**MINUTES OF THE PUBLIC HEALTH COUNCIL**

**Meeting of June 8, 2016**

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**

**PUBLIC HEALTH COUNCIL**

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**

**Henry I. Bowditch Public Health Council Room, 2nd Floor**

**250 Washington Street, Boston MA**

**Docket: Wednesday, June 8, 2016 9:00 AM**

1. **ROUTINE ITEMS:**
2. Introductions
3. Updates from Commissioner Monica Bharel, MD
4. Record of the Public Health Council Meeting May 11, 2016 **(Vote)**

**2. DETERMINATION OF NEED**

a. Norwood Hospital Request for approval of significant change to project scope and maximum capital expenditure Approved DoN Project No. 4-3C16 **(Vote)**

**3. PRELIMINARY REGULATIONS**

a. Informational briefing on proposed regulatory amendments to 105 CMR 700.000 – Implementation of M.G.L. c. 94C

b. Informational briefing on proposed regulatory amendments to 105 CMR 721.000 – Standards for Prescription Format and Security in Massachusetts

c. Informational briefing on proposed regulatory amendments to 105 CMR 722.000 – Dispensing Procedures for Pharmacists

**4. FINAL REGULATIONS**

* 1. Request for final promulgation of proposed amendments to 105 CMR 335.000 – Treatment of Persons Exposed to Rabies **(Vote)**

b. Request for final promulgation of proposed amendments to 105 CMR 360.000 – Tuberculosis Treatment Unit Standards for Admission, Treatment and Discharge (**Vote)**

c. Request for final promulgation of proposed amendments to 105 CMR 365.000 – Standards for Management of Tuberculosis outside Hospitals **(Vote)**

 **5. PRESENTATIONS**

 a. Overview of DPH campaign “Big Tobacco is Sweet Talking Our Kids”

*The Commissioner and the Public Health Council are defined by law as constituting the Department of Public Health. The Council has one regular meeting per month. These meetings are open to public attendance except when the Council meets in Executive Session. The Council’s meetings are not hearings, nor do members of the public have a right to speak or address the Council. The docket will indicate whether or not floor discussions are anticipated. For purposes of fairness since the regular meeting is not a hearing and is not advertised as such, presentations from the floor may require delaying a decision until a subsequent meeting.*

**Public Health Council**

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

**Date of Meeting:** Wednesday, June 8, 2016

**Beginning Time:** 9:16AM

**Ending Time:** 11:12AM

**Attendance and Summary of Votes:**

| **Board Member** | **Attended** | **Item 1c****Minutes of the May 11, 2016 Meeting** | **Item 2a****Determination of Need #4-3C16** | **Item 4a****Request for final promulgation of proposed amendments to 105 CMR 335.000 – Treatment of Persons Exposed to Rabies** | **Item 4b****Request for final promulgation of proposed amendments to 105 CMR 360.000 – Tuberculosis Treatment Unit Standards for Admission, Treatment and Discharge** | **Item 4c****Request for final promulgation of proposed amendments to 105 CMR 365.000 – Standards for Management of Tuberculosis outside Hospitals** |
| --- | --- | --- | --- | --- | --- | --- |
| Monica Bharel | Yes | Yes | Yes | Yes | Yes | Yes |
| Edward Bernstein | Yes | Yes | Yes | Yes | Yes | Yes |
| Derek Brindisi | Absent | Absent | Absent | Absent | Absent | Absent |
| Harold Cox | Yes | Yes | Abstain | Yes | Yes | Yes |
| John Cunningham | Yes | Yes | Yes | Yes | Yes | Yes |
| Michele David | Yes | Yes | Yes | Yes | Yes | Yes |
| Meg Doherty | Yes | Yes | Yes | Yes | Yes | Yes |
| Michael Kneeland | Yes | Yes | Yes | Yes | Yes | Yes |
| Paul Lanzikos | Yes | Yes | Yes | Yes | Yes | Yes |
| Denis Leary | Absent | Absent | Absent | Absent | Absent | Absent |
| Lucilia Prates-Ramos | Yes | Yes | Abstain | Yes | Yes | Yes |
| Jose Rafael Rivera | Yes | Yes | Yes | Yes | Yes | Yes |
| Meredith Rosenthal | Yes | Yes | Yes | Yes | Yes | Yes |
| Alan Woodward | Yes | Abstain | Yes | Yes | Yes | Yes |
| Michael Wong | Yes | Abstain | Yes | Yes | Yes | Yes |
| **Summary** | **13 Members Present, 2 Members Absent** | **11 Members Approved, 2 Members Abstained, 2 Members Absent** | **11 Members Approved, 2 Members Abstained, 2 Members Absent** | **13 Members Present, 2 Members Absent** | **13 Members Present, 2 Members Absent** | **13 Members Present, 2 Members Absent** |

