**MINUTES OF THE PUBLIC HEALTH COUNCIL**

**Meeting of August 23, 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: Tuesday August 23, 2016 9:00 AM**

1. **ROUTINE ITEMS:**
2. Introductions
3. Updates from Commissioner Monica Bharel, MD
4. Record of the Public Health Council Meeting July 13, 2016 **(Vote)**

**2. DETERMINATION OF NEED**

a. Kindred Hospital - Boston (Brighton) request for Transfer of Ownership to Curahealth Boston, LLC. Project No. 4-3C49 **(Vote)**

b. Kindred Hospital - Boston North Shore (Peabody), request for Transfer of Ownership to Curahealth Boston - North Shore, LLC Project No. 6-3C50 **(Vote)**

c. Kindred Hospital Northeast -Stoughton, request for Transfer of Ownership to Curahealth Stoughton, LLC Project No. 5-3C51 **(Vote)**

**3. PRELIMINARY REGULATIONS**

a. Informational briefing on proposed regulatory amendments to 105 CMR 100.000 – *Determination of Need*

b. Informational briefing on a newly proposed regulation 105 CMR 173.000 – *Mobile Integrated Health*

**3. FINAL REGULATIONS**

* 1. Request for final promulgation of proposed amendments to 105 CMR 170.000 –*Emergency Medical Services System* **(Vote)**

b. Request for final promulgation of proposed amendments to 105 CMR 380.000- *Approval of Bacteriological and Serological Laboratories* **(Vote)**

c. Request for final promulgation of proposed amendments to 105 CMR 620.000- *Bedding, Upholstered Furniture and Related Products* **(Vote)**

d. Request for final promulgation of proposed amendments to 105 CMR 630.000- *Plastic Bags and Plastic Film* **(Vote)**

e. Request for final promulgation of proposed amendments to 105 CMR 670.000- *Right to Know* **(Vote)**

**PRESENTATIONS**

a. Hospital Acquired Infections and Serious Reportable Events

*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:** Tuesday, August 23, 2016

**Beginning Time:** 9:13AM

**Ending Time:** 11:57AM

**Attendance and Summary of Votes:**

| **Board Member** | **Attended** | **Item 1c****Minutes of the July 13, 2016 Meeting** | **Item 2a****Determination of Need #4-3C49** | **Item 2b Determination of Need #6-3C50** | **Item 2c Determination of Need #5-3C51** | **Item 3a****Request for final promulgation of proposed amendments to 105 CMR 170.000 – Emergency Medical Services System** | **Item 3b****Request for final promulgation of proposed amendments to 105 CMR 380.000 – Approval of Bacteriological and Serological Laboratories** | **Item 3a****Request for final promulgation of proposed amendments to 105 CMR 620.000– Bedding, Upholstered Furniture and Related Products** | **Item 3a****Request for final promulgation of proposed amendments to 105 CMR 630.000 – Plastic Bags and Plastic Film** | **Item 3a****Request for final promulgation of proposed amendments to 105 CMR 670.000 – Right to Know** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Monica Bharel | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Edward Bernstein | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Lissette Blondet | Yes | Abstain | Yes | Yes | Yes | Abstain | Yes | Yes | Yes | Yes |
| Derek Brindisi | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Harold Cox | Absent | Absent | Absent | Absent | Absent | Absent | Absent | Absent | Absent | Absent  |
| John Cunningham | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Michele David | Absent | Absent | Absent | Absent | Absent | Absent | Absent | Absent | Absent | Absent |
| Meg Doherty | Yes | Absent | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Michael Kneeland | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Paul Lanzikos | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Lucilia Prates-Ramos | Absent  | Absent | Absent | Absent | Absent | Absent | Absent | Absent | Absent | Absent |
| Michael Rigas | Yes | Abstain | Abstain | Abstain  | Abstain | Abstain | Abstain | Abstain | Abstain | Abstain |
| Alan Woodward | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| **Summary** | **10 Members Present, 3 Members Absent** | **8 Members Approved, 2 Members Abstained, 3 Members Absent** | **9 Members Approved, 1 Member Abstained, 3 Members Absent** | **9 Members Approved, 1 Member Abstained****3 members absent** |  **9 Members Approved, 1 Member Abstained****3 members absent** | **8 Members Approved 2 Members Abstained****3 members absent** | **9 Members Approved, 1 Member Abstained****3 members absent** | **9 Members Approved1 Member Abstained****3 members absent** | **9 Members Approved 1 Member Abstained****3 members absent** | **9 Members Approved1 Member Abstained****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 Tuesday, August 23, 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; Lissette Blondet; Derek Brindisi; John Cunningham, PhD; Meg Doherty; Michael Kneeland, MD; Paul Lanzikos; Michael Rigas; and Alan Woodward, MD.

