**MINUTES OF THE PUBLIC HEALTH COUNCIL**

**Meeting of July 13, 2016**

**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, July 13, 2016 9:00 AM**

1. **ROUTINE ITEMS:**
2. Introductions
3. Updates from Commissioner Monica Bharel, MD
4. Record of the Public Health Council Meeting June 8, 2016 **(Vote)**

**2. DETERMINATION OF NEED**

a. North Shore Medical Center, Inc. request for approval of substantial capital expenditure and substantial change in service regarding new construction DoN Project No. 6-3C46 **(Vote)**

**3. PRELIMINARY REGULATIONS**

a. Informational briefing on proposed regulatory amendments to 105 CMR 315.000 – Cremation of Bodies Received from Outside Massachusetts

b. Informational briefing on proposed regulatory amendments to 105 CMR 460.000 – Lead Poisoning Prevention and Control

**3. FINAL REGULATIONS**

* 1. Request for final promulgation of proposed amendments to 105 CMR 270.000 –Blood Screening of Newborns for Treatable Diseases and Disorders **(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**

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

**Date of Meeting:** Wednesday, July 13, 2016

**Beginning Time:** 9:15AM

**Ending Time:** 11:26AM

**Attendance and Summary of Votes:**

| **Board Member** | **Attended** | **Item 1c**  **Minutes of the June 8, 2016 Meeting** | **Item 2a**  **Determination of Need #6-3C46** | **Item 4a**  **Request for final promulgation of proposed amendments to 105 CMR 270.000 – Blood Screening of Newborns for Treatable Diseases and Disorders** |
| --- | --- | --- | --- | --- |
| Monica Bharel | Yes | Yes | Yes | Yes |
| Edward Bernstein | Yes | Yes | Yes | Yes |
| Derek Brindisi | Yes | Abstained | Yes | Yes |
| Harold Cox | Yes | Yes | Yes | Yes |
| John Cunningham | Yes | Yes | Yes | Yes |
| Michele David | Absent | Absent | Absent | Absent |
| Meg Doherty | Absent | Absent | Absent | Absent |
| Michael Kneeland | Yes | Yes | Yes | Yes |
| Paul Lanzikos | Yes | Yes | Recusal | Yes |
| Lucilia Prates-Ramos | Yes | Yes | Yes | Yes |
| Meredith Rosenthal | Yes | Yes | Yes | Yes |
| Alan Woodward | Yes | Yes | Yes | Yes |
| **Summary** | **10 Members Present, 2 Members Absent** | **9 Members Yes, 1 Member Abstained, 2 Members Absent** | **9 Members Yes, 1 Member Recused, 2 Members Absent** | **10 Members Yes, 2 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, July 13, 2016 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; Michael Kneeland, MD; Paul Lanzikos; Lucilia Prates-Ramos; Meredith Rosenthal, PhD; and Alan Woodward, MD.

Absent member(s) were: Michele David, MD and Meg Doherty

Also in attendance were Elizabeth Scurria Morgan, First Deputy General Counsel at the Massachusetts Department of Public Health and Jennifer Barrelle, Director of Policy and Regulatory Affairs at the Massachusetts Department of Public Health.

Commissioner Bharel called the meeting to order at 9:15AM and made opening remarks before reviewing the agenda.

**ROUTINE ITEMS**

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

Commissioner Bharel congratulated Kevin Cranston, Assistant Commissioner and Director of the Bureau of Infectious Disease and Laboratory Sciences, on his recent swearing in as a member of the Presidential Advisory Council on HIV/AIDS.  She added that, in this role, he will serve a two-year term on this appointed body which advises the federal government on public health and clinical responses to the HIV/AIDS epidemic and oversees the implementation of the President’s National HIV/AIDS Strategy in conjunction with the Office of National HIV/AIDS Policy.