**PROCEEDINGS**

A regular meeting of the Massachusetts Department of Public Health’s Public Health Council (M.G.L. c. 17, §§ 1, 3) was held on Wednesday, June 8, 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; Harold Cox; John Cunningham, PhD; Michele David, MD; Meg Doherty; Michael Kneeland, MD; Paul Lanzikos; Lucilia Prates-Ramos; Jose Rafael Rivera; Meredith Rosenthal, PhD; Alan Woodward, MD; and Michael Wong, MD.

Absent member(s) were: Derek Brindisi and Denis Leary

Also in attendance were Margret Cooke, 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 9:16AM and made opening remarks before reviewing the agenda.

**ROUTINE ITEMS**

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

Commissioner Bharel provided an update on the Department’s accreditation process, and noted that DPH submitted over 355 examples of public health essential services documentation to the Public Health Accreditation Board (PHAB) on May 19, 2016. She added that the PHAB will conduct a site visit in the coming months, and concluded by thanking the Department’s accreditation team for their hard work on this effort.

Next, the Commissioner provided an overview of the state’s Make the Right Call campaign, to compliment the Good Samaritan Law which protects individuals from drug possession charges when an overdose victim or witness seeks medical attention. She indicated the intent of the law is to help reduce overdose deaths by removing barriers to calling 911 for medical assistance. The Commissioner then played a video from the campaign, and noted DPH also has several print campaigns throughout Massachusetts including the State without StigMA campaign which was recently highlighted in the Journal of the American Medical Association.

Once the video was over, she asked if Council members had any questions about the campaign.

Dr. Bernstein noted that the gentleman Kevin Rosario highlighted on the video has been working as a community support provider and indicated it was great to see him alive and successful, and added that it is a tribute to the work being done.

Mr. Rivera asked if this video and the campaign materials were available for use by community organizations.

The Commissioner noted they are available on the Department website, and the Department will provide information on that to Council members.

Mr. Lanzikos indicated it may be helpful to have closed captions on the video for broader accessibility.

Ms. Prates-Ramos asked if the video and associated materials were translated into other languages.

Commissioner Bharel indicated that the print materials are available in Spanish. She clarified that the video is designed for use by police departments around the state during their roll calls.

Lastly, Commissioner Bharel acknowledged the service of Dr. Michael Wong and Mr. Jose Rafael Rivera to the Public Health Council and the Department, and bid them farewell.

She then invited Dr. Wong and Mr. Rivera to say a few words.

Dr. Wong said it is hard to believe he has served on the Council for 10 years, and added the Council has done a lot in that time. He added it has been a pleasure to serve with so many esteemed members and that experiences like serving on the Council rejuvenate passion for important public health work.

Mr. Rivera echoed Dr. Wong’s words, and indicated he is looking forward to what lies ahead. He added that his time on the Council has been an amazing ride and every month he has learned something new. He thanked the Commissioner, Council members, and Department staff for all of their work and support during his tenure on the Council. He added a quote: “It is not enough to prepare our children for the world. We must also prepare the world for our children,” and concluded with thanks to the Department and Council members.

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

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

Commissioner Bharel asked if any members had any changes to be included in the May 11, 2016 meeting minutes. Seeing none, the Commissioner asked for a motion to approve the minutes.