Absent member(s) were: Harold Cox; Michele David, MD; and Lucilia Prates-Ramos

Also in attendance were Elizabeth ScurriaMorgan, 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 9:13AM and made opening remarks before reviewing the agenda.

**ROUTINE ITEMS**

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

Commissioner Bharel noted that there was a change to the docket. The application by Baystate Wing Hospital for a Determination of Need will be brought forth to the Council on a future date. Two new Council members were introduced and welcomed: Lisette Blondet, Director of the Massachusetts Association of Community Health Workers and Michael Rigas, Chief of Staff for the Massachusetts Department of Veterans Affairs.

Commissioner Bharel then highlighted her visit to two Sober Homes in Lynn and noted that beginning in September, only voluntarily certified sober homes will accept referrals from state funded programs including from the court system. She went on to thank the Bureau of Substance Abuse Services and specifically Cheryl Kennedy Perez for all her efforts with this work.

Next, the Commissioner detailed her tour of several programs in Worcester, including the Ronald McDonald Mobile Clinic, the UMASS-Memorial Emergency Department, and AIDS Project Worcester. She went on to thank Dr. Bernstein and his team for hosting her tour of Faster Paths to Treatment program at Boston Medical Center and complimented the ongoing work being done around the state to address the opioid epidemic.

The Commissioner then announced the launch of the Massachusetts Prescription Awareness Tool (MassPAT). She reported that as of the date of the meeting over 32,000 prescribers and pharmacists across the Commonwealth had registered for MassPAT and can now search their patients’ prescriptive history over the past year. MassPAT allows for enhanced functionality and the ability to conduct interstate data sharing.

Organizational changes at DPH were then discussed. The Commissioner welcomed Nora Mann to the Department as the new Director of Determination of Need Program and congratulated Benjamin Wood from the Bureau of Community of Health & Prevention who was recently promoted to Manager of Community Health Planning & Engagement. Tom Lyons was welcomed back to DPH as the Director of Communications.

Finally, effective August 15, 2016 the Bureau of Health Care Safety and Quality (BHCSQ) became two separate bureaus: the Bureau of Health Care Safety and Quality and the Bureau of Health Professions Licensure (BHPL). Eric Sheehan is now Bureau Director for the new, reorganized Bureau of Health Care Safety and Quality and Jim Lavery has been named the Bureau Director for the new Bureau of Health Professions Licensure.

The Commissioner asked if Council members had any questions or comments on these updates. Seeing none, she proceeded with the agenda.

**1. ROUTINE ITEMS**

**c. Minutes**

Commissioner Bharel asked if any members had any changes to be included in the July 13, 2016 meeting minutes. Seeing none, the Commissioner asked for a motion to approve minutes.

Dr. Woodward made a motion to approve, and Dr. Cunningham seconded the motion. All approved, except Mr. Rigas and Ms. Blondet who abstained from the vote as they were not present at the July meeting.

**2. DETERMINATION OF NEED**
**a. Kindred Hospital – Boston (Brighton) request for Transfer of Ownership to Curahealth Boston, LLC. Project No. 4-3C49 (Vote)**

**b. Kindred Hospital – Boston North Shore (Peabody), request for Transfer of Ownership to Curahealth Boston – North Shore, LLC Project No. 5-3C51 (Vote)**

**c. Kindred Hospital Northeast – Stoughton, request for Transfer of Ownership to Curahealth Stoughton, LLC Project No. 5-3C51 (Vote)**

The Commissioner invited Mike Sinacola, Interim Deputy Director of Health Care Safety and Quality, and Rebecca Rodman, Deputy General Counsel, to present on all three Kindred Hospital transfers of ownership to Curahealth. The Commissioner stated that after the presentation the Council would vote on each Determination of Need separately. The following representatives to the applicant were also invited to the table, following the presentation: Chester Crouch, CEO, Curahealth; Ken McGee, COO, Curahealth; and Emily Kretchmer, legal counsel.

