

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, January 22, 2016

Advisory Committee Members Present

Rory K. Geyer, PhD (Expert in CGMP)

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

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

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

Sylvia B. Bartel, RPh (Expert in USP<797>), left at 11:35 AM

Eric Kastango, RPh, MBA, FASHP (Expert in USP<797>)

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

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

Judith Barr, MEd, ScD, FASHAP (Expert in Pharmacoeconomics)-arrived at 10:08AM, left at 3:40PM

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

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

Advisory Committee Members Not Present

Francis McAteer (Expert in Microbiology)

Michael C. Thomas (Expert in Clinical Pharmacology)

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

Support Staff

Lindsey Tucker, DPH Associate Commissioner – arrived at 11:55 AM

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

David Sencabaugh, RPh, Executive Director, Board of Pharmacy

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

Board of Pharmacy Members

Tim Fensky, RPh

TOPIC:

1. WELCOME & CALL TO ORDER

10:03 AM

DISCUSSION: At 10:03 AM, Division of Health Professions Licensure Director James Lavery, JD called the meeting of the Pharmacy Advisory Committee to order. He stated that the meeting is a public meeting and is being recorded. He asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. He stated that he is recording the meeting. Members of the Advisory Committee and Board staff introduced themselves. There were

no remote participants.

NOTE: A quorum was present.

TOPIC:

2. **APPROVAL OF AGENDA**

10:05 AM

DISCUSSION: J. LAVERY asked if there were any changes to the agenda. None were noted.

ACTION: At 10:06 AM motion by E. KASTANGO seconded by C. BELISLE and voted unanimously to approve the agenda with no changes.

TOPIC:

3. **APPROVAL OF MINUTES FROM OCTOBER 5, 2015 MEETING**

10:06 AM

DISCUSSION: R. GEYER suggested clarifying his expertise to that of CGMP expert. C.

COLLINS will make the changes and will send the amended minutes to J. SULLIVAN for posting.

ACTION: At 10:06 AM motion by M. GONYEAU seconded by K. BYERS and voted unanimously to approve the minutes from the October 5, 2015 Pharmacy Advisory Committee Meeting with the suggested change.

TOPIC:

4. **DISCUSSION 247 CMR section 17**

10:07 AM

DISCUSSION: D. SENCABAUAGH stated that he had received feedback from some of the Advisory Committee members. He indicated that the group was given the draft of proposed Section 17 to review prior to the meeting. He stated that there has been a lot of work spent by Board Staff and Members alike, writing, reviewing, tweaking, and approving new and existing Pharmacy regulatory language. He stated, "The draft section you have reviewed during the past 6 weeks, represents the time, effort, and opinions of, not only Kelly Barnes and Bill Frisch (who did the lion's share of the job), but also all of the Board Members who reviewed it so carefully, line-by-line, over the course of many meetings ... So, your task is very important today, as, by the meeting end, we will have a consensus from you, the Advisory Committee, as to which comments will be brought forward to the Board of Pharmacy on February 2nd, for their consideration. The usual process when a regulation is approved by the Board to move ahead to the next step, is for the approved draft to go up to the Administration for what is called a EO 562 review, where it is looked at for how it may potentially affect costs, both to the public and the Government, and things like the impact on small businesses, and such, and then it comes back for a Public Comment Period and a Public Hearing. What is different about the approved Section 17, approved by the Board on November 24th, is that we have waited to submit this for the 562 review, until we were able to have this meeting, so that the Advisory Committee could weigh-in. So, that's why we are here today."

D. SENCABAUAGH indicated that he will lead the opening and whatever is approved as "consensus" by the end of the meeting which will be brought forward to the Board of Pharmacy at its February 2nd. He added that the Committee will review in chunks, looking at 11-12 of the 46 pages per hour and determining consensus along the way. He asked the committee to remember to offer alternatives to the items they feel need to be changed. He also asked for a committee member to bring the recommendations to the Board, and if there was not a volunteer, he would bring the comments forward on behalf of the Committee. He added that if a member is unable to voice their concern on a particular portion of the regulation, they still have the opportunity to do so during the public comment period.

A. CUNDELL voiced his concern about the regulations. He noted that rules are far too prescriptive and might be in conflict with USP <797>. He added that the cost of implementation may be prohibitive. He suggested that the standard could be USP <797> and then from that write general guidelines with details on how compounders in the Commonwealth can meet this standard.

The group reviewed the draft 247 CMR 17 regulations and H. ENGMAN captured the discussion on “Draft 247 CMR 17 Regulations with recommendations from the Advisory Committee.” It was noted during the discussion that pharmacies will have the option to apply for a waiver for certain regulations if needed and the waiver would be need Board approval.

The Committee was able to reach general consensus on the recommendations to be brought forward to the Board. It should be noted that not all of the decisions were unanimous. Some sections were flagged for further review and some sections had already been flagged for further review or language clarification. H. ENGMAN noted that the grammar could be reviewed and revised at a later date.

E. KASTANGO offered to present the recommendations to the Board at the February 2, 2016 meeting.

ACTION: At 3:42 PM motion by E. KASTANGO seconded by C. BELISLE and voted unanimously to accept all of the consensus and votes that were discussed today regarding 247 CMR 17 to be presented to the Board on February 2, 2016.

TOPIC:

7. CLOSING REMARKS/ADJOURNMENT

3:43 PM

ACTION: At 3:43 PM Motion by A. LAVINO seconded by C. BELISLE and voted unanimously to adjourn.

LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the January 22, 2016, Pharmacy Advisory Committee Meeting
2. Draft Minutes for the October 5, 2015 Pharmacy Advisory Committee Meeting
3. Draft 247 CMR 17 Regulations
4. Draft 247 CMR 17 Regulations with recommendations from the Advisory Committee.

Respectfully submitted,

Colleen K. Collins, PharmD, RPh
Pharmacy Investigator