**MINUTES OF THE PUBLIC HEALTH COUNCIL**

**Meeting of October 25, 2019**

**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, October 25, 2019 - 9:00 AM**

1. **EXECUTIVE SESSION**
	1. After a call to order, the Public Health Council will meet in Executive Session as authorized by M.G.L. c. 30A, s. 21(a)(3) for the purpose of discussing strategy with respect to litigation, specifically:
2. Vapor Technology Association v. Charlie Baker, in official capacity and Monica Bharel, in official capacity
3. Mass Dynamics et. al. v. Charles Baker, as Governor and Monica Bharel, as Commissioner of Public Health
4. Vapor Zone v. DPH et al.
5. Vapor Technology Association v. Charlie Baker, in official capacity and Monica Bharel, in official capacity
6. **EMERGENCY REGULATION**
	1. Request to Approve Proposed Emergency Regulation 105 CMR 800.000, *Severe Lung Disease Associated with Vaping Products* **(Vote)**
	2. Additional related regulations as may be necessary **(Vote)**

*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, October 25, 2019

**Start Time:** 9:21am **Ending Time:** 10:02am

| **Board Member** | **Attended** | **Vote: 105 CMR 800.000** |
| --- | --- | --- |
| Monica Bharel | Yes | Yes |
| Edward Bernstein  | Yes | Yes |
| Lissette Blondet | Absent |  |
| Derek Brindisi | Yes | Yes |
| Kathleen Carey | Yes | Yes |
| Harold Cox | Absent | Absent |
| John Cunningham | Yes | Yes |
| Michele David | Yes | Yes |
| Michael Kneeland | Yes | Yes |
| Keith Hovan | Yes | Yes |
| Joanna Lambert | Absent | Absent |
| Secretary Elizabeth Chen | Absent | Absent |
| Lucilia Prates-Ramos | Yes | Yes |
| Secretary Francisco Ureña | Yes | Yes |
| **Summary** | **10 members present, 4 members absent** | **10 members approve, 4 members absent** |

**PROCEEDINGS:**

An emergency meeting of the Massachusetts Department of Public Health’s Public Health Council (M.G.L. c. 17, §§ 1, 3) was held on Friday October 25, 2019 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; Derek Brindisi; John Cunningham, PhD; Michael Kneeland, MD; Keith Hovan; Lucilia Prates-Ramos; Michele David; Secretary Francisco Ureña and Kathleen Carey PhD

Absent member(s) were: Joanna Lambert, Lissette Blondet, Harold Cox and Secretary Elizabeth Chen

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

Commissioner Bharel called the emergency meeting to order at 9:21 AM and before moving into the public portion of our meeting, Commissioner Bharel requested the Public Health Council meet in Executive Session as authorized by M.G.L. c. 30A, s. 21(a)(3) for the purpose of discussing strategy with respect to litigation, specifically:

* Vapor Technology Association v. Charlie Baker, in official capacity and Monica Bharel, in official capacity
* Mass Dynamics et. al. v. Charles Baker, as Governor and Monica Bharel, as Commissioner of Public Health
* Vapor Zone v. DPH et al.
* Vapor Technology Association v. Charlie Baker, in official capacity and Monica Bharel, in official capacity

Ms. Prates Ramos made a motion to enter Executive Session, Dr. Bernstein seconded it.

Following the motion, a roll call of all members was conducted, and the Council moved into Executive Session at 9:22am.

Prior to moving into executive session, Commissioner Bharel asked all clear the room except for the Council and Department staff required to attend the executive session.

At the conclusion of the executive session, Department staff notified members of the public and other DPH staff they may re-enter the Council room.

The public portion of the Public Health Council meeting resumed at 9:39am.

Commissioner Bharel stated that on September 24, 2019 the Baker Administration declared a public health emergency and imposed a temporary ban on all vape products to allow us time to better understand what is making people sick and leading to deaths in some cases

The Centers for Disease Control and Prevention has issued clear warnings stating that the outbreak of these vaping-related illnesses and deaths cannot at this time be attributed to a single substance or product. Yesterday the CDC reported 1604 cases have been reported to them and 34 deaths. When we came together on September 24 to address this public health emergency, the Public Health Council approved the order to prohibit the sale of all vaping products in retail establishments, online, and through any other means, including all non-flavored and flavored vaping products, including mint and menthol, including tetrahydrocnnabinol (THC) and any other cannabinoid, in the Commonwealth. Further, an additional order expanded access to nicotine replacement therapy through a statewide standing order.

In continued response to the emergency that vaping-related lung disease presents for the Commonwealth, the Department now proposes an emergency regulation to ensure the continued and necessary prohibitions on sales of vaping products in Massachusetts in order to protect the public health.