Mr. Rivera made a motion to approve, and Dr. Bernstein seconded the motion. All approved, except Dr. Woodward and Dr. Wong who abstained from the vote as they were not present at the May meeting.

**2. DETERMINATION OF NEED**

**a. Norwood Hospital Request for approval of significant change to project scope and maximum capital expenditure Approved DoN Project No. 4-3C16 (Vote)**

The Commissioner invited Mike Sinacola, Interim Deputy Director for the Bureau of Health Care Safety and Quality, and Rebecca Rodman, Deputy General Counsel, to the table for a presentation of the DoN Staff Summary for Project #4-3C16, and invited the following representative of the applicant to the table: Kim Bassett, President, Norwood Hospital.

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

Dr. Wong thanked Mr. Sinacola for his presentation, and noted that the amendment represents a significant reduction in the original proposal. He asked for information on what led to the change, such as a reduction in catchment area.

Mr. Sinacola deferred to the applicant regarding the catchment area. He also noted that based on information the DoN Program received for its review, the occupancy rate is approximately 62-63% over the last several years. He indicated that was a determining factor in the Program’s decision.

Ms. Bassett added that one of the reasons for making this change is that there has been a shift from inpatient to outpatient settings and the hospital has seen a reduction in the need for inpatient beds. Additionally, she indicated that the hospital has seen a decrease in patient length of stay which has created efficiencies in the hospital. She added that the average daily census is about 78 patients, so additional rooms are not necessary. She noted the hospital has done a lot of work to improve patient flow and efficiency, so at this time it isn’t’ necessary to add another floor to the hospital.

Dr. Woodward noted that many of the downtown hospitals are continually at around a 90% occupancy rate, so it is concerning that the current occupancy rate is around 62%. He added that it is clear the volume at the hospital is decreasing, and he isn’t sure if that also means the market share is decreasing. He asked if there were any fiscal issues for the hospital or the Steward system as a whole.

Ms. Bassett responded she can only speak to the financial status of Norwood Hospital, and cannot speak to the status of Steward Health Care as a whole. She indicated the Hospital is very financially stable and she does not anticipate any issues in the future around financial viability. She concluded by saying that this change in application is due to a shift from inpatient to outpatient care.

Mr. Lanzikos asked if Steward Health Care is current in its reporting obligations to the Office of the Attorney General and any other state agencies.

Andy Levine, Esq., counsel to the applicant, responded that is not something he is aware of at this time but they are happy to return to provide an update on that in the future.

Mr. Lanzikos asked if DoN staff is aware of any deficiencies in Steward’s reporting obligations.

Mr. Sinacola added that Program staff is not aware of any issues around Steward Health Care’s reporting obligations, but the Program can get back to the Council on that issue.

Mr. Cox asked when the original request for DoN approval was made.

Mr. Levine responded that the original DoN was filed in 2013.

Mr. Cox noted that things have shifted radically in that period of time, and indicated that is a concern for individuals in the catchment area. He asked if there was any event to cause things to shift this dramatically, because otherwise the reasons offered as justification would have been apparent at the time the original DoN was filed.

Ms. Bassett responded there have been several leadership changes at the Hospital that have resulted in better patient flow and reduced length of stay. She added that, in her opinion, patients were staying in the hospital at least a day longer than they needed to be and that the hospital has worked with home health agencies, visiting nurse associations, and skilled nursing units to make sure that patients receive the care that they need in the most appropriate setting. She added that by doing so, the hospital has reduced the average length of stay by a day and as a result is able to accommodate more patients coming into the Hospital.

Dr. Bernstein asked if there are currently emergency department boarders at the Hospital, and if so what the length of stay is.

Ms. Bassett responded that is something the Hospital is working on, and depending on the day there will be boarders in the emergency department. She indicated she did not have information on the number of boarders or their length of stay, but she would be happy to follow up with that information. She added that over the past several months, the hospital has reduced the length of stay of a person being admitted by 80 minutes through patient flow changes and renovations. She added that presently patients coming into the emergency department wait on average around two and a half to three hours before being admitted.