The Commissioner noted that the Massachusetts Cancer Registry was recently recognized as one of 22 CDC National Program of Cancer Registries Registry of Excellence, indicating Registry submissions met the NPCR Advanced National Data Quality and Completeness Standard. She added that by meeting these high quality standards, the Registry’s data will be included in this year's United States Cancer Statistics report and other analytic data sets, and indicated this is a great recognition as we move toward becoming a more data-driven Department.

Commissioner Bharel then announced that the Bureau of Substance Abuse Services and the Communications Office were recently honored with a Telly Award for their “Stop Addiction in Its Tracks” campaign. She noted that the Telly Awards honor the very best fil and video productions, groundbreaking online video content, and outstanding local, regional, and cable TV commercials and programs. One of the commercials from the campaign was then played for members.

The Commissioner let members know DPH recently helped host the Public Health Minister of Afghanistan and the US Surgeon General, during which these officials visited several sites playing a key role in addressing the opioid epidemic. She added that thanks to DPH staff and partners around the state, Massachusetts is looked at as a national leader in this work.

Commissioner Bharel announced that the July meeting is Dr. Meredith Rosenthal’s last day on the Council, and added that she has brought an incredible wealth of knowledge and insight to the Council during her 10 years of service and will be missed. She then presented Dr. Rosenthal with a citation and DPH coin.

Dr. Rosenthal said it has been such a privilege to work on the Council, and she has nothing but respect for the Department and its employees.

1. **ROUTINE ITEMS**
2. **Minutes**

Commissioner Bharel asked if any members had any changes to be included in the June 8, 2016 meeting minutes. Seeing none, the Commissioner asked for a motion to approve the minutes.

Dr. Woodward made a motion to approve, and Dr. Bernstein seconded the motion. All approved, except Mr. Brindisi, who abstained from the vote as he was not present at the June meeting.

**2. DETERMINATION OF NEED**

**a. North Shore Medical Center, Inc. request for approval of substantial capital expenditure and substantial change in service regarding new construction DoN Project No. 6-3C46 (Vote)**

9:25 – Paul Lanzikos recused himself from voting on DoN Project No. 6-3C46, and left the room prior to the start of review for the project.

Commissioner Bharel gave an overview of the proceedings for today’s determination of need application, including an overview of those speaking.

The Commissioner invited Mike Sinacola, Interim Deputy Director for the Bureau of Health Care Safety and Quality, Ben Wood, Acting Director for the Office of Community Health Planning and Engagement within the Bureau of Community Health and Prevention, and Rebecca Rodman, Deputy General Counsel, to the table for a presentation of the DoN Staff Summary for Project #6-3C46.

Mr. Sinacola’s presentation reviewed the DoN staff summary of the project and recommendation of approval with conditions. He noted that DPH’s review indicates a more than 70% reduction in annual operational losses; a reduction in operation footprint allowing for a more appropriate number of medical surgical beds to meet present and future demand; overall modernization of healthcare facilities; and a significant increase in total psychiatric bed capacity to address deficiencies in behavioral health capacity and ongoing emergency department boarding.

Upon conclusion of Mr. Sinacola’s presentation, Commissioner Bharel invited Senator Thomas McGee, Representative Dan Cahill, and Representative Brendan Crighton to the table. Senator McGee proceeded to read a letter submitted on behalf of the Greater Lynn legislative delegation.

Senator McGee noted he was providing remarks today on behalf of the delegation, including House Minority Leader Bradley Jones; Representative Lori Ehrlich; Representative Donald Wong; Representative RoseLee Vincent; Representative Dan Cahill; and Representative Brendan Crighton, and indicated this has not been an easy process for the Lynn community. He asked the Council to consider the following conditions to approval of the determination of need: maintaining access to emergency services in Lynn; community and stakeholder engagement regarding continued access to essential services for residents of the service area; quarterly updates by North Shore Medical Center on the status of plans for the Union Hospital campus; and commitment to monitor, address, and support approaches that respond to the impacts of the service consolidation. He indicated that the proposed consolidation to Salem would leave Lynn as one of the largest communities in Massachusetts without a community hospital, and again urged Council members to consider the additional conditions during their review.

