**MINUTES OF THE PUBLIC HEALTH COUNCIL**

**Meeting of August 9, 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, August 9, 2017 - 9:00 AM**

1. **ROUTINE ITEMS**
   1. Introductions
   2. Updates from Commissioner Monica Bharel, MD, MPH
   3. Record of the Public Health Council July 12, 2017 Meeting **(Vote)**
2. **DETERMINATION OF NEED**
   1. North Shore Medical Center application for significant amendment to its’ previously approved DoN Project Number 6-3C46 **(Vote)**
3. **FINAL REGULATIONS**
4. Request for final promulgation of proposed amendments to 105 CMR 205.000, *Minimum Standards Governing Medical Records and the Conduct of Physical Examinations in Correctional Facilities* **(Vote)**
5. Request for final promulgation of proposed amendments to 105 CMR 720.000, *List of Interchangeable Drug Products* **(Vote)**
6. **INFORMATIONAL PRESENTATIONS**
7. Informational presentation: Implementation of the revised Determination of Need regulation, 105 CMR 100.000

1. Informational overview of the Office of Problem Gambling Services

*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, August 9, 2017

**Beginning Time:** 9:14AM **Ending Time:** 11:31AM

| **Board Member** | **Attended** | **Record of the Public Health Council July 12, 2017 Meeting (Vote)** | **North Shore Medical Center application for significant amendment to its’ previously approved DoN Project Number 6-3C46 (Vote)** | **Request for final promulgation of proposed amendments to 105 CMR 205.000, *Minimum Standards Governing Medical Records and the Conduct of Physical Examinations in Correctional Facilities* (Vote)** | **Request for final promulgation of proposed amendments to 105 CMR 720.000, List of Interchangeable Drug Products (Vote)** |
| --- | --- | --- | --- | --- | --- |
| Monica Bharel | Yes | Yes | Yes | Yes | Yes |
| Edward Bernstein | Yes | Yes | Yes | Yes | Yes |
| Lissette Blondet | Absent | Absent | Absent | Absent | Absent |
| Derek Brindisi | Yes | Yes | No | Yes | Yes |
| Harold Cox | Yes | Yes | Yes | Yes | Yes |
| John Cunningham | Absent | Absent | Absent | Absent | Absent |
| Michele David | Yes | Abstain | No | Yes | Yes |
| Meg Doherty | Yes | Yes | Yes | Yes | Yes |
| Michael Kneeland | Yes | Yes | Yes | Yes | Yes |
| Paul Lanzikos | Yes | Yes | Recusal | Yes | Yes |
| Lucilia Prates-Ramos | Absent | Absent | Absent | Absent | Absent |
| Secretary Francisco Ureña | Absent | Absent | Absent | Absent | Absent |
| Alan Woodward | Yes | Yes | Yes | Yes | Yes |
| **Summary** | **9 Members Present, 4 Members Absent** | **8 Members Approved, 4 Members Absent, 1 Member Abstained** | **6 Members Approved, 4 Members Absent, 2 Members Opposed, 1 Member Recused** | **9 Members Approved, 4 Members Absent** | **9 Members Present, 4 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, August 9, 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; Derek Brindisi; Harold Cox; Michele David, MD; Meg Doherty; Michael Kneeland, MD; Paul Lanzikos; and Alan Woodward, MD.

Absent member(s) were: Lissette Blondet; John Cunningham, PhD; Lucilia Prates-Ramos; and Secretary Francisco Ureña

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

Commissioner Bharel called the meeting to order at 9:14 AM and made opening remarks before reviewing the agenda.

**ROUTINE ITEMS**

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

The Commissioner began by announcing that the Governor Baker and the Department announced $500,000 in funding for five Houses of Correction to provide a wide range of treatment and recovery services to those incarcerated with an opioid use disorder.

These funds will target individuals within two months of release, and will play a critical role in supporting a population we know is significantly more susceptible to the opioid epidemic upon release. State data shows incarcerated individuals with a history of opioid use disorder are at a 56 times higher risk of opioid overdose death following their release, as compared to the general public.