Ms. Doherty entered the room at 9:27AM.

Upon conclusion of Mr. Sinacola’s presentation, the Commissioner asked if Council had any questions for Mr. Sinacola, Ms. Rodman, or the applicant’s representative.

Mr. Lanzikos inquired about the two applications in which DoN staff recommend Curahealth seek MassHealth approval. He noted the language is speculative and asked what are the true prospects of both facilities qualifying as a MassHealth provider.

Mr.Sinacola thanked Mr. Lanzikos for the question and stated that the applicant has agreed to work with MassHealth. He added that if the applicants are determined to be eligible to enroll in MassHealth, the applicant has agreed to pursue that enrollment. If the certification and enrollment requires a licensure change with the Division of Health Care Facility Licensure, the applicant has also agreed to do that.

Mr. Lanzikos then asked if the applicant believes they will qualify and if they see any potential obstacles to become certified.

Mr. Sinacola deferred to the applicant regarding the question of whether or not they anticipate obstacles in obtaining MassHealth certification.

Commissioner Bharel then invited the applicant to the table to answer the question and asked if there were any additional questions for the program.

Dr. Bernstein asked the program for clarification on whether the health equity issues were completely separate from their determination.

Mr. Sinacola stated that compliance with the office of health equity’s requirements were conditions of this approval.

Dr. Bernstein inquired on whether or not the applicant had complied with them and what the current status was.

Ms. Rodman responded saying that sometimes the Office of Health Equity is not able to conduct a site visit prior to DoN approval. In cases such as this, the agreement stands that the Office will go out (after approval) and that the applicant will comply with the requirements of the Office of Health Equity.

Dr. Bernstein thanked Ms. Rodman for her response and concluded from her response that it is a standard condition.

Commissioner Bharel then asked if there were any further questions for the program. Seeing that there were none, she then asked for the Curahealth staff to introduce themselves to the Council.

Chester Crouch, CEO of Curahealth; Ken McGee COO of Curahealth; and Emily Kretchmer, legal counsel were introduced to the Council.

Mr. Crouch responded to Mr. Lanzikos’ question regarding MassHealth. He stated that one of the three locations is currently a part of MassHealth but it is difficult to understand the nuances since Kindred has been operating the hospitals previously. He went on to say that he will work with the proper authorities to assess the need for MassHealth access. If there is a need and they can provide the service they will. He then noted that since one of the facilities is currently under MassHealth it would not surprise him if the other two became MassHealth certified, however that decision would fall under MassHealth’s purview.

Mr. Lanzikos asked if the exploration process has begun or whether they were waiting for approval of the DoN.

Mr. Crouch responded that they are waiting on this approval.

Commissioner Bharel asked if there were any further questions for the applicant.

Dr. Woodward stated they appear to be a relatively new corporation and that they will have 12 facilities with 3 in Massachusetts. He asked what other states are they currently operating in and if they are Kindred facilities as well.

Mr. Crouch responded that the Curahealth entity was formed specifically for the purchase of the 12 facilities. There are 3 hospitals in Arizona, 2 in Oklahoma, 1 in Tennessee and Louisiana, and 2 in Pennsylvania.

Dr. Woodward asked if Curahealth was formed to acquire Kindred.

Mr. Crouch responded that Curahealth was formed to acquire the 12 hospitals.

Dr. Woodward requested that Mr. Crouch inform the Council of the transition process of Kindred to Curahealth. He then asked if Kindred was involved in setting up this corporation.

Mr. Crouch indicated that Kindred was not involved in the formation of Curahealth and that they are completely separate entities in the transaction. He went on to say Curahealth is led by himself and Ken McGee and noted that combined they have close to 50 years of post-acute care and health care experience. Mr. Crouch noted that most recently they were a part of Reliant Hospital Partners which purchased the Braintree Rehabilitation Hospital in 2014 and thus have experience working in Massachusetts and understand some of the nuances here. He concluded by saying that they are committed to the care and delivery system that is currently in place and plan to further that model.

Dr. Woodward concluded that they were formed in essence to acquire the Kindred facilities. He continued by asking whether Kindred approached them or whether they had been working with Kindred previously and had been aware they were interested in selling the 12 facilities.