Upon conclusion of Senator McGee’s presentation, Commissioner Bharel invited Lynnfield Board of Selectman Chairman Phil Crawford to the table to provide remarks regarding the determination of need project.

Chairman Crawford noted that this project affects more than just Lynnfield, including Peabody, Saugus, and West Lynn, and over 150,000 residents in that area that now access services at Union Hospital. Mr. Crawford asked the Council to consider attaching the following conditions to approval of the determination of need: emergency services be kept on a permanent basis on the Union Hospital campus; North Shore Medical Center comply with conditions established in prior rulings, including establishing a planning committee that includes community leaders and elected officials; provide annual financial compensation to towns in the service area to compensate for increased drive time and the expense of emergency personnel responding out of service. He concluded by asking Council members to help preserve the safety of Lynnfield residents and the surrounding communities, and include the conditions discussed in approval of determination of need.

Upon conclusion of Chairman Crawford’s remarks, Commissioner Bharel invited Tyrek Lee, representative of the Allen Jackson Ten Taxpayer Group, to provide remarks on behalf of the Group.

Mr. Lee emphasized a need to analyze community health needs on an ongoing basis, as those needs shift rapidly. He also added that a diverse board at the hospital is critical. He noted the Group strongly supports the DoN program’s staff recommendation and thanked the Council for all the work to date, and indicated the Group is prepared to move forward and prepare for the future of healthcare.

Upon conclusion of Mr. Lee’s remarks, Commissioner Bharel invited Michael Toomey, representative of the Michael Toomey Ten Taxpayer Group, to the table to provide remarks on behalf of the Group.

Mr. Toomey thanked the Department and DoN staff for the professionalism and accessibility throughout this process. He noted that approval of this project would result in Lynn being the largest community in Massachusetts without a community hospital. He asked that these two campuses be treated as two separate hospitals with two separate primary service areas, and asked the Council to view the application in that way. He added that NSMC’s planning process excluded input from Lynn officials and community leaders, and noted these groups were not informed until decisions about the process had already been made. He raised concerns about the financial status of NSMC, and questioned the financial viability of the Salem Campus moving forward indicating ongoing analysis needs to occur.

Upon conclusion of Mr. Toomey’s remarks, Commissioner Bharel invited Leslie Greenberg, representative of the Leslie Greenberg Ten Taxpayer Group, to the table to provide remarks on behalf of the Group.

Ms. Greenberg indicated she gave staff a hard copy of longer testimony and would keep spoken remarks short. She noted the determination of need application is tied to the closure of Lynn’s only hospital. She indicated while saddened by the closure, they recognize the changes in the healthcare system that have led to this and that her group has negotiated with North Shore Medical Center several agreements to address the impact of losing Union Hospital in Lynn. She noted they are concerned with proposed changes in leadership, and asks for annual updates on progress to ensure work is ongoing. She asked Council members to consider asking NSMC to move more quickly to update its board composition to ensure representation of Lynn’s diverse population throughout the consolidation process.

Upon conclusion of Ms. Greenberg’s remarks, Commissioner Bharel invited Bob Norton, President of North Shore Medical Center, and Pam Lawrence from North Shore Medical Center to the table to provide remarks on the proposed project. Mr. Norton indicated that while he has made plans to retire, he has six months to continue doing good work at North Shore Medical Center. He reviewed components of the project and indicated that the proposal will allow the hospital to provide specialized acute hospital services on one campus and eliminate duplication of service. He indicated that the plan would move towards a community-based service model, while inpatient care has grown more technology-intensive and complex. He added that the construction project is one piece of an overall regional plan that will expand outpatient primary and specialty care services and expanded behavioral health capacity including substance use disorder treatment. He added that the plan would repurpose the former Spaulding Hospital site to house and expand inpatient psychiatric care. Additionally, Mr. Norton indicated that a planning group including community and elected officials was convened to discuss how to best address emergent and urgent care needs of the community moving forward. He indicated this group has met twice, has another meeting in September, and plans to have an update by one year of approval of the DoN. Mr. Norton added that North Shore Medical Center is in alignment with the principles outlined in Senator McGee’s letter, and appreciates all the work to date with the legislative delegation.

