**MINUTES OF THE PUBLIC HEALTH COUNCIL**

**Meeting of October 10, 2018**

**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 10, 2018 - 9:00 AM**

1. **ROUTINE ITEMS**
   1. Introductions
   2. Updates from Commissioner Monica Bharel, MD, MPH.
   3. Record of the Public Health Council September 12, 2018 Meeting. **(Vote)**
2. **DETERMINATIONS OF NEED**
   1. Further review of the following transfer of ownership: CareGroup, Inc.; Lahey Health System, Inc.; and, Seacoast Regional Health Systems, Inc. intend to integrate and create a new corporation, known for the time being as NewCo, which will serve as the sole corporate member of the new health care system.  **(Vote)**
3. **FINAL REGULATIONS** 
   1. Request to promulgate amendments to 105 CMR 700.000, *Implementation of M.G.L. c. 94C.* **(Vote)**
4. **PRESENTATIONS**
5. Informational report on an outbreak of HIV infection among persons who inject drugs: Northeastern Massachusetts, 2016-2018

*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 10, 2018

**Start Time:** 9:11am **Ending Time:** 11:36am

| **Board Member** | **Attended** | **Record of the Public Health Council September 12, 2018 Meeting (Vote)** | **DETERMINATIONS OF NEED**  **Further review of the following transfer of ownership: CareGroup, Inc.; Lahey Health System, Inc.; and, Seacoast Regional Health Systems, Inc. intend to integrate and create a new corporation, known for the time being as NewCo, which will serve as the sole corporate member of the new health care system.  (Vote)** | **FINAL REGULATIONS**  **Request to promulgate amendments to 105 CMR 700.000, *Implementation of M.G.L. c. 94C.* (Vote)** |
| --- | --- | --- | --- | --- |
| Monica Bharel | Yes | Yes | Yes | Yes |
| Edward Bernstein | Yes | Yes | Yes | Yes |
| Lissette Blondet | Absent | Absent | Absent | Absent |
| Derek Brindisi | Yes | Yes | Yes | Yes |
| Harold Cox | Yes | Yes | Yes | Yes |
| John Cunningham | Yes | Yes | Yes | Yes |
| Michele David | Yes | Yes | Yes | Yes |
| Meg Doherty | Yes | Not present at time of vote | Yes | Yes |
| Michael Kneeland | Yes | Yes | Yes | Yes |
| Joanna Lambert | Absent | Absent | Absent | Absent |
| Paul Lanzikos | Yes | Yes | Yes | Yes |
| Lucilia Prates-Ramos | Absent | Absent | Absent | Absent |
| Secretary Francisco Ureña | Yes | Yes | Yes | Yes |
| Alan Woodward | Yes | Yes | Yes | Yes |
| **Summary** | **11 Members Present, 3 Members Absent** | **10 Members approved, 3 members absent, 1 not present at time of vote** | **11 members approved, 3 members absent** | **11 members approved, 3 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, October 10, 2018 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; Derek Brindisi; Harold Cox; John Cunningham, PhD; Michele David, MD; Meg Doherty; Michael Kneeland, MD; Paul Lanzikos; Secretary Francisco Ureña; and Alan Woodward, MD.

Absent member(s) were: Lissette Blondet; Joanna Lambert; and Lucilia Prates Ramos

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

Commissioner Bharel called the meeting to order at 9:11 AM and made opening remarks before reviewing the agenda.

**ROUTINE ITEMS**

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

Commissioner Bharel began by discussing the tragic series of explosions with over 70 fires that impacted the Merrimack Valley Area in mid-September. The long-term impacts of this incident became apparent several days after the first explosions: almost 100 homes and businesses have been destroyed or damaged and about 9,000 homes had their gas turned off – with November 19th set as the full restoration date. DPH actively assisted the Governor’s quick response. On the evening of the explosions, our Department Operations Center (DOC) was activated. During the time the DOC was activated staff monitored impacts to EMS transports; patient distribution; long term care and healthcare facilities; service delivery programs; and group homes. DPH staff worked to put an alternate destination waiver in place for EMS to allow the evacuation and transport of affected individuals to emergency shelters. Since the incident, we’ve established a cross-bureau incident management team to assist the Governor and MEMA with their response, as public health issues arise.