Mr. Crouch responded to the question by saying that there are always conversations that occur between companies and potential buyers. He noted that Kindred did a very good job with the transaction to allow Curahealth to be successful. There are regulatory changes that are occurring and that Kindred is divesting some of its assets and there has been a very good transition plan put into place with 6 months to transfer all of the services. He went on to say that the transition plan that is currently in place will be good for employees, patients, and allows these facilities to continue to be successful.

Mr. Lanzikos asked if there will be a senior member of their management team, who is or will be a resident of Massachusetts.

Mr. Crouch answered the local CEOs are all residents of Massachusetts and have been in these facilities for a number of years.

Mr. Lanzikos inquired whether any of the 3 facilities in Massachusetts have any organized labor units operating within them.

Mr. Crouch answered that Boston-North Shore has a labor union.

Mr. Lanzikos asked if the union has expressed any concerns or supports for the transition.

Mr. Crouch indicated that the union has not expressed any concerns. He went on to say that within the last two weeks, they have met with leadership teams and held town hall meetings where no concerns were brought to the table and he is excited to work with them.

Mr. Lanzikos inquired whether they will continue to honor the union contract when they take over ownership.

Mr. Crouch replied in the affirmative.

Dr. Bernstein inquired whether there will be any job loss with this transition.

Mr. Crouch responded that he does not anticipate any job loss. All of the employees and leadership teams will transition from Kindred to Curahealth. He is very impressed with the personnel and leadership currently in place and hopes to refocus the team with more post-acute treatment management.

Mr. Lanzikos then asked staff to present the 6 month report relative to the applicant seeking and securing MassHealth certification to the council. Mr. Lanzikos then asked if in the view of staff, the effort to obtain certification was not successful and there was not a full faith effort is there any recourse relative to this approval.

Mr. Sinacola stated that they will certainly report back to the Council. The current regulation allows for staff to present to the Council potential revocation of the DoN.

Ms. Blondet stated that she would prefer that the recommendation from staff to the applicant be that they comply with MassHealth certification so that the applicant agrees to ensure they are MassHealth certifiable.

Ms. Rodman responded that they can’t complete the application for MassHealth without their license and the current DoN approval. The approval of the DoN is the best way to ensure the good faith effort will occur without overstepping.

Ms. Doherty stated that in the past Kindred has developed a Home Care company and inquired about the relationship Curahealth will be with those Home Care companies and whether there will be an option offered to patients.

Mr. Crouch responded that Curahealth will be solely focused on the 12 LTAC hospitals and they will work with all of the other post-acute segments to make sure that patients are placed appropriately, however their main focus will be the 3 hospitals.

Ms. Doherty asked in regards to ACOs and arrangements where there is a continuum of care expectation how will Curahealth manage that.

Mr. Crouch responded that they will partner with other post-acute care providers to be able to be involved in that continuum.

The Commissioner then asked if there were any further questions from the Council. Seeing none, the Commissioner asked members for a motion for approval of the Kindred Hospital - Boston (Brighton) request for Transfer of Ownership to Curahealth Boston, LLC.

Mr. Lanzikos made the motion, Ms. Doherty seconded the motion. All present members approved, except Mr. Rigas who abstained from the vote.

The Commissioner asked members for a motion for approval of the Kindred Hospital – Boston Northshore – Peabody- request for Transfer of Ownership to Curahealth Boston, LLC.

Mr. Lanzikos made the motion, Dr. Cunningham seconded the motion. All present members approved, except Mr. Rigas who abstained from the vote.

The Commissioner asked for approval of the Kindred Hospital – Northeast – Stoughton- request for Transfer of Ownership to Curahealth Boston, LLC.

Mr. Lanzikos made the motion, Dr. Cunningham seconded the motion. All present members approved, except Mr. Rigas who abstained from the vote.

**3. PRELIMINARY REGULATIONS**

**a. Informational briefing on proposed regulatory amendments to 105 CMR 100.000 – Determination of Need**

Commissioner Bharel invited Nora Mann, Director of the Determination of Need program, Jay Youmans, Special Advisor the Commissioner, Tom Mangan, Policy Analyst, Ben Wood, Manager of Community Health Planning & Engagement and Rebecca Rodman, Deputy General Counsel, to present on the proposed regulatory amendments to 105 CMR 100 Determination of Need.