Mr. Rivera noted that he was pleased to see ongoing conversations with the CHNA groups will continue, and asked if there have been conversations with community groups prior to now on the changes in project scope given it is such a large change and funding reduction.

Ms. Bassett responded that she has met with at least one of the local CHNAs, and discussed the funding.

Mr. Levine noted that conversations between the hospital and community groups are ongoing, and that specific dollar amounts had not been earmarked to date.

Mr. Rivera noted that for some initiatives changes of this size could effectively kill the work being done, and indicated those conversations should happen sooner versus later.

Ms. Bassett indicated she has been in her role as hospital president for about a year, and that she has met with the CHNAs to discuss where the hospital is in the construction process for the project and process to allocate community health initiative funds connected with the project.

Ms. Doherty asked for the hospital’s average length of stay, percentage of emergency department boarders, and whether the hospital was part of an accountable care organization.

Ms. Bassett responded that the hospital’s average length of stay is around 3.2 to 3.3. days. She added that while she did not have the ED boarding percentage, she would be happy to follow up with that information. She noted that Norwood Hospital is part of an ACO.

Ms. Doherty indicated that being part of an ACO is the imperative to reducing length of stay. She asked what home care partners the Hospital works with.

Ms. Bassett responded that Steward Health Care has its own home care agency, but the Hospital works with local agencies as well. She indicated the patient has the right to select a home care agency they choose.

Ms. Doherty indicated an ACO is a business model with goals of getting length of stay down, and now we are finding out post-acute care is just as expensive as inpatient care. She asked how all of this fits together for this ACO now and in the future.

Ms. Bassett indicated she feels the role of the ACO is not to lower the average length of stay, but to ensure the patient has quality care in the most appropriate, cost effective location. She added that part of it is about the length of stay, because there are risks associated with staying in the hospital longer versus a familiar setting. She concluded by saying it is her understanding that as patients move beyond the inpatient setting there are cost savings to the overall delivery system.

Ms. Doherty added that her concern is that there doesn’t seem to be a trend analysis and focus on population health management and asked how the hospital can adequately project bed need without such an analysis.

Ms. Bassett responded that while she cannot speak to the overall and future bed needs for the system, she does not foresee future changes to service lines that would cause an increase in inpatient admission at the hospital.

Dr. Bernstein asked what the mental health and substance use disorder needs were for the community and how the Hospital was accommodating that. Additionally, he asked as the Hospital prioritizes community needs if there was a focus on the opioid crisis.

Ms. Bassett responded that the hospital has 61 mental health beds, and the Steward system has the most of any system in the state at over 200. She added that those beds are often full, with an over 97% occupancy rate. She added that the hospital is exploring ways to possibly add more mental health beds at the hospital. Ms. Bassett noted that the hospital just completed its community health report, and that the hospital would use that document to help CHNAs prioritize their work.

Dr. Wong said he is troubled by the $20 million reduction in the project, and asked if there was an underlying problem with the metrics used in the initial proposal or if there is now a second set of metrics informing this amendment. He noted that while Ms. Bassett has indicated the overall financial health of Norwood Hospital is good we know that Steward Health Care is tackling significant issues right now and asked if there was an attempt to advertise a Cadillac system in order to come into the state, while not necessarily taking into account overall system needs in the state.

Ms. Bassett responded that the bulk of that $20 million was to build an entire new floor in order to bring more private rooms into the hospital. She indicated that the present configuration dramatically impacts patient flow and does not allow the hospital to maximize space and patient flow as triple and quadruple bed rooms were rarely fully occupied due to patient considerations, such as same gender in the room and infection control issues. She indicated that subsequent to the decision to build a floor of single bed rooms, the Hospital has found a way to maximize space available today and improve patient flow.

Mr. Levine added that while the application today pertains to Norwood Hospital, to respond to the more general question about the Steward health care system. He indicated that it is his understanding when the original Steward proposal went forward, it included spending of over $400 million in capital dollars and in 2014 it was documented the system had spent $423 million across the system. He noted the request before the Council today is a sea change, but over the past three years the average daily census was declined through successful strategic moves such as creating more single rooms. He added that upon review of this information, it was determined the expansion wasn’t necessary.

