

**MINUTES OF THE PUBLIC HEALTH COUNCIL**

**Meeting of October 20, 2016**

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**

**PUBLIC HEALTH COUNCIL  
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH  
Henry I. Bowditch Public Health Council Room, 2<sup>nd</sup> Floor  
250 Washington Street, Boston MA**

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**Docket: Thursday, October 20, 2016 2:00 PM**

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**1. ROUTINE ITEMS:**

- a. Introductions
- b. Updates from Commissioner Monica Bharel, MD
- c. Record of the Public Health Council September 1, 2016 Meeting **(Vote)**
- d. Record of the Public Health Council September 14, 2016 Meeting **(Vote)**

**2. DETERMINATION OF NEED**

- a. Boston Children's Hospital (Boston, MA) application for a substantial capital expenditure to build an 11 floor inpatient clinical building with inpatient renewal to main building; ambulatory renewal; and 8 floor ambulatory clinical building at 2 Brookline Place (Brookline, MA), Project No. 4-3C47 **(Vote)**
  
- b. Hallmark Health Systems (Medford, MA) request for Transfer of Ownership through which Wellforce, Inc. would become sole corporate member of Hallmark Health Systems and its two campuses, Melrose-Wakefield Hospital (Melrose, MA) and Lawrence Memorial Hospital (Medford, MA), Project No. 6-3C55 **(Vote)**

**2. FINAL REGULATIONS**

- a. Request for final promulgation of proposed amendments to 105 CMR 302.000 – *Congenital Anomalies Registry* **(Vote)**
  
- b. Request for final promulgation of proposed amendments to 105 CMR 315.000 – *Cremation of Bodies Received Outside Massachusetts* **(Vote)**

**4. PRELIMINARY REGULATIONS**

- a. Informational briefing on proposed regulatory amendments to 105 CMR 430.000 – *Minimum Standards for Recreational Camps for Children (State Sanitary Code, Chapter IV)*
  
- b. Informational briefing on proposed regulatory revision of 105 CMR 590.000 – *Minimum Sanitation Standards for Food Establishments (State Sanitary Code, Chapter X)*
  
- c. Informational briefing on proposed regulatory amendments to 105 CMR 127.000 – *Licensing of Mammography Facilities*

*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.*

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## Public Health Council

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

**Date of Meeting:** Thursday, October 20, 2016

**Beginning Time:** 2:02PM

**Ending Time:** 5:43PM

**Attendance and Summary of Votes:**

| Board Member         | Attended  | Record of the Public Health Council September 1, 2016 Meeting (Vote) | Record of the Public Health Council September 14, 2016 Meeting (Vote) | Item 2a Determination of Need #4-3C47 | Item 2b Determination of Need #6-3C55 | Final promulgation of proposed amendments to 105 CMR 302.000 – <i>Congenital Anomalies Registry</i> | Final promulgation of proposed amendments to 105 CMR 315.000 – <i>Cremation of Bodies Received Outside Massachusetts</i> |
|----------------------|-----------|--|---|---------------------------------------|---------------------------------------|---|--|
| Monica Bharel        | Yes       | Yes  | Yes   | Yes                                   | Yes                                   | Yes   | Yes  |
| Edward Bernstein     | Yes       | Yes  | Yes   | Yes                                   | Yes                                   | Yes   | Yes  |
| Lisette Blondet      | Yes       | Yes  | Yes   | Yes                                   | Yes                                   | Yes   | Yes  |
| Derek Brindisi       | Yes       | Yes  | Abstain   | Yes                                   | Yes                                   | Yes   | Yes  |
| Harold Cox           | Absent    | Absent   | Absent  | Absent                                | Absent                                | Absent  | Absent   |
| John Cunningham      | Yes       | Yes  | Yes   | Yes                                   | Yes                                   | Yes   | Yes  |
| Michele David        | Absent    | Absent   | Absent  | Absent                                | Absent                                | Absent  | Absent   |
| Meg Doherty          | Yes       | Yes  | Yes   | Yes                                   | Yes                                   | Yes   | Yes  |
| Michael Kneeland     | Yes       | Abstain  | Yes   | Yes                                   | Yes                                   | Yes   | Yes  |
| Paul Lanzikos        | Yes       | Abstain  | Yes   | Yes                                   | Yes                                   | Yes   | Yes  |
| Lucilia Prates-Ramos | Yes       | Yes  | Yes   | Abstain                               | Yes                                   | Yes   | Yes  |
| Michael Rigas        | Yes       | Yes  | Yes   | Yes                                   | Yes                                   | Yes   | Yes  |
| Alan Woodward        | Yes       | Abstain  | Yes   | Yes                                   | Yes                                   | Yes   | Yes  |
| <b>Summary</b>       | <b>11</b> | <b>8</b>   | <b>10</b>   | <b>10 Members</b>                     | <b>11 Members</b>                     | <b>11 Members</b>   | <b>11 Members</b>  |

|  |                                      |   |   |   |                               |                               |                               |
|--|--------------------------------------|---|---|---|-------------------------------|-------------------------------|-------------------------------|
|  | Members Present, 2<br>Members Absent | Members Approved, 2<br>members Absent, 3<br>Abstained | Members Approved, 2<br>members Absent, 1<br>Abstained | Approved, 2<br>Members Absent, 1<br>abstained | Approved, 2<br>Members Absent | Approved, 2<br>Members Absent | Approved, 2<br>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 Thursday, October 20, 2016 at the Massachusetts Department of Public Health, 250 Washington Street, Henry I. Bowditch Public Health Council Room, 2<sup>nd</sup> 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; Lucilia Prates-Ramos, Michael Rigas; and Alan Woodward, MD.