 Upon the conclusion of the presentation, the Commissioner asked if Council members had any questions for Nora or the team.

Mr. Lanzikos congratulated Nora on her appointment as Director of DoN. He then recommended that in the hearing process, whether it is under regulations or sub-regulations, that there be at least one session devoted exclusively to Long Term Care. He went on to say that the nursing facilities that we have today were not what were originally licensed 40-50 years ago. There are two significant varieties of need, one being short term rehab. Many of the applications that have been approved on the staff level have retooled themselves for that need at the expense of the necessary long-term beds for people with serious chronic conditions. Mr. Lanzikos said that we also need changes in that environment for long term stay, essentially, he said, we have two different structures that we need to account for and he doesn’t believe the Commonwealth has given these needs proper consideration. Mr. Lanzikos noted he was very happy to see the issue of MassHealth certification addressed. Over the last 10 years we’ve seen a number of inner city facilities close and move to the suburbs. They maintain their MassHealth status but they move away from the population that needs to be served. The issue of access for LTC is similar but inherently different than the access issues around other areas of the health care system. Also, Mr. Lanzikos noted that within the DoN definitions, there’s no definition of nursing facilities. He also noted when nursing facilities were discussed it referenced level 2, 3, and 4 beds. He stated level 3 beds no longer exist, and that nomenclature is no longer being used in state government: they are either skilled care beds or residential care beds. One of the things that is particularly of concern to him is existing residential beds, formally known has rest home beds, and how they can be readily changed to skilled beds without any considerations. He believes this is a serious loophole. He concluded that if we start losing residential care beds we’ll be in a very dire situation with regard to placing individuals who have long occurring behavioral health, dementia, and substance abuse issues.

Ms. Blondet commended the team on their shift to truly addressing systems. She went on to inquire about MassHealth shifting to an ACO model for reimbursements and wondered how closely aligned will the DoN regulations be with the system.

Ms. Mann informed Ms. Blondet and the Council that they used the HPC definition of system in order to have a consistency across the various regulatory schemes.

Ms. Blondet noted that she would like to see more alignment with MassHealth.

Mr. Youmans added that the definition comes from the HPC material change notification, which is the 958 CMR 7.00 regulation and allows the Department to look at the highest corporate entity which oversees the systems of care.

Ms. Doherty addressed certified home health care, and requested that it be included in both the definition and the provision of care. Home health care is not only providing the post-acute services and the transitional care but also a good majority of public health initiatives. She implored the team to consider certified home health care as a critical component of health care delivery in the Commonwealth and in the planning.

Ms. Mann thanked Ms. Doherty for her comment and went on to inform her and the Council that the program attempts to amend the regulation without having to make statutory changes and that there are certain constraints that they have due to the statutes governing DoN.

Ms. Doherty commented that as a provider and member of this committee how imperative these amendments are and she looks forward to having benchmarks and objective data that will allow for good decisions to be made.

Mr. Youmans thanked the Home Care Association for all of their hard work and look forward to working with them to better recognize value of the various providers. He went on to reiterate that in the regulation there are statutory constraints on how they can address certain aspects but they look forward to connecting and hearing creative questions and comments.

Mr. Brindisi noted he was interested in the community based health initiatives section of the proposal. He stated that he believed we currently have some good examples with municipalities engaging one another that can be used. He would like to know what the “gold standards” that are referenced to in the proposal means.

Ms. Mann addressed Mr. Brindisi’s question and noted that she understands his point and stated that the intention is to use in part the standards and practices already in place by local community engagement.

Mr. Wood stated the city of Worcester is a great example of their development of approval planning process. He reiterated the fact that they will learn from current good practices and continue engaging the community by going to local meetings etc.

Mr. Youmans noted that one of the program’s goals is to establish a guideline that can be used not only in regards to this subject, but in other areas as well, so that when community engagement is brought up we can have a objective set of guidelines for what is in many ways an subjective issue.

 Mr. Brindisi stated that he is sure they will engage nonprofits, community providers etc. and encouraged the program not to forget local municipalities.