The Commissioner then discussed the flu season. The Department has begun its annual education and surveillance work related to influenza. In addition to vaccination, there are routine prevention steps to help prevent the flu, including frequent handwashing or using hand sanitizer; covering your cough and sneeze; staying home when sick; and talking to your doctor if you think you have the flu. Last year’s flu season was the most severe in the last 40 years. While there is no way to predict in advance what this year’s season will be like, the Commissioner encouraged everyone to share these strategies with your networks and refer them to <https://www.mass.gov/influenza>, so we can limit the spread of flu this season.

Following the update on flu prevention, Commissioner Bharel discussed West Nile Virus. West Nile virus has been particularly active this year with 10% of the mosquito samples testing positive for the virus. There have been a record 38 cases of WNV infection in people so far and we anticipate that more will be added to that number. We have already surpassed 2012 when we had 33 cases, the largest number of cases in a single year in Massachusetts. The significant WNV activity is likely due to the combination of heat, humidity and rainfall supporting mosquito populations. Transmission of WNV from mosquitoes to people usually declines significantly by October but some risk will continue until the first hard frost.

There has also been an outbreak of acute hepatitis A infection, a viral infection that affects the liver and can cause severe illness, among residents experiencing homelessness and/or substance use disorder statewide. The Department released a public health alert and held a call with local boards of health officials about this serious outbreak, encouraging local health departments to work with clinical and community-based agencies providing services to people experiencing homelessness and those with substance use disorder, especially those injecting drugs, to educate them about the health risks and to offer the vaccine.

As of October 4th, 84 cases of hepatitis A were reported in the state with most concentrated in Boston but an increasing number in other cities and towns, including the Southeast and metro Boston areas. At a time when at least 10 other states have reported outbreaks, we continue to work with our local health departments to encourage and assist their education and vaccination efforts, and urge clinicians and local health departments to vaccinate through homeless outreach services, shelters, community health centers, hospitals, and other facilities where at-risk individuals seek care. She informed the Council that they can share with their networks DPH’s webpage regarding Hepatitis A – <https://www.mass.gov/service-details/hepatitis-a> – which has a fact sheet, translated into 12 different languages.

Finally, Commissioner Bharel shared that she recently attended the annual meeting of the Association of State and Territorial Health Officials (ASTHO) and while there, she accepted the ASTHO’s Vision Award on behalf of the Department’s Public Health Data Warehouse (which was formerly known as Chapter 55). She thanked Dana Bernson, Hermik Babakhanlou-Chase, Malena Hood, Cheryl Kennedy-Perez, Lauren LaRochelle, Elizabeth Scurria Morgan, and Leonard Young for the instrumental role they each played in designing and operationalizing the Public Health Data Warehouse.

This team continues their innovative application of data through the Department’s newly created Office of Population Health led by Abbie Averbach, who oversees this office as part of her work as Associate Commissioner at DPH.

With no further updates, the Commissioner asked the Council if they had any questions or comments.

With no questions or comments, the Commissioner proceeded with the docket.

**1. ROUTINE ITEMS**

**c. Record of the Public Health Council September 12, 2018 Meeting (Vote)**

Commissioner Bharel asked if any members had any changes to be included in the September 12, 2018 meeting minutes.

Seeing none, the Commissioner asked for a motion to accept the minutes. Mr. Lanzikos made the motion and Dr. David seconded it, all present members approved.