Commissioner Bharel refocused Council members on the question before them today, which is around reducing the scope of this project at Norwood Hospital.

Mr. Lanzikos indicated that while he would be prepared to vote on the application before the Council today, he would not be prepared to vote on an applicant from another Steward entity until the Council receives an updated report on the system and their reporting obligations. He added that more robust analysis of factors by applicants is necessary.

Ms. Doherty indicated there was a presentation to the Council regarding system-wide changes to reduce duplication in service and first class cardiac care at St. Elizabeth’s Hospital with patients with behavioral health issues going to the Carney Hospital, and she would like an update on those efforts. She added that it is difficult to pick just Norwood Hospital out when it is a part of an overall system and the services offered, and indicated that she is concerned that there does not seem to be planning across the system. She concluded by saying she is concerned by the prospect of closing beds at the hospital and what that could mean for the hospital’s future and what it could mean for the system as well.

Mr. Levine clarified that the amendment to the application is to reduce the number of proposed beds at the hospital, and would not result in a reduction to their existing licensed capacity. He indicated there is excess capacity at Norwood Hospital to date, so it would be counterintuitive to build additional capacity and would not be prudent. He concluded by saying based on where the hospital is today and looks to be trending forward the hospital is in good shape with the capacity it has today.

Ms. Doherty indicated she understands the effect of the amendment, but she would like to see a needs analysis of the system and where patients come from, and whether the hospital provides a value-add to the community.

Commissioner Bharel indicated she hears the Council’s request for more information from the Steward system and then brought Council members back to the question before them around reducing the project scope for the previously approved project at Norwood Hospital.

The Commissioner asked members for a motion for approval of significant change to project scope and maximum capital expenditure Approved DoN Project No. 4-3C16.

Dr. Rosenthal made motion, Dr. Woodward seconded the motion. Ms. Prates-Ramos, Dr. Cunningham, Mr. Cox, Mr. Rivera, and Ms. Doherty abstained.

Mr. Cox offered comments to clarify his reason to abstain. He indicated we are all interested in having a hospital system that supports the needs of all members of a community and there is something about the interchange that has occurred in a short amount of time that gives him some pause. And for these reasons, he feels he cannot vote for or against it at this time.

Dr. Bernstein asked why the hospital is requesting any beds when there is a 67% occupancy rate presently.

Ms. Bassett responded that the hospital is requesting to amend the project so no additional beds are added because it would be fiscally irresponsible to build a new floor and 35 beds to the hospital. She added that some of the efficiencies they have been able to create alleviate the need for additional capacity.

Mr. Cox added that part of what the Council is saying is related to the Steward system as a whole versus Norwood Hospital, and while the vote itself concerns only the Hospital it does tie into the Steward Health Care system as a whole.

Ms. Bassett responded that there is already capacity in the system for medical surgical patients, so adding additional capacity at Norwood Hospital would not help the system as there is excess capacity if needed. She indicated Norwood Hospital does transfer patients as necessary, but medical surgical patients are not transferred as there is excess capacity.

Mr. Levine added that over $8 million has been spent on strategic renovations at the hospital to improve the physical plant and decompress multi-bed room layouts. The project has been done in a phased approach, and through that approach the Hospital has seen in real time that there is no need for additional capacity.

Ms. Rodman indicated that under the existing regulation the Council has a somewhat narrow task in front of them to examine this project for this hospital versus for the system. She added that while that conversation can happen around how the DoN regulation should look moving forward, the question for members is a narrow one.

Dr. Woodward added he would agree, and noted that the presentation has been helpful in explaining that this is a reduction in proposed new capacity versus existing capacity. He added that there are questions of market share for the system and ongoing viability of the system given the network of services it provides, but indicated that is a larger and separate issue that the Steward system would have to address. He concluded by saying the Council should consider the application in front of them, and look for follow up on the broader system issues.