Dr. Woodward noted that the presentation was impressive work. He noted that the subject is one of concern. He looks forward to a much better process and believes in the past that the limited criteria for accessing each DoN was indeed frustrating. Dr. Woodward encouraged the program to come back and have a modernized process that will effectively look at public health and economic priorities. He also noted that geography and essential services need to be looked at carefully as the process continues. He concluded by applauding the program’s efforts and encouraged the possibility of a joint discussion with HPC leadership.

Dr. Bernstein inquired on how it would be possible to incentivize determination of needs of substance abuse and mental health from the private sector. He then went on to mention social determinants and encouraged the idea of expanding the view of how social determinants impact health.

Ms. Mann agreed with Dr. Bernstein, specifically about the social determinants of health. She then went on to say that as the program works on the development of health priorities they are going to see the profile of substance abuse and mental issues rise. The idea is to create incentives for those health systems to consider all of those things

Commissioner Bharel stated that she previously spoke to Dr. Bernstein about the DPH data warehouse and the use of data to determine what the social determinants of health are and how they affect health disparities. She then went on to note that this is all in line with the changes we are making here.

Dr. Bernstein applauded the presentation once again; stating that he believes this is the future of the Commonwealth and can be a model for the nation. He went on to discuss the importance of data in terms of accountability and decision-making and the necessity of having a partnership between the public and private sectors to have the adequate data to look at outcomes and make changes.

Dr. Cunningham commented that he supports the lowest aggregate cost but it needs to be linked with the assurance of quality of care.

Commissioner Bharel thanked Dr. Cunningham for his comment and noted that that is why throughout the presentation the word “value” is used so that quality and cost are both taken into account.

Ms. Blondet asked whether the program foresees DoN’s investing in public health infrastructure statewide. She specifically mentioned Community Health Workers and how they typically need training alluding to the possibility of DoN’s specifically impacting the training process etc.

Mr. Youmans responded saying that as part of the engagement process to create the sub regulatory guidelines for community health initiatives and health priorities, it is one of the things they are hoping to look at and broaden the term of what it means to invest in the community. He mentioned they have already been in contact with interested organizations to begin the conversation and would love to discuss with Ms. Blondet to hear her thoughts about how to foster engagement.

Mr. Lanzikos noted on page 20, on the governmental agencies when you have a nursing facilities proposal, he would reference the entity that needs to get a copy for the ease of the applicant. On page 26 under section B, Mr. Lanzikos inquires what happens in the 5th month and whether this is automatic approval.

Mr. Youmans responded saying that the timeline that is listed under 100.605 B is the current statutory timeline dictated to the department as it stands today. The department is allowed to delay up to one time for two months for a total of six months. The application process can be stayed if an independent cost analysis is requested.

Mr. Lanzikos stated on page 28, where delegated review is mentioned he would hope going forward we have no more delegated review of nursing facility applications. He recommended that nursing and ambulatory facilities are included in community benefit payments. On page 3, he noted the language is confusing and asked for clarification. He applauded the program’s work, once again, and stated he looked forward to them coming back to the Council with updates.

**b. Informational briefing on a newly proposed regulation 105 CMR 173.000 – *Mobile Integrated Health***

Commissioner Bharel then asked if there were any further questions from the Council. Seeing none, she thanked the team and invited Associate Commissioner Lindsey Tucker, Lauren Nelson, Director of Policy and Quality Assurance of the Bureau of Health Care Quality and Safety, Sondra Korman, Deputy General Counsel, to join Jay Youmans before the Council to present newly proposed regulation, 105 CMR 173, relative to Mobile Integrated Health.

10:43am Mike Rigas leaves the room and returns at 10:47am.

Upon the Conclusion of Associate Commissioner Tucker’s presentation, Commissioner Bharel asked if Council had any questions or comments.

Ms. Blondet noted that she sees much alignment between MIH and the role of Community Health Workers, she would like to see more of an explicit presence of the Community Health Worker in planning some of these activities as they are a part of the continuum of care. She also inquired on how the services are reimbursed.

Ms. Tucker responded saying that it is not part of our regulatory approach but is certainly a part of an ongoing conversation.

Ms. Blondet noted that she participated in three of the MassHealth revision work groups and not once did she hear this model mentioned.

Mr. Youmans stated in order for payers to consider this seriously, the licensure model has to be put in place. It’s outside of the scope of this regulation, but to your point, it will be interesting to watch.