Absent member(s) were: Michele David, MD and Harold Cox

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

Commissioner Bharel called the meeting to order at 2:02PM and made opening remarks before reviewing the agenda.

**ROUTINE ITEMS**

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

Commissioner Bharel began updates by discussing the accomplishments of the State Public Health Laboratory, she noted that over 225,000 lab specimens are tested annually; and the Lab Informs disease outbreak investigations; provides critical readiness to test for novel and emerging infections; and serves as a vital regional homeland security asset, providing time-sensitive testing for bioterrorism agents and environmental threats. The Commissioner shared that the Division of Capital Asset Management and Maintenance “DCAMM,” which manages the Massachusetts State Public Health Laboratory facility in Jamaica Plain, has announced the architectural firm for the initial design phase of the planned State Public Health Laboratory renovation. This design phase will proceed over the coming year and marks a critical chapter in the Lab’s history. She then thanked Dr. Mike Pentella, Assistant Commissioner Kevin Cranston, and the whole Lab team for their continued dedication and hard work on behalf of the Commonwealth.

The Commissioner then announced that the Bureau of Infectious Disease and Laboratory Sciences’ Immunization Program was recently awarded \$500,000 by the CDC over two years to advance evidence-based clinical strategies to improve rates of immunization against strains of the human papilloma virus

(HPV). She also shared that Roberta Crawford from our DPH Office of Preparedness and Emergency Management or “OPEM” was one of 20 members selected to serve on the Federal Emergency Management Agency Region 1 Regional Advisory Council, which serves all of New England. The Regional Advisory Council serves to enhance communications and preparedness for future disasters, while advising the regional FEMA administrator on issues specific to our region.

Next, Commissioner Bharel updated the Council on the successful online PMP launch, noting that we are now connected to 20 states for interstate data sharing as well as the U.S. Department of Veterans Affairs Massachusetts VA hospitals. She then discussed the Department’s opioid prescribing core competencies which is being incorporated within the curricula for more than 8,200 future prescribers across the Commonwealth, and have been adopted by the Massachusetts League of Community Health Centers across all member community health centers as central to safe prescribing and effective pain management.

The Commissioner also announced that the Department is partnering with Massachusetts Medical Society (MMS) in building a clinical didactic tool available free-of-charge for the purposes of continuing education on the core competencies.

Finally, Commissioner Bharel explained that on September 15th, DPH and the Baker Administration released an in-depth analysis of the state’s opioid-related deaths from 2013-2014. The findings, authorized by Chapter 55 of the Acts of 2015, revealed that opioid-related deaths have increased by 350 percent in Massachusetts in 15 years and marks the first time data from multiple state agencies – including DPH, the Office of the Chief Medical Examiner, the Department of Correction, MassHealth, and the Center for Health Information and Analysis – have been linked to give a comprehensive overview of deaths associated with the opioid epidemic. The Commissioner concluded by saying that the Department is pleased to unveil this report to combine state resources and aggregate data in an innovative way to better understand the drivers behind opioid and heroin-related overdoses, and we are hopeful that this new information will help us better understand the contours of this public health crisis as we continue to work on prevention, education and treatment in our communities to combat the opioid crisis in the Commonwealth.

The Commissioner then asked if the Council had any questions or comments regarding the updates.

Mr. Lanzikos asked if there were any data updates on the use of Narcan and its impact.

Commissioner Bharel replied that we do track some Narcan that is given but currently don’t have access to the information on all Narcan. In our most recent report that will be coming out there will be a report on Naloxone use in EMS. In the interest of time she noted that some details were left out but is more than happy to give a more robust summary of the Chapter 55 work and some of the Department’s plans for the future.

The Commissioner then asked if there were any additional questions. Seeing none, she proceeded with the agenda.

## **1. ROUTINE ITEMS**

### **c. Record of the Public Health Council September 1, 2016 Meeting (Vote)**

Commissioner Bharel asked if any members had any changes to be included in the September 1, 2016 meeting minutes. Seeing none, the Commissioner asked for a motion to approve the minutes.

Dr. Bernstein made a motion to approve, and Ms. Blondet seconded the motion. All approved, except Dr. Woodward, Mr. Lanzikos, and Dr. Kneeland who abstained from the vote as they were not present at the September 1<sup>st</sup> meeting.

### **d. Record of the Public Health Council September 14, 2016 Meeting (Vote)**

Commissioner Bharel asked if any members had any changes to be included in the September 14, 2016 meeting minutes. Seeing none, the Commissioner asked for a motion to approve the minutes.

Dr. Woodward made a motion to approve, and Mr. Lanzikos seconded the motion. All approved, except Mr. Brindisi who abstained from the vote as he was not present at the September 14<sup>th</sup> meeting.

## **2. DETERMINATION OF NEED**

### **a. Boston Children's Hospital (Boston, MA) application for a substantial capital expenditure to build an 11 floor inpatient clinical building with inpatient renewal to main building; ambulatory renewal; and 8 floor ambulatory clinical building at 2 Brookline Place (Brookline, MA), Project No. 4-3C47 (Vote)**

The Commissioner invited Nora Mann, Director of the Determination of Need Program, and Rebecca Rodman, Deputy General Counsel to present on a Determination of Need, Project Number 4-3C47, Boston Children's Hospital application for a substantial capital expenditure. Additionally, the Commissioner noted that the Applicant, as well as a representative from the City of Boston and Parties of Record would be providing comments to the Council on this pending matter. Upon conclusion of Ms. Mann's presentation, the Commissioner noted that she would invite the Boston Chief of Health and Human Services for the City of Boston, Felix Arroyo and designated representatives from the Parties of Record up to the podium to speak. She reminded them that they have 5 minutes to present to the Council. Following these comments, the Commissioner informed the Council that she would ask the Applicant to present comments. At that time, the Council will be able to ask questions. Commissioner Bharel also acknowledged and thanked the many members of the public who were in attendance.