**2.DETERMINATIONS OF NEED**

**a.Further review of the following transfer of ownership: CareGroup, Inc.; Lahey Health System, Inc.; and, Seacoast Regional Health Systems, Inc. intend to integrate and create a new corporation, known for the time being as NewCo, which will serve as the sole corporate member of the new health care system.  (Vote)**

Commissioner Bharel invited Nora Mann, Determination of Need Program Director, and Rebecca Rodman, Deputy General Counsel, to the table to review amendments to the DoN staff recommendation for the Beth Israel Lahey Health transfer of ownership.

Commissioner Bharel reminded the Council and audience that this is a recorded meeting and for those who are invited to speak to state their name for the record. Several ten tax payer groups were also available for comment.

Upon the conclusion of the presentation, the Commissioner invited a representative from the GOTEACH TTG to the table.

Bonnie Gilbert, Co-Chair of the GBIO and member of GOTEACH TTG, represented the group. Ms. Gilbert discussed the group’s outrage at the steps taken and conditions offered by DPH. She discussed the HPC report and how they noted this merger would likely raise commercial healthcare spending by at least $230 million per year. She urged the Council to revoke the DoN as this merger is not in the public’s interest. They asked that conditions be established that protect the premium payers including business and patient consumers in Massachusetts. She discussed Condition #5 and #6 and the lack of penalties and that there aren’t any measures to protect premium payers from annual increased costs.

Upon the conclusion of Ms. Gilbert’s statement, the Commissioner thanked her and the group for being here today and invited a representative of the applicant to the table to help address any questions.

Dr. Kevin Tabb, CEO of Beth Israel Deaconess Medical Center joined the table.

Dean Cox thanked GOTEACH TTG for their presentation and for drawing attention to how we can protect those that are most vulnerable. He asked DPH staff if our recommendations are strong enough or are there additional measures that should be considered.

Ms. Mann replied that in the event that any holder is not compliant with any part of its obligations, no part of the system can receive a DoN until it brings itself into compliance. This includes any one of its subsidiary entities. There is also the requirement that if they are not in compliance with the DoN, this body has the opportunity to assess, up to 5%, of the total value of this transaction to support community health initiatives. They have also required a level of granularity in reporting so that they can understand trends and see what is actually happening. She went on to say that they understand what was projected by HPC but they now have the opportunity to see what is going to happen and provide accountability and transparency on a year by year basis for those potential risks.

Ms. Rodman also added that they are recommending that the duration be for 10 years rather than 5. This would provide the Department a longer opportunity to monitor it and respond. She also clarified the penalty in condition 5 and 6. If the TMI is threatening the cost growth benchmark the money is going to be directed to the underserved populations, with the Council’s approval.

Dean Cox suggested that, in reference to item #9, it is important that affiliate organizations are engaged and part of the process. He would want to add, in writing, that they are at the table when those deliberations occur.

Ms. Mann replied that the affiliate organizations were only excluded, for when NewCo calculates their percent of their payer mix.

Dean Cox informed him that he was glad they made that stipulation. He also discussed the importance of having the affiliates at the table with NewCo and would like to have that added.

Ms. Rodman suggested that Dr. Tabb discuss how they are involved and how they can’t be involved.

Dr. Tabb began by stating that they believe they have the potential to do something very different in the Commonwealth. The objective evidence is that they have done everything that they said they would do and have kept cost down. Dr. Tabb went on to say that he has never dismissed concerns and issues that have been raised. The concerns and issues that are raised around cost of health care and access are legitimate concerns; they are not isolated to this transaction. The conditions being imposed are unprecedented in the Commonwealth and throughout the country. This is also not the only place where conditions will be imposed. He also noted that they will be making significant long term investments in community based institutions that address social determinants of health and access. To address, Dean Cox’s comment, Dr. Tabb stated that he embraces his concept. They do it currently and expect to continue it. Dr. Tabb concluded by saying that the only way to assure the money is well spent is to involve the community where the money will be spent.

Dean Cox stated that he appreciate his comment however, he has become more rigid about the kind of protections that need to be in place upfront. He wants to explicitly state that affiliates will be at the table with NewCo and proposed an amendment.