Ms. Blondet stated it could easily be captured with new ACO payment models.

Mr. Brindisi discussed slide 18 regarding low risk high value prevention services and questioned how many of the examples came from the trust fund. He would like to see the data of certain outcomes (i.e. prevention screenings) have proven effective. He inquired about why vaccines are under the direction of local public health.

Ms. Tucker replied stating that aforementioned language is directly from the statute and that they were bringing it to the regulation based on the statute.

Mr. Lanzikos noted that it is a very promising model. He shares the question and concern about payment for services because if MassHealth is not an active payer he can see potential disparity in terms of access to the service. He also noted if there is one provider per geographical region, if there was any concern about the lack of competition both in regards to quality and price.

Ms. Tucker distinguished between the ED avoidance component, which has to use the primary ambulance service, and non-ED avoidance component, which can use a combination of providers and EMS. One of the reasons they wanted the ED avoidance component to use the primary ambulance service is for clearer medical direction and control around 911 and non-911 MIH patients. She went on to say that we do think that there are possibilities within a geographic population and that different programs might be interested in particular patients.

Mr. Lanzikos inquired about the ED avoidance component and what considerations have been made to ensure that there is quality and proper pricing if there is only one provider selected.

Ms. Tucker replied that each locality has a primary ambulance provider who is already contracted and that this program will follow what is currently in place.

Mr. Lanzikos further asked that once the contracted providers are providing services how will it be determined that they are of appropriate quality.

Ms. Tucker explained that in terms of quality there are requirements within the regulation for data collection and data analysis specifically around quality.

Mr. Youmans also added there is a difference between ED Avoidance component and general MIH provisions. A primary ambulance service that is providing ED Avoidance today is already going and responding to 911 calls while getting reimbursed depending on the outcome of the call. The only thing that is changing here is that those services that get this permission will have the ability to have an alternate destination if appropriate for that patient.

Ms. Doherty stated the falls prevention, concussion testing are all examples of uncompensated home health. It’s interesting how people will make money because it’s never been compensated before.

Mr. Brindisi exits the room at 11:10am and returns at 11:16am.

Dr. Bernstein congratulated the team on program. He inquired on what provisions would be made for linkage of services. Specifically, he inquired on what links for social services, mental health, substance abuse etc. would be put in place.

Ms. Tucker replied that they would require detailed explanations of the partnerships and whether through an EMR or something else the documentation follows the patient for clear coordination and follow up.

Dr. Woodward stated that it is a huge potential, huge risk, huge complexity. He inquired on whether there are situations where it can be a 911 call and then it can be possibly diverted to behavioral health. He then stated that it is further compounded by the payment issue and questioned how do you integrate not only with the payers but with ACOs. He further questioned how would one get an ACO to agree and how do they deal with the complexities of OEMS systems and payment methodologies across the state. He concluded by saying it is a noble effort with huge complexities, however, he is excited to see how it evolves and requests to see data from the two trials and how well it worked elsewhere.

Ms. Blondet leaves the room at 11:14am and returns at 11:18am.

Dr. Kneeland asked how does the primary care physician may fit into the non-emergency situations and whether discussions are held with the PCP prior to.

Mr. Youmans replied that in the regulation they require a loopback consultation with the primary care provider and also noted that they have expanded the definition of medical director that allows them to be trained for the needs of the patient.

Dr. Kneeland replied saying that the medical director may not know the patient and the primary care physician might be aware of specific patient issues.

Ms. Doherty notes that the primary care physician may not always be accessible and that there are protocols at MassHealth that speak on this issue and that there may be protocols that address some of these issues.

Mr. Youmans further commented that as part of the approval process the applicant would have to submit protocols to the medical director for review.

Dr. Woodward noted that there are certain cases where the expertise of an emergency physician may be needed.

Mr. Youmans responded that the affiliate hospital medical director would have the final say over MIH medical director.

Mr. Lanzikos noted that the community based service system is also essential. He hopes that the protocols there are robust and hope that there are regular conversations between local social services and home health care etc.

Commissioner Bharel then asked if there were any other questions or comments from the group. Seeing none, the Commissioner informed the Council Members of the time and requested they stay for a few final votes. She then took a vote by raising of hands to determine if quorum will be made for the remaining votes. Seeing that the quorum is reached, the Commissioner continued with the agenda.