Commissioner Bharel thanked Mr. Norton for his remarks. Ms. Rodman made a procedural statement and noted that while the Council may add conditions to the approval, she indicated that the DoN process is robust and has a formalized process for receiving and reviewing comments, and at this time a request for further conditions is late and would not allow parties of record the opportunity to comment. She noted that North Shore Medical Center has agreed in principle with the further conditions outlined by the legislative delegation and suggested that, if both parties are willing, this commitment could be documented and added to the formal record for the DoN. She indicated this would also maintain the separation between DoN and essential services processes.

Dr. Woodward applauded the behavioral health component of the plan, as emergency department boarding is an ongoing issue. He indicated that emergency travel time has been expressed as a concern today, and noted that no 24-hour emergency services in the Lynn community would be a concern. He noted that it is critical in this process to look at the possibility of maintaining a satellite emergency facility in Lynn, which it sounds like is being looked at, as well as urgent care. He added that lack of 24-hour emergency care for a community the size of Lynn would be a risk to the population. Dr. Woodward stated that, if this isn’t to be added as a condition, it be looked at and clearly stated in the letter of commitment.

Mr. Norton indicated that the planning group has met twice already and meetings will be ongoing. He indicated that no options have been taken off the table at this time, but that review of these options will require ongoing discussion. He added that the Medical Center does not intend to take the entire three years to complete this review, but has consistently committed to ensuring full emergency services be maintained in Lynn while the Medical Center completes construction for the Salem campus project.

Dr. Woodward indicated that while there is a plan to address behavioral health boarders, consolidation of two large emergency departments into a bigger physical plant could lead to boarding of medical/surgical patients if the outflow is not properly planned and controlled for.

Mr. Cox noted that on condition #6, indicating a more diverse hospital board, if it would be useful to insert the number of members to be added for clarity. He also inquired the breadth of process and teeth associated with updates being provided as part of condition #7. He indicated he is not sure what should be added to the condition, but as written now it feels weak.

Mr. Sinacola indicated that the intent of the condition is that DoN staff would receive updates for review, and present those to the Council, to help ensure ongoing health and safety. He indicated that if the reports show the applicant is not adequately ensuring health and safety there could be opportunity to request additional updates or requirements.

Ms. Rodman indicated that it is important to note there are two separate processes occurring, and that through the essential services closure process the applicant is required to provide the Department with quarterly updates. She indicated that the update to the Council in a year would provide an opportunity for the Council to review what has happened over the last year and to ask for more information or further actions. She noted that, because this project will not be complete in a year, there is an opportunity for the Council to have continued input.

Mr. Cox said he sees that is the intent with the Council being the final arbiter, but was looking to better understand the language and whether it could be strengthened.

Ms. Rodman noted that this update process has worked well for the Council, as indicated by Ms. Greenberg’s comments concerning the 1997 DoN approval and that is the intent of the condition on this application.

Dr. Kneeland asked about the process for board members to be appointed and how the decision is made.

Mr. Norton responded that North Shore Medical Center has a nominating board that considers candidates on a yearly basis and makes recommendations to the full board. He added that those recommendations are then ratified by the full Partners board.

Dr. Bernstein indicated it would be helpful to have an update on plans for emergency services within a year of approval versus putting this off for three years. He spoke of his experience at Boston Medical Center during the merging of two hospitals and cultures, and noted that the same seems to be happening here. He asked what the strategy would be for this process.

Mr. Norton indicated that this is work that has been occurring over the past 15 years, and is hard work. He added that presently there is an obligation to return in a year with an update.

Dr. Bernstein asked if the Medical Center has a plan to address health equity because that seems to be driving conditions like board representation and maintaining essential services, and ensuring that is part of the bigger picture.

