**MINUTES OF THE PUBLIC HEALTH COUNCIL**

**Meeting of November 8, 2017**

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**

**PUBLIC HEALTH COUNCIL**

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**

**Henry I. Bowditch Public Health Council Room, 2nd Floor**

**250 Washington Street, Boston MA**

**Docket: Wednesday, November 8, 2017 - 9:00 AM**

1. **ROUTINE ITEMS**
	1. Introductions
	2. Updates from Commissioner Monica Bharel, MD, MPH
	3. Record of the Public Health Council October 11, 2017 Meeting **(Vote)**
2. **DETERMINATION OF NEED**
	1. Boston University Goldman School of Dental Medicine application for substantial capital expenditure for new construction and renovation to its licensed dental clinic **(Vote)**
3. **FINAL REGULATIONS**
	1. Request for final promulgation of proposed amendments to 105 CMR 725.000, *Implementation of an Act for the Humanitarian Use of Marijuana* **(Vote)**
4. **INFORMATIONAL PRESENTATIONS**
5. Informational presentation on the DPH Center for Birth Defects Research and Prevention, and collaborative Zika virus surveillance with the Bureau of Infectious Disease and Laboratory Sciences

*The Commissioner and the Public Health Council are defined by law as constituting the Department of Public Health. The Council has one regular meeting per month. These meetings are open to public attendance except when the Council meets in Executive Session. The Council’s meetings are not hearings, nor do members of the public have a right to speak or address the Council. The docket will indicate whether or not floor discussions are anticipated. For purposes of fairness since the regular meeting is not a hearing and is not advertised as such, presentations from the floor may require delaying a decision until a subsequent meeting.*

**Public Health Council**

Attendance and Summary of Votes:

Presented below is a summary of the meeting, including time-keeping, attendance and votes cast.

**Date of Meeting:** Wednesday, November 8, 2017

**Beginning Time:** 9:32AM **Ending Time:** 10:49AM

| **Board Member** |  **Attended** | **Record of the Public Health Council October 11, 2017 Meeting (Vote)** | **DETERMINATION OF NEED****Boston University Goldman School of Dental Medicine application for substantial capital expenditure for new construction and renovation to its licensed dental clinic** | **FINAL REGULATIONS** **Request for final promulgation of proposed amendments to 105 CMR 725.000, Implementation of an Act for the Humanitarian Use of Marijuana** |
| --- | --- | --- | --- | --- |
| Monica Bharel | Yes | Yes | Yes | Yes |
| Edward Bernstein | Yes | Yes | Recused | Yes |
| Lissette Blondet | Yes | Abstained | Yes | Yes |
| Derek Brindisi | Absent | Absent | Absent | Absent |
| Harold Cox | Absent | Absent | Absent | Absent |
| John Cunningham | Yes | Yes | Yes | Yes |
| Michele David | Absent | Absent | Absent | Absent |
| Meg Doherty | Absent  | Absent | Absent | Absent |
| Michael Kneeland | Yes | Yes | Yes | Yes |
| Joanna Lambert | Yes | Abstained | Yes | Yes |
| Paul Lanzikos | Yes | Yes | Yes | Yes |
| Lucilia Prates-Ramos | Yes | Yes | Yes | Yes |
| Secretary Francisco Ureña | Yes | Not present at time of vote | Yes | Yes |
| Alan Woodward | Absent | Absent | Absent | Absent |
| **Summary** | **9 Members Present, 5 Members Absent** | **6 Members Approved, 5 members Absent, 2 members abstained, 1 not present at vote** | **8 members approve, 1 member recused, 5 members absent**  | **9 members approved, 5 members absent** |

**PROCEEDINGS**

A regular meeting of the Massachusetts Department of Public Health’s Public Health Council (M.G.L. c. 17, §§ 1, 3) was held on Wednesday, November 8, 2017 at the Massachusetts Department of Public Health, 250 Washington Street, Henry I. Bowditch Public Health Council Room, 2nd Floor, Boston, Massachusetts 02108.

Members present were: Monica Bharel, MD, MPH; Edward Bernstein, MD; Lissette Blonde; John Cunningham, PhD; Michael Kneeland, MD; Joanna Lambert; Paul Lanzikos; Lucilia Prates-Ramos and Secretary Francisco Ureña

Absent member(s) were: Derek Brindisi; Harold Cox; Michele David, MD; Meg Doherty; and Alan Woodward, MD.

Also in attendance was Margret Cooke, General Counsel at the Massachusetts Department of Public Health.

Commissioner Bharel called the meeting to order at 9:32 AM and made opening remarks before reviewing the agenda.