To help combat this trend, major services supported by the funding include:

• Access to Medication Assisted Treatment (MAT) including buprenorphine and Extended Release Injectable Naltrexone

• Case management services to facilitate a successful transition from a correctional services environment back into the community

• Linkages to community-based treatment and recovery support services.

These grants are a good example of using information from the Administration’s unprecedented Chapter 55 report to strengthen our data-informed approach to prevent overdoses and save lives.

Commissioner Bharel then informed the Council that Ronnie Rom and the Office of Rural Health were recognized by the Health Resources and Services Administration for the outstanding quality performance of Massachusetts Critical Access Hospitals in achieving the highest reporting rates and levels of improvement over the past year. The 10 top-performing states – Massachusetts, Wisconsin, Maine, Utah, Minnesota, Illinois and Pennsylvania (which were tied), Michigan, Nebraska, and Indiana -- invested federal Office of Rural Health Policy funds into quality improvement projects and developed technical assistance resources to improve high-quality care in the community.

The Commissioner concluded by announcing a few personnel updates. Kerin Milesky has been appointed the Director of the Office of Preparedness and Emergency Management (OPEM). Kerin has served as Acting Director of OPEM since February 2017. In this role she has demonstrated strong leadership, communication, and management skills along with an ability to work collaboratively within DPH and with our many federal, state and local partners. Under Kerin’s leadership, OPEM will continue to partner with local, statewide and federal partners.

Ron Benham, Director for the Bureau of Family Health and Nutrition, is planning on retiring in early 2018. Ron started with the Department in 1983 and has served as Bureau Director since 2009. The Commissioner expressed the Department’s sincere gratitude to Ron for all his years of service, and for graciously agreeing to stay with DPH longer than originally anticipated in order to ensure significant succession planning and a smooth transition of leadership. A more formal celebration for Ron will be announced as his departure date approaches.

With no further updates, the Commissioner asked if the Commissioner had any questions or concerns regarding the updates. Seeing none, she proceeded with the docket.

Meg Doherty arrives at 9:17am.

**1. ROUTINE ITEMS**

**c. Record of the Public Health Council July 12, 2017 Meeting (Vote)**

Commissioner Bharel asked if any members had any changes to be included in the July 12, 2017 meeting minutes.

Seeing none, the Commissioner asked for a motion to accept the minutes. Ms. Doherty made the motion and Dr. Bernstein seconded it. All present approved except Dr. David who abstained as she was not present at the July 12th meeting.

**2. DETERMINATION OF NEED**

**a. North Shore Medical Center application for significant amendment to its’ previously approved DoN Project Number 6-3C46 (Vote)**

Commissioner Bharel then briefly discussed the process for the Determination of Need (DoN) presentation.

Through the original North Shore Medical Center DoN process in 2016, several ten-tax payer groups were formed. These groups submitted oral and written comments into the record regarding NSMC’s proposed changes to its originally approved DoN, which were provided to Council members in preparation for today’s meeting. A representative from one of those groups was present to speak before the Council today.

DoN staff will present their recommendation to the Council. After the staff presentation, representatives from the Leslie Greenberg Ten Taxpayer Group will be invited to speak. There are also representatives of the applicant here to answer any questions.

She asked that Council members hold all questions until conclusion of all the presentations.

With that, the Commissioner 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 North Shore Medical Center’s request for significant amendment to previously approved DoN Project Number 6-3C46.

Prior to their presentation, the Commissioner asked Mr. Lanzikos to leave the room as he has recused himself from participating in the determination of need application.

Mr. Lanzikos left the room at 9:20am.

Upon the conclusion of Ms. Mann’s presentation, representatives from the Leslie Greenberg ten-taxpayer group were invited to speak before the Council.

Ms. Leslie Greenberg introduced herself to the Council. She discussed concerns regarding the reduction of Med-Surg and Psych beds in comparison to the need. The ten-taxpayer group (TTG) requested the following from the Council:

1. Add average ED length of stay time data to trigger referral to the Public Health Council.
2. Give Medical-Surgical ED length of stay, wait, and boarding times the same

scrutiny as the psychiatry ED length of stay, wait, and boarding times in the staff recommendation.