Mr. Norton responded that North Shore Medical Center has already begun interviewing candidates for the board, and added that examining health disparities should be part of the updated health needs assessment.

Dr. Woodward asked what the status of the letter of commitment was at this time.

Ms. Rodman indicated the Council may request such a letter.

Dr. Woodward responded that this letter is critical, and it sounds like both sides are in agreement. He added that the letter should be secured.

Dr. Bernstein also expressed concern around emergency department boarding, and asked the applicant what they consider an acceptable level of boarding.

Mr. Norton responded that the commitment to double the number of inpatient psychiatric beds will help alleviate some of the need right now, but added that access is an issue statewide and he expects the increased beds will be filled quickly. He instructs staff no level of boarding is acceptable, and that patients should be moved to acceptable patient settings as soon as they are in the door. He noted that the new emergency department was designed with that in mind, and expands capacity while adding a dedicated observation area. He added that we all need to focus of appropriate use of the emergency department, for both financial and access reasons, and that should become part of ongoing planning.

Mr. Cox returned to the letter of commitment, and indicated there are three important things that be added to that letter: 1) number of members to be added to the board; 2) stakeholder engagement and community involvement; and 3) quarterly updates, as those items are not part of the staff’s recommendation.

Ms. Rodman indicated that items 2 and 3 are part of the essential services process to date, and that DPH has begun receiving quarterly updates. She recommended that this letter be treated separately from the DoN today, and advised the Council request the letter, allowing the respective groups to work on the details. She indicated the letter could be brought back to the Council for review, but that it is separate from the DoN before the Council today.

Mr. Cox indicated he was willing to entertain this approach, and asked that the letter come back to the Council for review.

Andy Levine, legal counsel to North Shore Medical Center, came to the table to make a comment. He noted that there is some overlap presently across the essential services and DoN reporting requirements regarding review of emergent and urgent care services.

Commissioner Bharel noted that what she is hearing is that the Council is requesting this letter of commitment to respond to some of the concerns addressed today. She asked Mr. Norton if that was his understanding of the discussion today, and if he was willing to commit here today to providing that letter.

Mr. Norton indicated that was his understanding, and North Shore Medical Center was willing to commit to and provide the Council with this letter.

Commissioner Bharel requested a motion to approve, with conditions as specified in the DoN staff summary,North Shore Medical Center, Inc.’s request for approval of substantial capital expenditure and substantial change in service regarding new construction DoN Project No. 6-3C46.

Dr. Woodward specified that this motion for approval would be approval with the conditions as specified in the staff summary.

Commissioner Bharel indicated that this approval would be with the conditions as presented in the staff summary.

Dr. Woodward made a motion to approve the project; Dr. Rosenthal seconded the motion. All approved.

Dr. Rosenthal left the room briefly at 10:48AM, and returned at 10:50AM.

Dr. Cunningham and Dr. Bernstein left the room briefly at 10:49AM, and returned to the room at 10:53AM.

Mr. Lanzikos returned to the room at 10:51AM.

1. **PRELIMINARY REGULATIONS**

Commissioner Bharel indicated that a quorum of members had returned to the Council room, and that the Council would proceed with their agenda.

**3a. Informational briefing on proposed regulatory amendments to 105 CMR 315.000 – Cremation of Bodies Received from Outside Massachusetts**

Commissioner Bharel invited Jim Ballin, Deputy General Counsel, to the table for a presentation on proposed amendments to 105 CMR 315.000, *Cremation of Bodies Received from Outside Massachusetts*.

Upon conclusion of the presentation, the Commissioner asked if Council members had any questions for Mr. Ballin.

Mr. Lanzikos asked how frequently bodies to be cremated are received from out of state.

Mr. Ballin indicated that this procedure does occur, and that part of the reason for this law and regulation is that each neighboring state has different rules regarding handling of these bodies.

Seeing no further questions, the Commissioner thanked Mr. Ballin for his presentation. She then indicated a change in agenda, due to the time, and announced that the presentation requesting final approval of proposed amendments to the newborn screening program regulation, 105 CMR 270.000, will occur prior to the informational presentation on the lead poisoning prevention and control regulation, 105 CMR 460.000.