Upon the conclusion of Ms. Mann's presentation, Commissioner Bharel invited Chief of Health and Human Services for the City of Boston, Felix Arroyo to present before the Council.

Chief Arroyo read a letter on behalf of City of Boston Mayor Marty Walsh and in support of the Boston Children's Hospital Determination of Need application. In the statement, Chief Arroyo stated that Mayor Walsh apologized for not being able to be present himself. The Mayor stated, in the letter, the importance of Boston Children's Hospital not only to the city but also as an example elsewhere and noted his own personal experience with Children's Hospital as a patient and their ability to address complex medical challenges. The letter also commented on building in the Longwood Medical area and concerns on density, traffic and design, and the impact it has on the entire city. Mayor Walsh noted that Children's Hospital has been responsive in addressing these key issues. He acknowledged the concerns regarding the Prouty Garden, but noted that he believes this project will not only offer the city a far

greater good, but will also foster great advances in medicine. He concluded by reaffirming Children's Hospital's work with the community, mentioning Medicaid patients and its assistance with community health centers.

Commissioner Bharel thanked Chief Arroyo and invited the Ann Gamble Ten Tax Payer Group, represented by Attorney Gregor McGregor of McGregor & Legere to present before the Council.

Mr. McGregor stated that his client feels the current conditions in the Staff Summary are incoherent and contain loopholes and provisions that he believed could be easily challenged by the hospital. Mr. McGregor stated his belief that the DoN staff did not review the Hospital's business assumptions in the application; that the Navigant report said that it did not question the Hospital's financial assumptions; and he questioned the project's reliance on the international pediatric health care market. With respect to Condition 8, he said that while the cost containment goal may currently be at 3.6%, there is no way to insure that that does not fluctuate. He further stated that the conditions do not address the Hospital's ability to pass on construction costs that are exempt from Condition 8. Mr. McGregor noted that there is currently no precedent or authority for Condition 8. He concluded by saying despite pulling patients away from other Massachusetts providers, the Hospital asserts this project is not for Massachusetts' patients and he questioned the validity of assurances of international patient demand. Mr. McGregor on behalf of his client, requested that the application be dismissed, and if the PHC is unable to dismiss the application, he requested that the decision be delayed.

Commissioner Bharel thanked Mr. McGregor for being present and invited the Pultinas Ten Tax Payer Group, represented by Kay Matthew, to speak before the Council.

Ms. Mathew stated that the Pultinas Ten Tax Payer Group's goal has been to bring transparency and thoughtful analysis to the decision making process for the Hospital's expansion. She stated that taxpayers bear the burden of Children's Hospital's tax-exempt status and that they continue to question the necessity of the Hospital's expansion. They do agree that Children's Hospital requires renovation and modernization, but question the need for new in-patient acute care beds on Longwood Avenue. Ms. Matthew shared her belief that the data submitted about future patients and past discharges is contradictory and many would agree that depending on international patients is mere speculation about the future. They are most concerned about the impact of this expansion on access to affordable care for low-income Boston children and they are not convinced the Hospital has adequately addressed this issue. Ms. Mathew further stated that the Prouty Garden is clinical space, and although there is no precedent in the DoN regulations for considering green space as a factor in healing, they believe that that the loss of this garden will profoundly impact the Hospital environment. Ms. Mathew concluded by addressing the community benefits allocation process. She stated that DPH has prioritized treatment goals for behavioral health and substance abuse and that their group recommends the Hospital's \$53 million in community benefits should also prioritize these goals. They also ask that DPH be fully involved with the allocation process and that the designated committee hold its meetings open to the public.

Commissioner Bharel thanked Ms. Mathew and invited the Ten Taxpayer Group for Improving Health for Children, represented by Sarah Morris.

Ms. Morris is a parent of a lifelong patient at the Hospital and supports the Hospital's request for a new clinical building on the Longwood campus. Ms. Morris shared her daughter's story. While the lifesaving equipment and skills were available at Children's, Ms. Morris described the open environment of the

acute patient beds, the lack of privacy, and the lack of space in the NICU, even to the point of fitting a single chair near a baby's isolette. Ms. Morris noted that her daughter was in the NICU for 295 days and due to lack of space her family was unable to spend the night. She further stated that private clinical space should be guaranteed and not tied to an additional medical diagnosis. Ms. Morris described the lack of privacy that families have due to only a thin curtain separating families from one another. She stated that the current plan for expansion will not only provide privacy for families and address space concerns but will also allow for Children's Hospital to continue its work of impacting the lives and healing patients.

Commissioner Bharel thanked Ms. Morris and informed those in attendance that the Department has heard their thorough, thoughtful, and emotional testimonies and appreciate them sharing their perspective and that they are important part of this process. She then invited the Applicant, Boston Children's Hospital, represented by Sandra Fenwick, President and CEO, and Dr. Kevin Churchwell, Executive Vice President for Health Affairs and Chief Operating Officer.