1. Base the triggers for Council review on **reducing** times, not just keeping them at current levels. We propose half of what the current times are.
2. We ask you to eliminate the suggestion that the hospital be relieved of responsibility if wait times increase for reasons beyond its control.

Upon the conclusion of Ms. Greenberg’s presentation, the Council was invited to ask questions.

Dr. Woodward inquired as to why they did not include a Med-Surg occupancy rate and how they responded to the request from the ten-taxpayer group. He also indicated the TTG’s suggestions seem reasonable.

Ms. Mann spoke to why they didn’t add the Med-Surg reporting and noted that it speaks to the capacity and the occupancy numbers. With Med-Surg they are seeing an occupancy rate in the high 70s but not in the high 90s.

Dr. Woodward stated that in the geography it is a significant decrease in occupancy and suggested they monitor Med-Surg occupancy closely. He also requested NSMC respond to the other requests.

Ms. Cooke asked the Council to have a full discussion and then make any motions to changes.

Commissioner Bharel asked Ms. Rodman if she wanted to clarify anything in regards to the requests that were made by Ms. Greenberg and how that would be implemented in terms of amendments.

Ms. Rodman stated that the Council can move to amend conditions. It must be done as a motion in which the members vote.

Dean Cox asked if they could explain what the action is that can be taken by the Council based upon the data that was received.

Ms. Mann replied that it correlates to the overall authority. She noted that we do not have the authority to tell a hospital or system that they must build more beds or cannot close beds but instead are requiring data that will make a clear case for need. The opportunity for the PHC is to then be able to ask North Shore Medical what their plan is to address capacity needs given the data.

Dean Cox then made a clarifying statement inquiring if this was a bully pulpit.

Ms. Mann replied that it is part bully pulpit and part referring back to the language that North Shore used. North Shore stated that they were building shell space to construct additional beds based on need. If we can show them need then the alternative is for North Shore to take action.

Dr. Bernstein asked if they could define what is beyond reasonable control.

Ms. Rodman replied that if we see numbers that show increased ED boarding times we aren’t asking NSMC to provide a list of outside factors that would cause the increase. Instead we are looking for information on the geography of patients, their wait times, where are they being placed afterwards etc. and why shell space isn’t being utilized.

Dr. Bernstein stated that the ten-taxpayer group made a good point that there is extra income in the system to meet those needs.

Ms. Doherty asked for clarification on whether diagnosis was included in the analysis of the first condition.

Ms. Mann replied that one of the requirements in 1(d) is the primary and secondary diagnoses for any of the psych patients that are admitted.

Ms. Doherty replied that the reason she asked is due to the crisis in senior care, especially with dementia patients. Since care for dementia patients varies based on symptomatology, she inquired why the geripsych component is carved back.

Ms. Mann informed Ms. Doherty that that is a question that she will let the applicant reply.

Dean Cox asked that DoN staff remind the Council what their purview is.

Ms. Rodman stated that if the referral indicators are a concern the Council has the opportunity to have this brought back before them. Program staff can present data and NSMC can answer questions and give their own presentation. The Council could then make recommendations.

Dr. Bernstein inquired if that means they can mandate.

Ms. Rodman replied that NSMC is agreeing that if they cannot satisfy the Council with an alternative plan they have the shell space to open additional beds.

The Commissioner then invited the following representatives from the applicant group to the table to answer any questions: David Roberts, MD President of NSMC, Andy Levine attorney representing NSMC from Donoghue, Barrett & Singal.

Dr. David noted that in a previous DoN, Partners informed the Council that their priority was to care for the underserved. The particular part of the state where NSMC is located seems to have underserved needs that need to be met. She inquired why there is such a significant decrease in this particular DoN.

