribute, Dispense or Possess Controlled Substances.
18. MGL Chapter 94C § 12 Issuance of Registration to Manufacture or Distribute Controlled Substances.
19. MGL Chapter 94C § 13 Suspension or Revocation of Registration; Report of Criminal Violations; Controlled Substances Affected Placed under Embargo; Forfeiture; Notice to Bureau.
20. MGL Chapter 94C § 14 Suspension of or Refusal to Renew Registration Pending Proceedings in Cases of Imminent Danger to Public.
21. 247 CMR 11 Registration Under the Controlled Substances Act. Draft Regulations.
22. 247 CMR 21 Registration of Outsourcing Facilities. Draft Regulations.
23. 247 CMR 17 Draft Regulations.

Respectfully submitted,

Colleen K. Collins, PharmD, RPh
Pharmacy Investigator