Ms. Fenwick introduced herself to the Council and thanked the Council and DoN staff for their work. Ms. Fenwick noted that she was speaking on behalf of patients, families, community members and clinicians. The vast majority of this project ties back to the urgent need for new facilities to address the lack of an up-to-date infrastructure and the need to care for the high acuity patients that they currently serve. Ms. Fenwick stated that routine occupancy today at Children's Hospital exceeds on average 85-90% and that running a hospital on that level creates enormous problems. She further stated that there are times where staff move up to a 100 patients a day in order to accommodate gender, age and acuity mix issues, and that this puts a burden on both staff, patients, and their families. She explained that on the day of the PHC meeting, they had an occupancy rate of 99%; had only two beds available in the hospital, that they turned away two transports the previous night before, and 5 patients spent the night in the PACU. She noted that the project is not just about providing private rooms but about providing the space and accommodating the services for those that need care today. She then addressed Medicaid and Prouty Garden. Ms. Fenwick noted that the Hospital has a longstanding commitment to all children especially children who are in need. They have the largest number of children being cared for in the Medicaid program, their commitment has been there and will remain there. They are the second largest provider to children receiving Medicaid in Massachusetts. With respect to the Prouty Garden, Ms. Fenwick stated that it had been a difficult process and decision for everyone, and that BCH had spent many years looking for alternatives that would allow for preservation of the Garden and provide the necessary upgrades, renovation, and clinical space. She explained that they had looked at many different options; weighed cost, program disruption, etc.; that they understood the need for respite space and greenery and have included significant green space in the proposed project to address those needs. She indicated that the plan includes a quarter of an acre out door garden (in addition to other indoor and rooftop spaces), noting that the Prouty family has been involved and supports the plans.

Ms. Fenwick addressed the nature of the patients they see, noting that they see very sick patients, that they continue to implement program changes in order to provide care in an ambulatory setting to as many patients as appropriate, that the proposed project will help accommodate that, and that this

project and the need for it is about the kids; concluding that she hoped that as the Council made its decision that members keep the children and their families at the center.

Commissioner Bharel announced that they will now take questions from the Council to either the applicant or the program staff.

Mr. Lanzikos asked how many quaternary hospitals are there in the United States.

Ms. Fenwick replied that there are approximately 35 free standing pediatric hospitals that serve tertiary/quaternary care.

Mr. Lanzikos asked what are the closest hospitals [that serve tertiary/quaternary care] to Massachusetts.

Ms. Fenwick answered that there is a small hospital in Hartford, Connecticut as well as Philadelphia.

Mr. Lanzikos asked Ms. Fenwick, to the best of her knowledge, are there many pediatric patients that require this level of care leaving Massachusetts to seek care from other facilities.

Ms. Fenwick replied that relatively few leave Massachusetts, however, there are some rare conditions that are sometimes cared for elsewhere but it's relatively small.

Mr. Lanzikos asked for confirmation whether they believe they care for the vast majority of Massachusetts pediatric patients that require that level of care.

Ms. Fenwick replied in the affirmative.

Mr. Brindisi stated that relative to Factor 9 it appears that Children's will contribute \$53 million in a 7-10 year period. He noted that the advisory committee appears to include members of Brookline and Boston, suggested that since over 25% of patients are not from the area, perhaps some CHI funds should be directed more broadly.

Josh Greenberg, Vice President, Government Relations was invited to the table to answer Mr. Brindisi's question. Mr. Greenberg stated that through their community health needs assessment it is their intention that most funding goes towards behavioral health concerns. They also have seen themselves as a statewide provider for behavioral health needs and as a consequence of that, they have reached out to DPH that they should look for initiatives as a part of the community benefits planning that address statewide behavioral health needs. They helped launched a kids' mental health campaign that has helped in the school setting regarding screenings etc.

Mr. Brindisi asked for clarification stating that it is safe to say that the staff will be adhering to broad coverage throughout the state with these community benefit dollars.

Mr. Greenberg replied that they are trying to work with the staff to put together a process around the allocation of DoN dollars. They are trying to do this thoughtfully and responsibly and thus have not

made specific allocation of dollar decisions today. He noted that public community meetings have taken place to help determine the best way to allocate dollars.

Mr. Brindisi asked if this were to be approved today how can staff and the Council hold the hospital accountable and spread out the allocation of dollars.

Mr. Lanzikos raised concerns about transparency and accountability given the significant amount of CHI funding in this project. He wondered whether the plan, once formulated, would be brought back to the PHC.

Ms. Mann pointed to the plan and stated that the process of determining what the priorities are and the allocation of funds to those priorities is committed to the advisory group, they make that decision.

Mr. Lanzikos explained that he understands that but usually that is incorporated into the approval of the Determination of Need, as a condition. Since the Community Health Initiatives is not a condition he inquired on whether that will be coming before the Council as a separate vote.

Ms. Rodman replied that that will not be coming back before the Council and that approval is solely for the Determination of Need. She further stated that quite often when there is a larger project, the determination of where funds will go is not fully resolved at the time of approval. In this case, an advisory committee has been meeting and there will then be a funding committee that will work with the hospital to make those determinations. From her understanding that will be a public and transparent process. The Department has approved this process but does not oversee the actual funding choices.

Mr. Lanzikos hoped that the process would be public and transparent. He asked the following sentence to be interpreted: "once a specific plan is developed funding can commence upon approval by the Public Health Council."

Ms. Mann responded stating that there are many standard situations in which the plan is already prepared at the time of approval. However, this committee has been meeting, as recently as this past Tuesday, and is still working on the plan. If the DoN is approved, that would include the approval of the process that is currently being undertaken. However, it's not the Department's role to make such a decision about where the money goes but the funding committee itself.

Mr. Lanzikos asked for clarification that typically that is something that is reflected in the approval.

Ms. Mann stated that is correct.

Mr. Lanzikos asked if the applicant would be willing to come back before the Council to report on the spending plan.

Ms. Fenwick stated absolutely.

Mr. Lanzikos referred to the proposed regulations in the context of what he perceived as improved process for ensuring accountability and asked if the applicant would be willing to report on the impact of the \$53 million.