**3. FINAL REGULATIONS**

**a. Request for final promulgation of proposed amendments to 105 CMR 170.000 –*Emergency Medical Services System* (Vote)**

Commissioner Bharel then invited Mike Sinacola, Interim Deputy Director of Health Care Safety and Quality, to join Sondra Korman, and Lauren Nelson to present the request for final promulgation of proposed amendments to 105 CMR 170.000 –*Emergency Medical Services System*.

Upon the conclusion of Mr. Sinacola’s presentation, the Commissioner asked the Council if there were any questions or comments. Seeing none the Commissioner asked for a motion to approve the final promulgation of proposed amendments to 105 CMR 170.000 –*Emergency Medical Services System*.

Dr. Woodward made a motion to approve, Dr. Bernstein seconded the motion. All present members approve with exception of Mr. Rigas and Ms. Blondet who abstained.

**b. Request for final promulgation of proposed amendments to 105 CMR 380.000- *Approval of Bacteriological and Serological Laboratories* (Vote)**

**c. Request for final promulgation of proposed amendments to 105 CMR 620.000- *Bedding, Upholstered Furniture and Related Products* (Vote)**

**d. Request for final promulgation of proposed amendments to 105 CMR 630.000- *Plastic Bags and Plastic Film* (Vote)**

**e. Request for final promulgation of proposed amendments to 105 CMR 670.000- *Right to Know* (Vote)**

Commissioner Bharel then invited Jim Ballin, Deputy General Counsel, to the table to present a summary of four regulations that were that were previously put out for public comment under Chapter 30A and no comments were received.

Upon the conclusion of Mr. Ballin’s presentation, the Commissioner asked if there were any questions or comments. Seeing none, she called for a vote for each regulation.

The Commissioner asked for a motion of approval for final promulgation of proposed amendments to 105 CMR 380: Approval of Bacteriological and Serological Labs.

Mr. Brindisi made the motion and Dr. Woodward seconded it. All members approved with the exception of Mr. Rigas who abstained.

The Commissioner asked for a motion of approval for final promulgation of proposed amendments to 105 CMR 620.000- *Bedding, Upholstered Furniture and Related Products.*

Ms. Doherty made the motion and Dr. Bernstein seconded the motion. All members approved with the exception of Mr. Rigas who abstained.

The Commissioner asked for a motion of approval for final promulgation of proposed amendments to 105 CMR 630.000- *Plastic Bags and Plastic Film*

Dr. Cunningham made the motion and Dr. Woodward seconded it. All members approved except Mr. Rigas who abstained.

The Commissioner asked for a motion of approval for final promulgation of proposed amendments to 105 CMR 670.000- *Right to Know.*

 Mr. Lanzikos made the motion, Mr. Brindisi seconded the motion. All members approved with the exception of Mr. Rigas who abstained.

Mr. Lanzikos left the meeting at 11:34am and did not return.

**PRESENTATIONS**

**a. Hospital Acquired Infections and Serious Reportable Events**

Commissioner Bharel asked for an abbreviated version of the Hospital Acquired Infections and Reportable Events presentations and, once again, invited Lauren Nelson to the table. She also invited Kate Fillo Quality Improvement Manager, Bureau of Health Care Safety and Quality and Dr. Alfred DeMaria, State Epidemiologist to present on Serious Reportable Events and Healthcare Associated Infections.

Upon conclusion of both presentations Commissioner Bharel asked if there were any questions from Council.

Dr. Cunningham left the meeting at 11:54am and did not return .

In response to the Hospital Acquired Infections presentation, Dr. Woodward inquired about the incidents with the trauma units and how it is dramatically down from the previous year but higher than national expectations. He asked if there was a rationale for that.

Dr. DeMaria noted that we are comparing to trauma units in other states and there is a very different environment in terms of regional trauma centers versus referral of the most severely injured patients to tertiary care. It’s more beneficial to look at the Massachusetts comparator and rates over time.

Commissioner Bharel indicated that the next meeting will be held September 14, 2016, and requested a motion to adjourn.

Mr. Brindisi made a motion to adjourn; Dr. Woodward seconded the motion. All approved.

The meeting adjourned at 11:57AM.