**4. FINAL REGULATIONS**

1. **Request for final promulgation of proposed amendments to 105 CMR 270.000 –Blood Screening of Newborns for Treatable Diseases and Disorders (Vote)**

Commissioner Bharel asked Mr. Ballin to remain at the table and invited Michael Pentella, Director of the State Public Health Laboratory, Roger Eaton, Director of the New England Newborn Screening Program, and Anne Comeau, Deputy Director of the New England Newborn Screening Program, to join him for a presentation requesting approval of proposed amendments to 105 CMR 270.000, *Blood Screening of Newborns for Treatable Diseases and Disorders*, for final promulgation.

Upon conclusion of the presentation, the Commissioner asked if Council members had any questions for Mr. Pentella, Mr. Eaton, Ms. Comeau, or Mr. Ballin.

Seeing no questions, the Commissioner thanked Dr. Comeau, Dr. Eaton, Mr. Pentella, and Mr. Ballin for their presentation. She then requested a motion from the Council to approve the proposed amendments to 105 CMR 270.000, *Blood Screening of Newborns for Treatable Diseases and Disorders*.

Dr. Rosenthal made a motion to approve the proposed amendments for promulgation, which was seconded by Dr. Bernstein. All approved.

**3b. Informational briefing on proposed regulatory amendments to 105 CMR 460.000 – Lead Poisoning Prevention and Control**

Commissioner Bharel asked Mr. Ballin to remain at the table, and asked Paul Hunter, Director for the Childhood Lead Poisoning Prevention Program within the Bureau of Environmental Health, and Alicia Fraser, Assistant Director for the Environmental Epidemiology Program within the Bureau of Environmental Health, to join him for an informational presentation on proposed amendments to 105 CMR 460.000, *Lead Poisoning Prevention and Control*.

Upon conclusion of the presentation, the Commissioner asked if Council members had any questions for Mr. Hunter, Ms. Fraser, or Mr. Ballin.

Dr. Kneeland asked if there is any data on the number of false negatives with capillary testing.

Mr. Hunter indicated that DPH does have data on that and it is a small number, but he would need to bring that information back to members.

Mr. Lanzikos asked how these regulations affect homeowners of older dwellings.

Mr. Hunter indicated that, since 1988, Massachusetts has had a legal requirement for notification at the transfer of any property, informing owners of their responsibilities under the law and a 10-day contingency to have the house inspected for lead at their expense.

Mr. Lanzikos asked, since he purchased his home in 1985, if he had a child who came to live in the house under the age of six whether there would have been notification to the homeowner through the birth or adoption of a child.

Mr. Hunter responded not routinely, unless the house has been re-rented since implementation of tenant lead law notification.

Commissioner Bharel added that there is universal lead screening in Massachusetts, so all children are screened.

Commissioner Bharel indicated that the next meeting will be held August 10, 2016, and requested a motion to adjourn.

Dr. Bernstein made a motion to adjourn; Dr. Cunningham seconded the motion. All approved.

The meeting adjourned at 11:26AM.

LIST OF DOCUMENTS PRESENTED TO THE PHC FOR THIS MEETING:

* Minutes of the Public Health Council Meeting June 8, 2016
* Copy of staff memo and recommendation for North Shore Medical Center’s request for approval of substantial capital expenditure and substantial change in service regarding new construction DoN Project No. 6-3C46
* Copy of regulation and presentation discussing proposed regulatory amendments to 105 CMR 315.000 – Cremation of Bodies Received from Outside Massachusetts
* Copy of regulation and presentation discussing proposed regulatory amendments to 105 CMR 460.000 – Lead Poisoning Prevention and Control
* Copy of regulation and presentation requesting final promulgation of proposed amendments to 105 CMR 270.000 –Blood Screening of Newborns for Treatable Diseases and Disorders

Commissioner Monica Bharel, Chair