Commissioner Bharel stated the basis for the actions of September 24th, as follows:

* As described in the DPH September 24, 2019 memo to the Council, clinicians here in Massachusetts and across the country began raising concerns in August 2019 related to possible cases of unexplained vaping-associated pulmonary illness.
* On August 30, 2019, the Centers for Disease Control and Prevention (CDC) released a clinical advisory providing background information on e-cigarette products, information on the multistate outbreak of severe pulmonary disease associated with e-cigarettes, and clinical features of patients with severe pulmonary disease, with a recommendation clinicians report all cases of severe pulmonary disease of unclear etiology and a history of e-cigarette product use within the past 90 days to state or local health departments.
* In response to trends nationwide, CDC recommendations, and growing public health concerns in Massachusetts, I declared on September 11 that all suspected cases of unexplained e-cigarette or vaping-associated pulmonary disease be immediately reportable to our Department of Public Health for the next 12 months. Since that declaration, the Department has received 184 reports from clinicians of suspected vaping-related disease in Massachusetts residents. Of these reports, the Department has reported to the CDC 16 cases which meet the CDC definition for confirmed case, and 30 cases which meet the CDC definition for probable case; the remainder still remains under Department investigation.
* These reports of vaping-related illness represent a threefold increase in reports received and five times the number of confirmed cases reported to Council members a month ago. Additionally, during that same timeframe, the Department also reported one fatality as a result of vaping-related disease.
* While cases still show a history of vaping and a history of using vaping products containing tetrahydrocannabinol (THC), nicotine, or a combination of both, the cause of the disease continues to remain unknown. To date, no specific vaping product, including the related devices and liquids, or other substance has been identified as linked to all cases.
* Due to the continued, significant danger vaping products present during the ongoing investigation into the cause of vaping-related disease, the CDC issued guidance last week advising that since the specific compound or ingredient causing lung injury is not yet known, the only way to assure that you are not at risk while the investigation continues is to consider refraining from use of all e-cigarette, or vaping, products.
* In addition to the public health concerns which Commissioner Bharel had outlined, in response to pending litigation related to the ban on sales of vaping products.

Commissioner Bharel then proposed the Council vote to approve emergency regulations to maintain the ban during what will be an ongoing regulatory process. These regulations will serve to preserve the existing ban on sales of vaping products in order to protect public health, continue our investigation into instances of this disease in Massachusetts residents, and learn from the CDC’s nationwide investigation. The proposed emergency regulation adopts all Orders issued pursuant to the Governor’s Declaration.

Mr. Brindisi asked if this regulation will stay in place beyond the ban.

Ms. Cooke stated there will be a public comment period and will be filed today if we pass the regulation. There may be some changes to the regulations in response to public input and then will come back to the PHC for approval. Emergency Regulations stay in place for 90 days if we do not file promulgation.

Mr. Brindisi asked if the nicotine replacement therapy could be explained further.

Commissioner Bharel stated that we emphasized nicotine cessation accessibility would be put in place to decrease cost barriers for access for FDA approved nicotine replacement treatments over the counter to decrease insurance barriers.

Secretary Urena asked if there is data on the usage of nicotine replacement therapy.

Commissioner Bharel stated DPH will be evaluating the data regarding NRT, but it can be difficult since many therapies are over the counter but is part of our plan.

Dr. Cunningham asked if the CDC data shows nicotine only lung disease confirmed cases.

Commissioner Bharel stated it fluctuates but usually around 10% and the CDC advisory stated to avoid any of the products if people want to be safe since the cause is not known, but there is an association in many of the cases with nicotine only but the cause is unknown at this time at the CDC level.

Dr. Cunningham asked if we pass emergency regulation today that would go into effect the afternoon, does the Monday deadline still remain in effect.

Ms. Cooke stated the ban would be kept in place for THC products absent flower product for vaping and the judge would have to separate out nicotine and THC.

Dr. Cunningham with a new regulation in place, would there be a specific separation of which part will be banned.

Dr. Kneeland stated that 10% is not a small number and is significant.

Dr. Bernstein asked if there will be a preamble or just the regulation alone.

Ms. Cooke stated that it would be the regulation standing alone.

Dr. Bernstein asked if we can look into taxes on cigarettes to see if there is an increase in use and the black market on these products.

Dr. Cunningham asked if DPH is tracking the frequency of vaping in terms of dose response.

Commissioner Bharel stated the definition is if used in the past 90 days, but will need to look into the frequency of use.

Dr. Bernstein asked if the flower is included

Ms. Cooke stated yes the flower is included and all THC products

Commissioner Bharel stated that this regulation covers everything that the ban covered.

Dr. Bernstein asked if the PHC is voting on the entire regulation.

Commissioner Bharel stated yes.

Commissioner Bharel stated that we still want to allow for prescriptions for medical marijuana.

Dr. Bernstein stated that we would want to allow all FDA approved products and should include over the counter medications and treatments.

Commissioner Bharel stated that the standing order would be to decrease the insurance barrier and not changing prescription criteria.

Commissioner Bharel asked if there is motion to change 800.035from nicotine replacement therapy to over the counter nicotine replacement therapy.

Dr. Bernstein made the motion; Secretary Urena seconded it, all other present members approved.

Commissioner Bharel requested that the Council vote to approve the proposed regulation, 105 CMR 800.000, on an emergency basis, which would take effect immediately upon filing with the Secretary of State’s office.

Mr. Brindisi made a motion to approve the regulation; Dr. David seconded it, all other present members approved.

Commissioner Bharel stated that this concludes our final agenda item for the day. A friendly reminder, our next meeting is scheduled for Wednesday, November 20, 2019, at 9AM.

She then asked for a motion to adjourn. Dr. David made the motion, Dr. Carey seconded it. All present members approved.

The meeting adjourned at 10:02AM.