Commissioner Bharel indicated that Dr. Rosenthal made a motion to approve the application that was seconded by Dr. Woodward. She asked members for a vote to approve the application. All present members approved, except Ms. Prates-Ramos and Dr. Cox who abstained from the vote.

 **3. PRELIMINARY REGULATIONS**

**a. Informational briefing on proposed regulatory amendments to 105 CMR 700.000 – Implementation of M.G.L. c. 94C**

Commissioner Bharel invited Jonathan Mundy, Director of the Office of Prescription Monitoring and Drug Control program within the Bureau of Health Care Safety and Quality, Lauren Nelson, Director of Policy and Quality Improvement within the Bureau of Health Care Safety and Quality, and Rebecca Rodman, Deputy General Counsel, to the table for an informational briefing on proposed regulatory amendments to 105 CMR 700.000 – Implementation of M.G.L. c. 94C.

Upon conclusion of the presentation, the Commissioner asked if Council members had any questions for Mr. Mundy, Ms. Nelson, or Ms. Rodman.

Dr. Cunningham asked why the term “ultimate user” versus just “user” in the definition of prescription.

Mr. Mundy responded that this language aligns with the federal Drug Enforcement Agency’s definition.

Mr. Rivera added that sometimes a prescription, such as naloxone, is given to a person who is not the ultimate user.

Commissioner Bharel added she believes the definition is in line with the federal definition for consistency.

Ms. Doherty asked about the changes to language for midlevel prescribing practitioners and what impact those will have.

Ms. Rodman responded that the regulation will specify that nurses need to submit a copy of their prescribing guidelines established with a supervising physician. She added that this would codify existing practice.

Ms. Doherty asked what level of supervision pharmacy interns must be given in order to immunize.

Mr. Mundy responded that a trained pharmacist be present in order for an intern, who is also trained, to administer an immunization.

Ms. Doherty asked for a better understanding of what supervision means here: if that required direct supervision or just that the pharmacist be present or have established guidelines.

Ms. Rodman noted that joint guidance exists between DPH’s Drug Control Program and Board of Registration in Pharmacy, and would need to be updated as a result of the proposed amendments.

Mr. Lanzikos suggested that instead of “ultimate user” the term “any user” be used in the definition of prescription. Ms. Doherty echoed a change to the term “ultimate user” would be useful, as prescriptions may be present in the home that someone accesses.

Ms. Cooke responded that it is her understanding “ultimate user” is a term of art the federal government uses, and it behooves the state to align with that language to ensure compliance.

Dr. Woodward asked how nine years of age was picked for the change in immunization age.

Mr. Mundy indicated this was a recommendation from the Bureau of Infectious Disease and Laboratory Sciences to expand access to vaccination. He indicated the age in the existing regulation is 18 years old, and added that the regulation contains language specifying this is not to substitute for a patient’s relationship with their health care provider.

Dr. Woodward asked if the Massachusetts Chapter of the American Academy of Pediatrics had weighed in on this change at all.

Commissioner Bharel indicated they have been involved, and Kevin Cranston can speak more to that during his presentations later on the agenda.

Dr. Woodward briefly left the meeting at 10:37AM and returned at 10:40AM.

Dr. Kneeland asked how much education someone has before becoming a pharmacy intern.

Mr. Mundy responded that pharmacy school is now a six year program resulting in a PharmD. He added that generally students receive this training as they enter their fifth year and intern in practice settings.

Mr. Lanzikos asked for clarification on physician’s order for a vaccine at a pharmacy, and whether that was required for flu shots.

Mr. Mundy responded that there are standing orders at pharmacies that allow for vaccines to be administered.

Commissioner Bharel further clarified that from the patient’s perspective, the patient is walking in and receiving the vaccine but in actuality there is a standing order authorizing the vaccine.

Seeing no further questions, the Commissioner asked Ms. Nelson to move to the next presentation.

**b. Informational briefing on proposed regulatory amendments to 105 CMR 721.000 – Standards for Prescription Format and Security in Massachusetts**

Dr. Bernstein briefly left the meeting at 10:40AM and returned at 10:42AM.