Ms. Fenwick agreed and stated that the goal is to improve the circumstances of children with mental and behavioral health issues and agree with some of the other comments that this is where a majority of their focus should be.

Mr. Lanzikos stated that Children's Hospital serves the entire Commonwealth and hopes to see some of the impact of community health initiatives extend to the communities in which they have other facilities, not just the Greater Boston area. He further informed them that he hopes there is as much transparency in this process as possible.

Mr. Greenberg replied that they have a full-time evaluator as part of the project to ensure that they are able to evaluate impact and report back. He also informed the Council that they have been doing extensive work regarding children who are brought into the emergency room with behavioral health needs and created a consortium of 9 other hospitals across the state that will help track where these children are coming from, their diagnoses etc.

Ms. Blondet stated that the letter from the Mayor was well as the comments from the Ten Tax Payer Groups were very powerful and compelling. She stated that although the Council does not decide on how the \$53 million is spent it is a significant amount of money that can address one health condition in a significant way. She further stated that this money could also leverage additional dollars from the state and national foundations and would like to learn more about the process. She indicated that she did not feel as though she had enough information and remained concerned about the uncertainty of the hospitals projections with respect to international patients. Ms. Blondet noted that she cares very much about the MassHealth population, commended Condition 8, and would like the applicant to enlighten the Council on if there are any strategies of attracting international patients.

Ms. Fenwick addressed international patient demand and the unique services provided at Childrens: Children currently has thousands of patients coming from 100 countries; that their numbers are growing and, in that context, she referenced the contracts and relationships the hospital has with governments and insurance companies around the world. Ms. Fenwick also mentioned that they have gone service by service, looking at services, some of which are not offered at the other 35 Children's Hospitals, and that people travel to Children's because there are no other alternatives, and that BCH is viewed as a place that provides excellent service and value with low costs, quality, and expertise.

Addressing the international demand, Dr. Churchwell added that international patients are coming from countries where they have been promised health care and they don't have a system in their country to provide high quality critical services. Because of this they have reached out to hospitals in Europe and in others across the US, but they have found that because of Children's value, expertise and reputation they'd rather send their patients to them.

Addressing Ms Blondet's concerns relative to the CHI funding plan, Ms. Rodman said that DPH community benefits staff has been working closely with the advisory committee and the hospital on the plan that's being developed, and that, as is the case in every DoN with CHI funding, the advisory committee and funding committee decide how the money is used. The Department can offer input and understanding of the health care needs but cannot make the decision.

Dr. Kneeland added where the community groups are from and Ms. Blondet asked if we are approving whether there is a community process or not.

Ms. Rodman stated that there is still room to identify who is on this committee and informed the Council that they are approving whether they have a robust planning process essentially although it is not a complete process. She then explained that due to this being such a large project if it is not approved there are no community funds and that it is difficult for the applicant to make a complete plan to commit these funds just in case.

Ms. Fenwick noted that their intention is to have an impact and that the money will be directed to the community to address certain needs. They want to make the allocation of funds broad so that it helps more children but they also want it to be deep so that it has impact.

Mr. Lanzikos stated that he understands that the Council cannot direct funding but noted the importance of the transparency and coming together of the process in joining of support of the initiative.

Ms. Mann informed the Council that from her understanding, from speaking with our Community Health Initiatives staff, that this is not rare that we don't have the full plan.

Ms. Cooke asks Attorney Rodman to speak to prior DoNs.

Ms. Rodman stated that when the plan has not been complete, the Public Health Council has voted to approve given the acceptance by the CHI staff. She informed the Council that they are certainly able to ask BCH to come back to present information at a later date so that we have that transparency.

Mr. Greenberg informed the Council that they take this seriously and had the Hospital audited by an external organization to make sure they were doing community benefits correctly. He also mentioned that have a board committee on community services as well as a community advisory board with members that are diverse and from across the state.

Dr. Cunningham asked whether they charge international patients more to potentially recover some of the infrastructure cost.

Ms. Fenwick replied that is correct.

Dr. Cunningham asked staff if there was a relationship to Condition 8 and the DoN process.

Ms. Rodman responded that in the DoN regulations when making a Determination of the Need the Council can prescribe any other conditions reasonably related to the scope of the project. Although

Condition 8 itself is not one that had been imposed before, conditions are frequently added, that it is specifically set out in the regulation and is well within the authority of the Department and Council.

Dr. Bernstein asked for clarification on whether behavioral health includes substance abuse.

Ms. Fenwick stated the current program has 16 psychiatric beds and has opened up 12 intermediate care beds and the project calls for an additional 4. There is an inpatient program, outpatient and consultation services so it's a comprehensive behavioral health program. Substance abuse is embedded in that but they also have a program that was founded by John Knight that deals with substance abuse.

Dr. Bernstein stated there has been a compelling argument for capacity and privacy and asked what there's a change in the economics of the international patients' countries and don't have the same source. He inquired what their plan is.

Ms. Fenwick informed Dr. Bernstein that their plan is to have a diversified portfolio and is why they have worked with various countries rather than just one area of the world

Dr. Churchwell stated it's not a building capacity issue in other countries but a people problem regarding the infrastructure around care.

Ms. Fenwick that there is also a lack of pediatric specialists and that there is a need for a team of people. She noted they are trying to help nationally and internationally to keep the kind of care that can be done in those countries or states local.

Ms. Blondet leaves at 4:07pm and returns at 4:10pm.

In response to a question from Dr. Woodward about condition 8, and Children's agreement not to pass on costs on to Massachusetts payers, Doug Vanderslice, Senior Vice President and Chief Financial Officer, stated that most of the funding is coming from existing equity, some will be coming from cash flow and little bit from debt, and that the construction cost itself over time becomes a part of operating cost through depreciation. The construction cost is built in its just recognized over a period of time.