**ROUTINE ITEMS**

**Updates from Commissioner Monica Bharel, M.D., MPH**

Commissioner Bharel opened the meeting by announcing that a Joanna Lambert has joined the Council. Ms. Lambert has a background in healthcare administration, in both hospital and community health center settings, with an emphasis on operations, finance, and quality improvement.  She received her BA in Economics from Brandeis University, and MPH from Boston University.  She currently works as an executive consultant with East Boston Neighborhood Health Center, spearheading a project to develop a Patient Navigation Center.

The Commissioner then informed the Council the CDC recently released National Immunization Survey for 2016, and that Massachusetts ranks number one in the country for 19-35 month olds vaccinated with MMR vaccine, DTaP vaccine, and the combined series of 7 vaccines recommended for children before they turn age 2.

In state fiscal year 2016, the Baker Administration expanded the state Childhood Vaccine Trust to include coverage for all federally recommended childhood and adolescent vaccines, returning Massachusetts to the status of a universal vaccine state.

She noted that she is proud of this latest accomplishment and proud of the work of our Immunization Program, which has worked to make Massachusetts’ immunization efforts a model for the nation.

Next, Commissioner Bharel announced that Glynnis LaRosa, the director of the Public Health Nursing Program at the Bureau of Infectious Disease and Laboratory Science, received the Lillian Wald Service Award at the American Public Health Association’s annual meeting in Atlanta.

This is the most prestigious public health nursing award in the country and honors individuals or organizations who exemplify the best of public health through their professional work or advocacy.

Ms. LaRosa has worked with DPH for 18 years, and she has contributed to the department and the public health field in so many ways. The Commissioner previously had the pleasure of speaking to students at a summer program called “Outbreak” that Ms. LaRosa helped to develop. The program introduces public health to middle and high school students from around the state, and it does so in a very exciting and interactive way.

Nora Mann, the director of our Determination of Need Program, was recently honored as one of the 2017 Top Women of Law by Massachusetts Lawyers Weekly. The Top Women of Law awards celebrate the contributions and accomplishments of women lawyers throughout the Commonwealth.

In addition to these individual awards, the contributions of the department were recognized during our own employee recognition award just last week. The Commissioner presented awards to more than 60 staff for their achievements over the past year.

The work of DPH staff will also be recognized during the Commonwealth’s annual performance recognition awards for state employees.

These special awards focus attention on consistent, positive achievements by both individuals and teams who demonstrate innovation and dedication to their work, as well as concern for the public trust and a commitment to excellence.

This year, DPH’s Records Access Officer, Helen Rush-Lloyd, and our First Deputy General Counsel, Elizabeth Scurria Morgan are part of a group from across EOHHS to receive a Commonwealth Citation for Outstanding Performance for their excellent work implementing the state’s new public records law.

And, the Chapter 55 Team from DPH will receive the Carballo Governor’s Award for Excellence in Public Service, which is given annually to only 10 employees or groups of employees who exemplify the highest standards of public service. The Chapter 55 Team is receiving the award for their groundbreaking work to examine the underlying causes and determinants of the opioid epidemic.

Next, Commissioner Bharel mentioned that the President’s Commission on Combatting Drug Addiction and the Opioid Crisis unanimously approved and released its final report.

Several of the key recommendations in this report stem from effective efforts in Massachusetts, such as revamping the MassPAT system and developing core competencies for medical students on pain management and addiction prevention.

In the year since the revamped MassPAT system was put into place, over 6.5 million searches have been conducted by health care providers and 97% of all prescribers that prescribed at least one Schedule II or III opioid have registered with the MassPAT, which are both huge achievements.

Concluding her updates, Commissioner Bharel asked if the Council had any questions or comments.

With no questions, the Commissioner proceeded with the docket.

**1. ROUTINE ITEMS**

**c. Record of the Public Health Council October 11, 2017 Meeting (Vote)**

Commissioner Bharel asked if any members had any changes to be included in the October 11, 2017 meeting minutes.

Seeing none, the Commissioner asked for a motion to accept the minutes. Dr. Bernstein made the motion and Dr. Kneeland seconded it. Ms. Blondet and Ms. Lambert abstained as they were not present at the October 11th meeting. All other present members approved.

Due to a quorum issue, the Commissioner announced that there would be a change in the order of the docket. She announced that the request for final promulgation of proposed amendments to 105 CMR 725.000, Implementation of an Act for the Humanitarian Use of Marijuana would be brought forth to the Council next.

**2. FINAL REGULATIONS**

**Request for final promulgation of proposed amendments to 105 CMR 725.000, Implementation of an Act for the Humanitarian Use of Marijuana**

The Commissioner invited Eric Sheehan, Director of the Department’s Bureau of Health Care Safety and Quality; Bryan Harter, Director of the Bureau’s Medical Use of Marijuana Program; Dr. Marc Nascarella, Director of the Department’s Environmental Toxicology Program; and Beth McLaughlin, Senior Deputy General Counsel, to present on final proposed changes to the Department’s regulation 105 CMR 725.000, Implementation of an Act for the Humanitarian Medical Use of Marijuana.