Dr. Roberts replied that NSMC serves an underserved population upwards of 70% of patients are either Medicaid or Medicare. There was a decrease in funds committed to the project because both NSMC and Partners suffered financial loss. If the demand exceeded capacity, they could meet the need.

Dr. David followed-up by saying that Partners stated they had an endowment for the underserved and therefore acknowledged that this situation would be a good use of utilizing the endowment.

Dr. Roberts replied that he could not speak towards an endowment.

Mr. Brindisi stated he would like to hear more from the applicant aside from financial reasons as to why they believe there is no longer a need and that they can scale back on capacity.

Dr. Roberts replied that they are building 24 new Med-Surg beds; they brought an additional 8 beds online, and 10 beds in the emergency/observation unit. They believe the total of 42 Med-Surg beds will meet the needs of the city of Lynn. Hospital censuses have fallen, lengths of stays are shortening, and they believe they can meet the need with 42 Med-Surg beds. If the demand exceeds that they will be able to add the additional 24 beds.

Mr. Brindisi asked how many beds does Union Hospital have now.

Dr. Roberts replied that current occupancy is 42 beds. On average 42 patients are on the Med-Surg census on a daily basis.

Mr. Brindisi then asked how many Med-Surg beds did they originally request.

Dr. Roberts informed him they originally requested 48.

Dr. Woodward asked if the 10 beds in ED were originally planned a year ago.

Dr. Roberts replied that while he was not here a year ago, the 10 ED beds were in the plans.

Dr. Woodward informed him that he didn’t believe it was fair to count the 10 ED beds.

Ms. Doherty asked for the psychiatric census at Union Hospital.

Dr. Roberts replied that there are 20 beds on each floor (child psychiatry and geriatric psychiatry) with 16-18 census per floor. Adult psychiatry is on their Salem campus. One of the advantages of the proposal is allowing patients to be serviced in one facility. He also informed them that they see an average a 90,000 patients in their ED in one year.

Ms. Doherty asked where do they transfer ED patients if that becomes necessary.

Dr. Roberts replied that they don’t transfer many patients for Med-Surg since they are a full service hospital. They send about 130 people a year to Mass General for open-heart surgery but they keep most ED patients.

Ms. Doherty asked for clarification if their intent was to be a full service hospital plus the addition of expanding psychiatric services.

Dr. Roberts replied that they believe the Med-Surg footprint they are creating will meet the need for the community but if demands change they can shell out an additional 24 beds within a year. They also believe the numbers show they will be able to meet the need of the community for those who seek adult acute psychiatric care. If demand increases for that they believe they can increase the number of beds in under a year.

Dr. Woodward referenced an article in the Globe and suggested that he hopes if they cannot transfer patients in “x” period of time that they admit those patients to decrease ED boarding time and alleviate the acuity of psychiatric patients. He also asked them to address the concerns of the ten-taxpayer group

Dr. Roberts discussed the duality of treating patients with multiple symptoms along with psychiatric needs. Their numbers suggest they will be able to do that in a timely fashion. He also discussed another point in the article about the necessity of psychiatrists and that he hoped their relationship with Mass General would allow them to easily staff.

Dr. Woodward asked for the average length of stay in the ED for Med-Surg patients versus psychiatric patients.

Dr. Roberts informed him that it is 16 hours for psychiatry and 6.5 for admitted medicine patients. For those that are discharged it is 2.5 hours for medicine.

Dr. Woodward compared their number to state averages.

Dr. Roberts mentioned they have very few private rooms and the impact of flow on their ED numbers.

Dr. Woodward noted that he would like to see Med-Surg flow be added to the other metrics that are specified.

Dr. Roberts noted that they have a flow committee and plan to see to the numbers being decreased.

Ms. Rodman pointed out that in subsection F of the first condition, which discusses average turnaround time for both psychiatric and Med-Surg patients, if they made that a referral indicator that would give us the opportunity, if we see a Med-Surg problem, to use that a reason to discuss this further with the applicant.