Ms. Rodman replied that in Condition 9 they can add that consultation will be done with affiliates.

Dean Cox withdrew the amendment until language is drafted.

Dr. Tabb stated that he does not see an issue with this amendment.

Meg Doherty arrives at 9:57am.

Dr. Bernstein asked for clarification about accountability and the affiliates.

Ms. Rodman informed him that they don’t think the affiliate should be held accountable to what the holder is doing. Dean Cox is referring to engaging the affiliate in the planning. They are specifically asking the holder to focus on the Masshealth payer mix within its subsidiaries.

Mr. Lanzikos asked if they could elaborate on the relative importance of the social determinants of health in the delivery of care. He also asked how the community will be involved.

Dr. Tabb stated that they recognize and acknowledge that much of what contributes to health and illness extends beyond traditional medical care. While they can’t discuss specifics of their conversations with the Attorney General, Dr. Tabb stated that he wanted to make clear that Beth Israel/Lahey Health will be making significant long term investments in community based institutions. He discussed their network of affiliated community health centers.

Mr. Lanzikos asked if he anticipates that they will be active decision makers.

Dr. Tabb replied that he wants to be careful about using the words “active decision makers” since it was pointed out that the onus is on them as the holder.

Mr. Lanzikos then asked about condition #3 and how they plan on informing the public on the status of the affiliation.

Dr. Tabb stated that he can’t state the exact detail at the moment but they will make large efforts through a host of different communication vehicles. The report would be submitted annually to the Council.

Mr. Lanzikos asked if staff anticipated whether these reports would be presented to the Council as they come in.

Ms. Mann informed him that their plan with all of the reports is to do an analysis and then present to the Council on an annual or semiannual basis.

Dr. Cunningham asked what the total value of the transaction is.

Ms. Mann informed him that it is $5.2 billion.

Dr. Cunningham asked if they would request that the HPC does a CIMR in 5 year if they haven’t already done one.

Ms. Mann replied that they are an independent agency so they cannot require it.

Dr. Woodward discussed the cost and the potential for a cost increase. He asked what assurance they can provide that they will be more cost effective.

Dr. Tabb stated that while this Council cannot directly address this issue, they are taking a hard stance on what it can address. He also informed him that there are other regulatory bodies that can and will impose additional conditions. He also stated that they are making these assurances to this own board and constituents that this is the right model for them to move forward with.

Dean Cox asked how these recommendations that the staff have put forth will protect safety net hospitals that are not part of the system but work alongside you.

Dr. Tabb replied that the recommendations will ensure that the safety net hospitals and community health centers will be affiliated with a strong and vibrant system that can invest in the things that support the communities that they serve and that we serve. He also discussed the financial distress that some of those hospitals and chc’s are in and how this model will help support them.

Dean Cox asked are there protections that have to be put in place to protect those hospitals and CHCs.

Dr. Tabb stated that the concerns that exist cannot be solely solved by this transaction; however, there should be concern about sustainability if this doesn’t move forward.

Ms. Mann added that BI-Lahey would be required to describe their efforts and the impact of their efforts using measurable metrics. Community appropriate discharges will have to be reported to us.

Mr. Brindisi focused on condition #6 and asked if they can explain what consists of a community provider investment plan.

Dr. Tabb stated that he can’t do that at the moment since it needs to be developed with the community. He also discussed the 10 year term of the agreement.

Mr. Brindisi stated that he doesn’t see where community engagement is suggested and would like to see that language added.

Ms. Mann stated that they are not talking about the formal CHI plan.

Mr. Brindisi asked if those dollars would be reinvested and will be they reflected in capital improvements.

Ms. Rodman replied that this is a plan that needs PHC approval and they will have an opportunity to weigh in on.

Commissioner Bharel then asked Ms. Rodman for the amended language to condition #9.

Ms. Rodman stated that it currently says “No later than 6 months from the date that the transaction is complete, the holder shall submitted a proposal for review by the Department detailing how it will address the low percentage of MassHealth in its payer mix.” They will add that the “holder must ensure that this proposal is developed with the direct involvement of the holder’s contracted affiliate hospitals.