Dr. Woodward referred to chart 20 on page 27 showing depreciation and interest are the in the increased operating costs which was responsive to his question. He then raised a concern is about the Prouty Garden saying it is a very real and emotional issue to many people, and was wondering if Children's could assure people that it is doing as much as it can to move and protect as much soil and vegetation as possible.

Ms. Fenwick noted that they have been in constant communication with the Prouty family and the Prouty foundation board has been in support and will continue to support it. They are also working to remove statuary, trees, etc. and have already removed and transplanted trees so that they can bring back as much of the gardens as possible when new gardens and the previous garden are replaced.

Dr. Kneeland thanked everyone for their presentation and believes they have heard many fine ideas. He asked for validation on three points: that the hospital has an immediate need for beds, an immediate need for more outpatient facilities, and an immediate need to address privacy concerns.

Ms. Fenwick replied they have an immediate need for all three.

Mr. Brindisi said relative to the private spaces, what assurances do we have that in 20 years from now, that the new space is optimal.

Ms. Fenwick replied that she doesn't really know what the needs will be in 20 years; most of their facilities are currently almost 30 years old and in regards to depreciation they typically judge based on a 25 year period. She stated that this is a 25 year plan but she cannot say that they can predict exactly.

Mr. Brindisi inquired whether space will be optimal in the near future since they anticipate such a large number of international patients.

Dr. Churchwell replied that they follow the DPH guidelines on the health care hospital building and that the guidelines are stringent upon the need for single patient rooms. They will continue to follow DPH rules and guidelines as they evolve or stay the same.

Mr. Brindisi referenced Factor 9 and noted there was a proposal made to have a broad based community coalition he noted that it should be statewide based.

Mr. Lanzikos made a motion to amend the first sentence of Condition #7 and proposed inserting Boston Children's Hospital shall prepare "and implement" a plan. The motion was seconded by Dr. Cunningham. All approved.

Mr. Lanzikos asked when the annual reports will begin and how long is it anticipated to continue.

Ms. Rodman replied that the annual reports will begin in April 2017 and continue annually at least until 5 years after project implementation with the option for another 5 years at discretion of the Department.

Mr. Lanzikos asked if Ms. Rodman's statement will be reflected in the minutes.

Ms. Rodman replied in the affirmative and stated that it is also in the condition itself.

Mr. Lanzikos requested that in addition to releasing the report to the Department that it is also released to the Health Policy Commission.

Ms. Rodman stated that as a party of record, the Health Policy Commission will have access to the report and it will automatically go to them.

Mr. Lanzikos asked if that will be reflected in the minutes.

Ms. Rodman stated that it will but it is also statutory obligation as a party of the record.

Commissioner Bharel stated that with no further questions before the Council votes, she would like to recognize that Boston Children's Hospital has agreed to insure that the advisory committee work is statewide, inclusive and, transparent. In the determination of their use of Factor 9 dollars DPH will work with BCH to assure they report back to the Council including on the impact of their investments.

Dr. Woodward suggested that it be included in Condition #4 but if it's included and it has been agreed to, it may not need to be added in that way. He asked legal counsel about this.

Ms. Rodman stated we have done this before and that it does not need to be a condition to make it obligatory.

Commissioner Bharel stated that with no further questions she'd like to ask for a motion to accept the staff recommendation for approval of Children's Hospital Determination of Need as amended. Seeing none, she proceeded with the vote.

Dr. Woodward made the motion and Dr. Cunningham seconded it. All present members approved except Ms. Blondet who abstained.

**b. Hallmark Health Systems (Medford, MA) request for Transfer of Ownership through which Wellforce, Inc. would become sole corporate member of Hallmark Health Systems and its two campuses, Melrose-Wakefield Hospital (Melrose, MA) and Lawrence Memorial Hospital (Medford, MA), Project No. 6-3C55 (Vote)**

Dr. Woodward left the room at 4:28pm and returned 4:31pm.

Commissioner Bharel then asked Nora Mann and Rebecca Rodman to remain at the table to present on a Determination of Need, Project Number 6-3C55, Hallmark Health Systems request for Transfer of Ownership.

Commissioner Bharel noted that State Representative Paul Donato, Assistant Majority Leader was present to provide comments on the Transfer of Ownership but had to leave due to timing.

Upon the conclusion of Ms. Mann's presentation, Commissioner Bharel invited the Applicant represented by Charles Whipple, Executive Vice President and Chief Legal Officer of Hallmark Health Systems. James Herrington, Chairman of the Board and Dr. Wayne Wivell, Medical Staff President, both Hallmark Health Systems, as well as Norman Deschene, President and CEO of Wellforce will be available for additional questions.

Mr. Whipple stated that Dr. Wayne Wivell unfortunately is not able to attend and Mr. Herrington will make a statement.

Mr. Herrington thanked the Commissioner and members of the Council. He stated Hallmark Health is a system of care that is comprised of community hospitals, ancillary and community based services, and physician practices in geographic areas north of Boston. Collectively they have provided health care services for the communities they serve for over 100 years. As a standalone community hospital system

their availability to provide needed services has become increasingly challenging due to health care reform and an environment of ever growing cost and declining revenues. They recognize that for them to remain a provider of high quality/low cost services they must become a part of another provider system. Their board believes that this can be achieved by becoming a fully integrated partner of Wellforce. As a third and equal founding member they will have an equal voice in governance that will be intimately involved in decisions that will promote greater access to care locally in a more cost effective setting. The relationship with Wellforce is three-fold: first, they will be positioned to create a robust system of integrated services that provides high quality coordinated care locally; second, through greater access to integrated clinical programs they will be able to effectively and efficiently manage population and health needs that state federal policies demand; third, this proposed affiliation will allow the new Wellforce to make investments in their two hospitals both in the facilities and the technology to meet the current and future needs of the community.