Mr. Mundy, Ms. Nelson, and Ms. Rodman then gave an informational briefing on proposed regulatory amendments to 105 CMR 721.000 – Standards for Prescription Format and Security in Massachusetts.

Upon conclusion of the presentation, the Commissioner asked if Council members had any questions for Mr. Mundy, Ms. Nelson, or Ms. Rodman.

Seeing none, she asked Ms. Nelson to move to the next presentation.

**c. Informational briefing on proposed regulatory amendments to 105 CMR 722.000 – Dispensing Procedures for Pharmacists**

Mr. Mundy, Ms. Nelson, and Ms. Rodman then gave an informational briefing on proposed regulatory amendments to 105 CMR – 722.000 – Dispensing Procedures for Pharmacists.

Upon conclusion of the presentation, the Commissioner asked if Council members had any questions for Mr. Mundy, Ms. Nelson, or Ms. Rodman.

Mr. Lanzikos asked if the proposed amendments to the definition of “hospital employee” also pertain to the definition of “clinic employee”.

Mr. Mundy responded those definitions do align through the proposed changes.

Dr. Bernstein asked if changes to this regulation address partial fill language in the recently passed opioid law.

Ms. Rodman indicated it did not, as that speaks to the practice of a pharmacist which she believes will be addressed by the Board of Registration in Pharmacy.

Dr. Bernstein asked if there was any place in this regulation or others to add in a process by which hospitals could take back unused medications.

Ms. Rodman indicated there have been some federal changes around the take back role to work with hospitals and pharmacies, and that is an ongoing process. She added that it is not something the Department has the authority to do within this regulation, but is something we are monitoring and looking into.

Dr. Woodward indicated there are many left over opioids and many studies indicating it is safe to flush these down the toilet, and may be something the Department could indicate as a safe approach.

Commissioner Bharel indicated the DPH website has information on safe ways to dispose of these medications, such as in coffee grounds, but given the potential for environmental impacts the Department cannot endorse the toilet flushing method.

Ms. Doherty indicated there are federal regulations for hospice residences where the medications are to be returned to the family versus to the hospice agency or licensed personnel. She added that regulation and approach is a concern.

Seeing no further questions, Commissioner Bharel thanked Mr. Mundy, Ms. Nelson, and Ms. Rodman for their presentations.

**4. FINAL REGULATIONS**

The Commissioner invited Kevin Cranston, Associate Commissioner and Director of the Bureau of Infectious Disease and Laboratory Sciences, and Alison Mehlman, Senior Deputy General Counsel, to the table for request to promulgate proposed amendments to three regulations.

Before proceeding with his presentation, Commissioner Bharel asked if Mr. Cranston would like to address the change in immunization practice in pharmacies previously discussed.

Mr. Cranston responded that while he would not like to speak on behalf of the Massachusetts Chapter of the American Academy of Pediatrics, the Bureau of Infectious Disease is in constant communication with the Academy. He added that the Academy has expressed a broad principle of preferring immunizations be administered in the medical home, but recognizing the important role pharmacies can play in ensuring timely immunization. Mr. Cranston then moved to his first presentation requesting approval to promulgate proposed amendments to 105 CMR 335.000.

**a. Request for final promulgation of proposed amendments to 105 CMR 335.000 – Treatment of Persons Exposed to Rabies (Vote)**

Upon conclusion of the presentation, the Commissioner asked if Council members had any questions for Mr. Cranston or Ms. Mehlman.

Seeing no further questions, Commissioner Bharel asked Council members for a motion to approve for promulgation proposed amendments to 105 CMR 335.000 – Treatment of Persons Exposed to Rabies.

Dr. Wong made a motion to approve, and Ms. Doherty seconded the motion. All present members approved the proposed amendments.

**b. Request for final promulgation of proposed amendments to 105 CMR 360.000 – Tuberculosis Treatment Unit Standards for Admission, Treatment and Discharge (Vote)**

The Commissioner asked Mr. Cranston and Ms. Mehlman to remain at the table for a request for final promulgation of proposed amendments to 105 CMR 360.000 – Tuberculosis Treatment Unit Standards for Admission, Treatment and Discharge.