Dr. Woodward said that he believes that would address someone of the concerns and also suggested that Med-Surg be added in a section A under condition 1. He would also like to follow their average length of stay for admitted and transferred patients in both and psych and Med-Surg.

Mr. Levine said that he believes that they can incorporate that.

Dr. Bernstein asked for more information on the fiduciary relationship with Partners.

Dr. Roberts informed him that they are subsidiary to Partners Health Care. Each entity has a fiduciary responsibility to run their organizations well. Partners sets targets for each entity around that performance if they meet that performance and still have a capital need then Partners acknowledges that and gives them the funds to do that.

Dr. Bernstein asked in terms of the assessment in the needs of the community if there is an aging population with higher incidence of dementia etc. or substance abuse issues, how have they incorporated that into their planning.

Dr. Roberts replied that they are very much committed in taking care of those folks. He discussed counselors, resources etc. They believe that have capacity for local patients that need to be acutely admitted.

Dr. Woodward asked the applicant if they are willing to commit to reducing the boarding time for psychiatric patients and setting a reasonable goal.

Dr. Roberts informed the Council that they are committed to working hard to reduce the boarding time but setting a number may be difficult.

Dr. Woodward noted that he would like to have them come back in a year or two to report that their numbers have decreased by percentage.

Dr. Bernstein requested data on dual diagnosis of substance abuse and mental health.

Ms. Rodman read the changes in condition 1 subsection A and condition 2 subsection D.

Dean Cox asked if they would be able to address the 3rd requested condition from the ten-taxpayer group, specifically in what would trigger action at this time.

Ms. Rodman suggested that they would not include that in a specific number because factors change and they want to have the flexibility to see how those numbers compare to not only the state but the health care market.

Dr. Roberts noted that automatic triggers for building additional beds doesn’t make sense in this complicated environment. For example, temporary staffing changes could require additional beds but they would still not have the staff to cover. He said that he would be happy to come back before the Council to explain why numbers may have increased and their action plan but automatic triggers as a condition to build would not suffice in their environment.

Dr. Bernstein asked about the relationship with Partners and whether they would be able to send psychiatric fellows etc.

Dr. Roberts replied that although they do provide support, it is a recruitment problem nationally.

Ms. Rodman also noted that it is DPH’s determination to ask NSMC to come back before the Council.

Ms. Cooke also noted that this data is public and will be shared with the stakeholders.

Dean Cox asked the ten-taxpayer group if they receive this data will that satisfy their concerns.

Diane Hill from the Leslie Greenberg Ten-Taxpayer group responded that the trigger isn’t for the hospital to automatically build shell but that the trigger is to come back to this forum. A reduction is fair rather than their previously stated desire of 50%. She also stated that if the number isn’t reduced that should be the trigger to come back before the Council.

Dean Cox confirmed that they are okay with the language as it is being amended.

Ms. Hill informed him that they would like to come back if there is a material decrease rather than an increase. She also noted that the problem with access to the data is that they are not in the position to come back before the Council unless DPH staff deems it necessary. They are asking that the Council gives a measure so that if it is not met they can assure it is brought forth for discussion.

Dr. Woodward suggested removing the word “material” and that if there was an increase that should be the stimulus for it to come back before the Council.

Ms. Rodman suggested to not amend the language but provide an opportunity for the parties to return before the Council when data has been released.

The ten-taxpayer group accepted that update.

Ms. Rodman read the updated conditions.

Mr. Brindisi explained why he opposes the vote and how he believes NSMC has gone back on their promises to the members of the Lynn community.

Commissioner Bharel asked if there a motion to accept amended conditions as stated. Dr. Woodward made the motion, Dr. Kneeland seconded it. All present members approved except Mr. Brindisi who opposed.

Dr. Roberts asked for clarification about when they come back, specifically asking if it would be after they build the new facility.

Ms. Rodman replied it would be 1 year following opening date of the new psychiatric capacity at Salem hospital.

Ms. Cooke asked if there is there a motion to accept the conditions as amended with the timeframe for reporting to the PHC.

Dean Cox asked members of the Council if there is any value in having NSMC come back prior to the build being completed.