Upon the conclusion of Mr. Herrington's presentation, Commissioner Bharel asked the Council if they had any questions for the applicant or program staff.

Dr. Bernstein asked if there were any DoN requirements on diversity of the board.

Ms. Mann deferred to the applicant to speak on the makeup of the board.

Mr. Herrington said that their board is comprised of 16 individuals, the majority residing in the service area. Those 16 members include one ex-officio member, there are 4 women and 11 men with currently no minority members. A month ago, they began the process of bringing on new members, specifically applicants who will help to bring diversity to the board.

Commissioner Bharel asked if there were any further questions from the Council. Seeing none, she called for a motion to accept the staff recommendation for approval of the Hallmark Health Systems' Determination of Need.

Ms. Doherty made the motion, Mr. Brindisi seconded it. All present members approved.

## **1. FINAL REGULATIONS**

### **a. Request for final promulgation of proposed amendments to 105 CMR 302.000 – *Congenital Anomalies Registry* (Vote)**

The Commissioner asked Alison Mehlman, Senior Deputy General Counsel, to present to the Council on a proposal to accept proposed amendments to 105 CMR 302.000: CONGENITAL ANOMALIES REGISTRY.

Upon conclusion of the presentation, the Commissioner asked if Council had any questions, seeing none she asked the Council to make a motion to approve the amendments.

Dr. Bernstein made a motion to approve; Ms. Prates-Ramos seconded the motion. All present members approve.

Dr. Kneeland left at 4:48 pm.

Dr. Kneeland returned at 4:52 pm.

**b. Request for final promulgation of proposed amendments to 105 CMR 315.000 – *Cremation of Bodies Received Outside Massachusetts (Vote)***

The Commissioner asked Jim Ballin, Deputy General Counsel, to present to the Council on a proposal to accept proposed amendments to 105 CMR 315.000: CREMATION OF BODIES RECEIVED OUTSIDE MASSACHUSETTS.

Upon conclusion of the presentation, the Commissioner asked if Council had any questions.

Dr. Bernstein asked if this regulation is meant to prevent foul play in other states – for instance if someone is murdered in another state and the body is sent to MA. Mr. Ballin indicated that the regulations seek to make sure there are no loopholes when transferring bodies.

Commissioner Bharel then asked if there were any further questions, seeing none she asked the Council to make a motion to approve the amendments.

Dr. Bernstein motions to accept the amendments; Ms. Blondet seconds the motion. All present members approve.

**4.PRELIMINARY REGULATIONS**

**a. Informational briefing on proposed regulatory amendments to 105 CMR 430.000 – *Minimum Standards for Recreational Camps for Children (State Sanitary Code, Chapter IV)***

The Commissioner asked Jana Ferguson, Deputy Director of the Bureau of Environmental Health, Steve Hughes, Director of the Community Sanitation Program, Dave Williams, Senior Environmental Analyst of the Community Sanitation Program, and Jim Ballin, Deputy General Counsel to present on proposed amendments to 105 CMR 430.000: MINIMUM STANDARDS FOR RECREATIONAL CAMPS FOR CHILDREN (STATE SANITARY CODE, CHAPTER IV).

Ms. Doherty left at 4:53 pm.

Ms. Doherty returned at 4:59 pm.

Upon conclusion of the presentation, the Commissioner asked if Council had any questions.

Mr. Rigas asked whether the proposed tobacco use restriction covers medical marijuana. Mr. Williams responded that the regulation would cover tobacco and nicotine delivery devices. Mr. Rigas asked if this included e-cigarettes. Mr. Williams indicated that it does and that the regulation is silent on medical marijuana. Mr. Rigas asked why e-cigarettes are included. Mr. Hughes indicated that there was a past incident and there are so many different delivery devices that no form of device is acceptable. Mr. Hughes added that many camps are inspected by public health nurses and this has been brought up by the nurses as a particular concern.

Mr. Brindisi asked about the skill level of swimmers and whether or not it is addressed in this regulation. Mr. Hughes responds that he believes Mr. Brindisi is referring to Christian's Law, which is under a separate regulation. That regulation will be presented to the Council in the future.

Dr. Bernstein asked if CPR is required at camps. Mr. Williams replied indicating that it is a requirement for all health supervisors.

Dr. Kneeland asked if AEDs are available at camps. Mr. Williams responded that AEDs are not covered in these regulations but several camps have them on site. Dr. Kneeland suggests that all camps have them, but only if individuals are competent to use them.

Mr. Lanzikos questioned how comparable these regulations are to those in other New England states. Mr. Hughes indicated that these regulations are as stringent as those in other states. Most New England states reference ACA (American Camping Association) national standards as does MA. MA references MCA (MA Camping Association) standards as well. Mr. Lanzikos asked if MA regulations are as rigorous as those in other states. Mr. Hughes answered yes.

Dr. Bernstein suggested adding naloxone rescue kits to the medical supplies at camps, if adding AEDs.

Dr. Woodward asked why the number of licensed camps has decreased (15% over a 10 year period). Mr. Williams explained that many sports clinics are right now not technically licensed camps. Mr. Williams explained that many "short term" camps limit the number of days so as not to have to adhere to licensing, which is why the proposed amendments include decreasing the number of days a camp operates in order to be licensed. Mr. Williams indicated that MA is not necessarily losing camps - certain camps/clinics have been able to work around the current regulations.