Upon conclusion of their presentation, the Council was asked if they had any questions or comments.

Secretary Ureña arrives at 10:10am

Mr. Lanzikos asked for clarification on slide 14. He inquired as to whether an RMD can require the cuttings anytime outside of the 90 day period.

Ms. McLaughlin replied that staff will be providing sub-regulatory guidance as to the timeframe for that.

Mr. Lanzikos asked if they anticipate what the timeframe will be.

Dr. Nascarella stated the expectation for how the clones will be distributed is consistent with same regulations that apply to the distribution of the sale of seeds. The availability of clones to an RMD would be the same as timeframe as the availability of seeds.

Mr. Lanzikos inquired about the news reports discussing potential challenges of getting product to Martha’s Vineyard and Nantucket due to federal restriction. He asked if there has been work done around that.

Mr. Sheehan replied that from a Commonwealth perspective there are PCRs that are awarded to both Nantucket and Martha’s Vineyard. We have been working with the industry to identify potential solutions for laboratory testing piece. I can’t provide an answer regarding federal practice for you today but as for the Commonwealth we have been engaged with the industry to find solutions.

Mr. Lanzikos asked if they have modest or high anticipation regarding the solution.

Mr. Sheehan replied that unfortunately he does not have an answer.

Dr. Cunningham asked if there was any concern regarding 102 PCRs in a pipeline that may not be very big in diameter.

Mr. Sheehan replied that from a program’s perspective they always look at anticipated volume for processing applications. He informed the Council they are certainly staffed enough to address the ongoing needs from a compliance and processing perspective.

Ms. Blondet asked if there are any provisions to assure dispensaries are linguistically accessible to diverse populations.

Mr. Sheehan informed her that they certainly encourage all RMDs that they work with to be as accessible as possible in different languages. He informed her that that is something they can continue to advocate for.

Ms. Blondet asked for clarification as to whether it is just a suggestion at the current moment or if it is a part of the guidance.

Mr. Sheehan replied that the patient themselves are under the care of a physician and they are having a dialogue with the physician and working with the RMDs for access. He went on to say that there is no requirement for other materials.

Ms. Blondet asked about patient access and noted that she was informed it could be cumbersome for patients to apply. She asked if there is an explicit role, for example, a CHW, orienting or coaching patients to get the services that they need.

Mr. Sheehan responded saying that in their collaboration with RMDs there are trainings and educational materials provided prior to the sale and distribution of the marijuana. He noted that they can continue to advocate for information to be provided and translated.

Dr. Bernstein asked about marketing and labeling. He asked to be educated on the requirements and whether there are similar standards in place as there are for drugs like Tylenol.

Mr. Sheehan replied that labeling requirements are in the regulation to assure that correct information is being provided to patients at the point of sale.

Dr. Nascarellla also responded stating that in comparison to Tylenol, there are not standards in place. Marijuana is prohibited from being marketed with the same type of medical claims that drugs like Tylenol have. We do proceed to assure that the product in terms of levels of contaminants and THC are measured in a manner that is consistent with that of how active ingredients are measured in Tylenol.

Commissioner Bharel asked the group to discuss packaging.

Ms. McLaughlin stated that there are requirements in the existing regulations that discuss the packaging: plain, opaque, tamper proof etc. Some changes that were made to packaging include, marijuana use during pregnancy and breast feeding may pose potential harms.

Dr. Bernstein asked how the package is protected from being tampered.

Mr. Sheehan replied that the RMDs have security mechanisms in place to assure that it is not tampered with at the point of sale. He noted that this issue changes once it is in the community, it becomes difficult for the department to monitor. However, there are rigorous testing requirements before it is distributed at the point of sale.

Dr. Nascarella replied that the packaging at RMDs prevents tampering and the product itself, prior to be offered for retail sale, is tested in a laboratory for contaminants.

Ms. Lambert asked if the number of RMDs and labs commensurate with the patient population growth. She also asked if there was growth management strategy.

Mr. Sheehan replied that they focused on the accessibility of safe and quality product during the application redesign process. He stated that it is difficult to provide a forecast for what potential growth looks like.

Dr. Cunningham asked how do the 5 statewide RMDs deliver product and get to the correct location.

Mr. Harter replied that they have detailed transportation guidance. Transportation vehicles have GPS tracking, two agents, and have to be in constant contact with the RMD.