Mr. Brindisi state that he would appreciate that since the original commitment has changed.

Dr. David stated she’s not sure if it would be helpful if they are not able to take action.

Dr. Kneeland replied that it would be necessary to get this information from all hospitals.

Dr. Woodward suggested they come back 6 months after the build.

Dr. Roberts informed the Council that they meet with community members often.

Ms. Cooke asked again if there is there a motion to accept the conditions as amended with the timeframe for reporting to the PHC (1 year after the build out).

Dr. Woodward made the motion, seconded by Dr. Bernstein. All members approved except Mr. Brindisi, Dr. Bernstein, and Dean Cox who opposed. The motion was approved.

With no further questions, the Commissioner asked for motion to accept the staff recommendation for approval with amendment of North Shore Medical Center’s request for significant amendment to previously approved DoN Project Number 6-3C46.

Dr. Woodward made the motion, Dr. Kneeland seconded it. All present members approved with the exception of Mr. Brindisi and Dr. David who opposed.

Dr. David leaves the room at 11:01am and returns at 11:06am.

Dr. Kneeland left the meeting at 11:01am and did not return.

**3. FINAL REGULATIONS**

**a. Request for final promulgation of proposed amendments to 105 CMR 205.000, Minimum Standards Governing Medical Records and the Conduct of Physical Examinations in Correctional Facilities (Vote)**

Mr. Lanzikos returns 11:04

The Commissioner called the meeting back to order at 11:08am and then invited Dr. Al DeMaria, Medical Director for the Bureau of Infectious Disease and Laboratory Sciences; Paul Halfmann, Assistant Director of the Community Sanitation Program within the Bureau of Environmental Health; and Sondra Korman, Deputy General Counsel for the Department, to the table to present proposed amendments to 105 CMR 205.000: *Minimum Standards Governing Medical Records and the Conduct of Physical Examinations in Correctional Facilities*.

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

Ms. Doherty inquired that if the complete blood count is required because the individuals may not have had health care for a long period of time, what about other routine laboratory tests?

Dr. DeMaria replied that the expectation is that they will use history and physical exam directed decision-making. In terms of diagnostic testing, it will be done according to the community standard of care. The expectation of the community standard of care is that appropriate testing would be done in the context of the history of physical examination.

Ms. Korman elaborated by stating that section D has not changed in terms of the list of required diagnostic tests, and that includes the PPD skin test.

Dr. David inquired about smoking history not being listed. She also asked about the various methods of TB testing and what the preference is.

Dr. DeMaria replied that the there is some controversy regarding TB testing, but for serial testing the skin test is preferred. He then informed the Council that the smoking history would be under the requirement for substance use screening.

With no further questions or comments, the Commissioner asked for a motion to approve proposed amendments to 105 CMR 205.000.

Dr. David made the motion, Ms. Doherty seconded the motion. All present members approved.

**3. FINAL REGULATIONS**

**b. Request for final promulgation of proposed amendments to 105 CMR 720.000, List of Interchangeable Drug Products (Vote)**

The Commissioner proceeded with the docket and invited Eric Sheehan, Director of the Bureau of Health Care Safety and Quality; Lauren Nelson, Director of Policy and Regulatory Affairs for the Bureau; and Rebecca Rodman, Deputy General Counsel for the Department, to the table to present proposed amendments to 105 CMR 720.000: *List of Interchangeable Drug Products*.’

After their presentation, the Commissioner asked if the Council had any questions or comments. Seeing none, the Commissioner asked for a motion to approve the regulation as amended.

Dr. Woodward made the motion, Dr. Bernstein seconded the motion. All present members approved.

**4. INFORMATIONAL PRESENTATIONS**

Due to timing and quorum the informational presentations were postponed to later date.

The Commissioner reminded the Council that the next meeting is Wednesday, September 13, 2017 at 9AM. She then asked for a motion to adjourn. Dr. David made the motion Mr. Brindisi seconded it. All present members approved.

The meeting adjourned at 11:31AM.