Mr. Lanzikos asked what portion of the fees charged by camps actually cover expenses. Mr. Williams indicated that the camp fees are often quite low, approximately \$50.00. Cities/towns may charge a higher fee if necessary. This is decided by city/ local board of health.

**b. Informational briefing on proposed regulatory revision of 105 CMR 590.000 – *Minimum Sanitation Standards for Food Establishments (State Sanitary Code, Chapter X)***

The Commissioner asked Jana to remain at the table and, Mike Moore, Director of the Food Protection Program, Diane Bernazzani, Retail Food Safety and Training Coordinator of the Food Protection Program, and Kay Doyle, Deputy General Counsel to join her to present on the proposed amendments to 105 CMR 590.000: STATE SANITARY CODE CHAPTER X--MINIMUM SANITATION STANDARDS FOR FOOD ESTABLISHMENTS.

Dr. Cunningham left the meeting and did not return.

Upon conclusion of the presentation, the Commissioner asked if Council had any questions.

Mr. Rigas acknowledged that the regulations allow a patron to request a report at a food establishment, and asked if the program has considered posting reports on site, similar to current system in New York

City. Mr. Moore indicated that five or six cities/towns have adopted similar grading systems. The program would like to see the effect of these new regulations before looking at that model.

Dr. Woodward noted that under bed and breakfast (B&B) establishments, the regulations are allowing an increase of up to six rooms or more before also receiving a food permit. He questioned if there have been any significant outbreaks of foodborne illness in B&Bs? Mr. Moore indicated that the program has not received any reports. The program does receive questions from boards of health concerning the rental of individual rooms, as the boards do not have the capacity to inspect each establishment. Increasing the number of rooms assists the local boards of health.

Mr. Brindisi asked about the current standard inspection report form. He questioned if it will be updated and distributed. Mr. Moore explained that the current form used now is either the DPH form or a local form that is DPH approved. Over the last few years the program has encouraged local boards to use forms that are comparable to the 2013 FDA guidelines. Mr. Brindisi then asked about individuals that grow their own produce – urban farms – or have chickens and wish to sell their own eggs and wondered if these activities are regulated. Mr. Moore responded that, by statute, fresh uncut fruits and vegetables are exempt from DPH regulations. Refrigerated eggs are exempt from licensing.

Mr. Lanzikos asked if catering kitchens are covered under this regulation, specifically if a caterer prepares and transports food, how does that caterer become licensed. Mr. Moore replied that a caterer is licensed by the board of health in the city where the kitchen (and food is prepared) is located. If a caterer is transporting food, the caterer must show that permit in the town where the food is being delivered/served. A banquet hall will likely already have a separate license.

Dr. Bernstein asked about the capacity to inspect all food establishments in MA. Mr. Moore indicated that there are currently approximately 50,000 retail food establishments in MA that are inspected by the local city/town boards of health. The Commissioner asked about state level inspectors. Mr. Moore stated that the state level inspectors focus on the 2800 food manufacturing and seafood establishments in the state. Dr. Bernstein again asked if there is capacity to address the expansion in these regulations. He cautions that the public takes these things for granted until something goes wrong. Ms. Ferguson noted that the Food Protection Program encourages local boards of health to have well trained staff and provides technical assistance and materials to all boards of health. The program is committed to helping local boards of health enforce the regulations at the local level.

The Commissioner indicated that the next information briefing is the last on the agenda for today's meeting.

**c. Informational briefing on proposed regulatory amendments to 105 CMR 127.000 – *Licensing of Mammography Facilities***

The Commissioner again asked Jana to remain at the table, that Jim Ballin, Deputy General Counsel return and be joined by Jack Priest, Director of the Radiation Control Program, and Karen Farris, Supervisor of the Healing Arts/Mammography Unit at the Radiation Control Program to present on proposed amendments to 105 CMR 127.000 LICENSING OF MAMMOGRAPHY FACILITIES.

Upon conclusion of the presentation, the Commissioner asked if Council had any questions.

Dr. Bernstein suggested that the notification process and materials need more depth in order to explain false negatives, false positives etc. and patient options for next steps. He suggested standardizing notification, perhaps developing a model template. Further information was provided by Ms. Ferguson. She explained that this (standardized communication) is not reflected in these regulations, but in 2014 both the Bureau of Health Care Quality and the Board of Registration in Medicine (BORIM) sent out information to physicians/clinicians on how to notify patients, what language to use in written communication, etc. This information is online. The Department's Bureau of Community Health and Prevention (BCHP) Cancer Program sent out this information as well. The Radiation Control Program will reinforce this message when developing training and guidance materials. Mr. Priest indicated that links to this information can be put on the Program's website.

Commissioner Bharel emphasized to the Council that the Department is taking regulatory review very seriously, conducting in depth reviews that enhance, modernize and streamline the regulations while promoting good public health. The Commissioner highlighted that the Department cannot accomplish this without the leadership of the Public Health Council members. The Commissioner thanked the members for enduring a three and one-half hour meeting and praised their dedication and devotion to the work of the Department.

Mr. Lanzikos asked if the practice of members receiving red-lined versions of the regulations had changed as he did not receive them. Dr. Woodward and other members indicated they had received them. Mr. Lanzikos stated that perhaps he did not print all of the attachments he received. Commissioner Bharel confirmed that the practice has not changed and members should receive copies of the red-lined regulations.

Commissioner Bharel called for a motion to adjourn. Ms. Doherty made the motion and Dr. Bernstein seconded it. All approved.

Commissioner Bharel reminded the members that the next meeting is scheduled for Wednesday November 9, 2016 at 9:00 am. The meeting adjourned at 5:43 pm.

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