Mr. Lanzikos asked if someone is a current medical marijuana user and becomes incarcerated, are they able to continue that treatment.

Mr. Sheehan replied they would have to get back him on that regarding the legality of the situation.

Dr. Bernstein asked if the hospital has to have a license to provide a patient with treatment if they are hospitalized.

Mr. Sheehan replied that they allow for caregiver institutions and any entity could apply to become and institutional caregiver to allow for a patient with prescription and valid medical marijuana card to receive treatment on the premises.

Ms. Blondet asked if there was a way to track the racial and ethnic profiles of the patient population.

Mr. Sheehan said that they track limited patient profile information in their online MMJ system. The purpose of that is for the RMD to verify and validate the patients. He went on to say they can see if there are additional fields that they can track while maintaining patient privacy.

Ms. Blondet asked if they can add zip code to list of ways they track patients.

Mr. Sheehan replied that they currently track by zip code.

With no further questions, the Commissioner the asked for a motion to accept the amendments to 105 CMR 725.000.

Dr. Cunningham made the motion, Ms. Blondet seconded it. All present members approved.

**3. DETERMINATION OF NEED**

**Boston University Goldman School of Dental Medicine application for substantial capital expenditure for new construction and renovation to its licensed dental clinic**

Commissioner Bharel then asked Nora Mann, Director of the Determination of Need Program, and Rebecca Rodman, Deputy General Counsel, to the table to present the staff recommendation for Boston University Goldman School of Dental Medicine’s application for substantial capital expenditure for new construction and renovation to its licensed dental clinic.

Before the presentation, Dr. Bernstein left the room as he has recused himself from participating on this determination of need application.

Dr. Bernstein recuses himself at 10:22am and does not return.

Upon the conclusion of Ms. Mann’s presentation, the Council was asked if they had any questions.

Ms. Blondet inquired as to whom is a part of interdisciplinary care team.

Dr. Jeffrey Hutter, Dean of Henry M. Goldman School of Dental Medicine and John Guarente Associate Dean for Clinical Affairs joined the table.

Dr. Hutter replied that they plan to work with other health care providers as part of the team. The team would potentially consist of a medical student, a physician assistant, nurse practitioner in training etc. thus requiring additional space. He mentioned that they are currently working with Boston University’s PA program and are also looking to collaborate with other training programs.

Dr. Guarente also noted that that they have added the collaborative spaces to fit all providers.

Ms. Blondet stated in health care environment moving towards integrated care she would hope that these integrated teams would include people outside of BU. She encouraged the applicant to think broader and include community health workers

Dr. Hutter stated that the global population health department oversees dental health centers and the externships that students participate at those dental health centers.

Ms. Lambert asked if there is a project timeline and if this will increase the number of DMD candidates.

Dr. Hutter replied that they never planned to increase the number of their students. The expansion of the facility is to better complete current tasks.

Dr. Guarente stated that the timeline right now is for the projected to be completed within 30 months of January 1st.

Mr. Lanzikos asked how this project impacts the training deployment of other dental health care providers at the school.

Dr. Hutter replied that they do not have a hygiene program at the school. They do have hygienists that practice and are a part of the education. They do have a continuing education program for dental assistants, he noted that the project was created with all of them in mind as they are part of the integrated dental team.

Secretary Ureña asked if there would be any disruption to the student’s curriculum.

Dr. Hutter stated that they have been planning the construction for 8 years. He noted that they have been communicating plans to students and staff but knew that despite minor disruptions they would stay open.

Secretary Ureña then thanked them for services they provide for veterans and inquired if there would be a possibility for expanded services with this expansion.

Dr. Hutter replied that the certainly hopes so and he will support that.

Mr. Lanzikos asked how much focus do they provide in meeting the needs of those who have special needs, i.e. those in nursing facilities etc.

Dr. Guarente informed him that they have geriatric program that makes home visits and can go to facilities to provide as much care as they can.

With no further questions, the Commissioner asked for motion to accept the staff recommendation for approval of the BU Goldman School of Dental Medicine request for substantial capital expenditure.

Mr. Lanzikos made the motion, Secretary Ureña seconded it. All present members approved.

Mr. Lanzikos leaves the room at 10:46am and returns at 10:47.

Secretary Ureña leaves at 10:46am and does not return.

Due to lack of quorum the Informational presentation on the DPH Center for Birth Defects Research and Prevention, and collaborative Zika virus surveillance with the Bureau of Infectious Disease and Laboratory Sciences was postponed.

The Commissioner reminded the Council that the next meeting is Wednesday, December 13, 2017 at 9AM. She then asked for a motion to adjourn. Mr. Lanzikos made the motion Ms. Prates Ramos seconded it. All present members approved.

The meeting adjourned at 10:49AM.