Dean Cox made a motion to adopt that language, Dr. Woodward seconded it. All members approved.

With no further questions, the Commissioner asked if there is a staff recommendation for approval of this transfer of ownership is approved as amended. Mr. Lanzikos made the motion, Dr. Woodward seconded it. All present members approved.

**FINAL REGULATIONS**

**a. Request to promulgate amendments to 105 CMR 700.000, *Implementation of M.G.L. c. 94C.* (Vote)**

Commissioner Bharel then invited Jim Lavery, Director of the Bureau of Health Professions Licensure, Lauren Nelson, Director of Policy and Regulatory Affairs for the Bureau, Diane Barry, Deputy General Counsel, and Rebecca Rodman, Deputy General Counsel, to present a request for approval of amendments to the Department’s drug control regulation.

Dr. Bernstein and Secretary Urena step out at 10:45am and returns at 10:48am.

Upon the conclusion of their presentation, the Council was invited to ask questions.

Mr. Lanzikos asked under what circumstances would pharmacists administer medication.

Ms. Nelson informed him that the drugs that are listed are all extended release injectable drugs and are administered infrequently. The law allows patients to not have to see their clinicians whenever they need a dosage thus allowing the prescriber to monitor the administration of the drug and the patient to not have to see the clinician for every injection.

Ms. Nelson also informed Mr. Lanzikos that this is a voluntary measure. If the pharmacy decides that it would like to participate then they would need to follow the requirements that are listed.

Mr. Laznikos asked what type of oversight will be done once its implemented.

Ms. Nelson replied that patients would be routinely assessed by their clinicians, the list of drugs provided is limited and that a prescription must be provided.

Mr. Lanzikos asked if this is occurring in other states.

Ms. Nelson informed him that Connecticut does practice this.

Dr. Cunningham asked about the clinician involvement in regards to the prescription.

Ms. Nelson informed him that the first dose must be given by the clinician.

With no further questions or comments, the Commissioner asked for a motion to approve the proposed amendments to the regulation.

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

**4. PRESENTATIONS**

**a. Informational report on an outbreak of HIV infection among persons who inject drugs: Northeastern Massachusetts, 2016-2018**

Commissioner Bharel then invited Kevin Cranston, Assistant Commissioner and Director of the Bureau of Infectious Disease and Laboratory Sciences, to the table for a presentation on the Department’s role in this investigation, as well as review the investigation’s findings. The Commissioner also acknowledged Dr. Charles Alpren, the Epidemic Intelligence Service Officer assigned by the CDC to assist with the investigation and who is here today. Dr. Al DeMaria also joined Mr. Cranston for his presentation

Upon the conclusion of their presentation, the Council was invited to ask questions

Mr. Lanzikos leaves at 11:27am and does not return

Dr. Kneeland asked if they can explain what is meant by genetic distance, specifically low genetic distance.

Dr. DeMaria replied that they can sequence the gene themselves or get information from viral resistance testing that gets done routinely in patients. It is a preliminary gene that mutates to resistance to the drugs that interfere with RNA replication.

Dr. Woodward asked about the new user level educational materials and how much awareness is there of how diseases are spread via injection.

Mr. Cranston stated that that is a harm reduction point of education. He then discussed needle sharing and how for some individuals sharing less would have to occur first before they get to the point where they seek assistance from a rehabilitation program.

Dr. Bernstein asked about PREP.

Mr. Cranson stated that while PREP is successful, this is something that they’ve looked into to see if it is useful to this population. For this population, PREP would be a daily dosage for some.

With no further questions or comments, the Commissioner reminded the Council that the next meeting is Wednesday, November 14, 2018 at 9AM.

She then asked for a motion to adjourn. Dr. Bernstein made the motion Dr. Kneeland seconded it. All present members approved.

The meeting adjourned at 11:36AM.