Dr. Rosenthal and Dr. David left the meeting at 10:49AM. Dr. Rosenthal returned at 10:52AM and Dr. David returned at 10:54AM.

 Upon conclusion of the presentation, the Commissioner asked if Council members had any questions for Mr. Cranston or Ms. Mehlman.

Seeing no further questions, Commissioner Bharel asked Council members for a motion to approve for promulgation proposed amendments to 105 CMR 360.000 – Tuberculosis Treatment Unit Standards for Admission, Treatment and Discharge.

Dr. Bernstein made a motion to approve, and Ms. Prates-Ramos seconded the motion. All present members approved the proposed amendments.

**c. Request for final promulgation of proposed amendments to 105 CMR 365.000 – Standards for Management of Tuberculosis outside Hospitals (Vote)**

The Commissioner asked Mr. Cranston and Ms. Mehlman to remain at the table for a request for final promulgation of proposed amendments to 105 CMR 365.000 – Standards for Management of Tuberculosis outside Hospitals.

Upon conclusion of the presentation, the Commissioner asked if Council members had any questions for Mr. Cranston or Ms. Mehlman.

Seeing no further questions, Commissioner Bharel asked Council members for a motion to approve for promulgation proposed amendments to 105 CMR 365.000 – Standards for Management of Tuberculosis outside Hospitals.

Dr. Woodward made a motion to approve, and Dr. Wong seconded the motion. All present members approved the proposed amendments.

Commissioner Bharel also formally recognized Mr. Cranston’s recent promotion to Associate Commissioner of the Department.

 **5. PRESENTATIONS**

 **a. Overview of DPH campaign “Big Tobacco is Sweet Talking Our Kids”**

Commissioner Bharel invited Lea Susan Ojamaa, Director of the Division of Prevention and Wellness within the Bureau of Community Health and Prevention, to the table for a presentation on the Department’s recent campaign, “Big Tobacco is Sweet Talking Our Kids”.

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

Mr. Rivera thanked Ms. Ojamaa for all of her work. He asked that when thinking about flavored products we should keep menthol in mind as that can be a starting point for many people.

Dr. Woodward pointed out HB 4361, which is an omnibus tobacco bill that would put Massachusetts on the forefront. He noted the bill would prohibit sales of tobacco products at pharmacies, prohibit e-cigarette sales through vending machines, and restrict use at various sites such as schools. Dr. Woodward indicated while there was a proposal to restrict flavored products it did not make it into the bill, so he encourages everyone to contact their local board of health on the issue of flavored products.

Dr. Bernstein noted it is really important when working with youth to focus on critical thinking and use peers to show how they’re being manipulated.

Ms. Ojamaa noted the Department’s 84 Program, which is a youth movement that has been instrumental in work done at the local and state level. She indicated that the 84 stands for the percentage of youth who do not use tobacco products and added that this is a core part of their work and it is great to see them interact on this issue.

Dr. Woodward indicated Tobacco Free Massachusetts is recognizing Mayor Walsh for his work to eliminate tobacco in parks at the end of June.

Dr. Cunningham left the meeting at 11:12AM and did not return.

Mr. Lanzikos indicated he’s having a hard time understanding the arguments tobacco companies are able to make at the local level, and whether local efforts have been stopped due to tobacco companies.

Ms. Ojamaa responded that the industry says it is not what they are doing, but instead is the actions of youth. Additionally, the industry says they are engaged in responsible retailing. However, we’ve seen advertisements at counter height at the register. There are local boards who do not pursue changes because of letters received from the industry indicating they may sue the board if this issue moves forward.

Dr. Woodward added that the industry will sell it as an anti-small business issue.

Mr. Rivera added that youth would appreciate a change from in program name to 94 to reflect the increase in 84% to 94% in tobacco-free youth.

Commissioner Bharel indicated that the next meeting will be held July 13, 2016, and requested a motion to adjourn.

Mr. Cox made a motion to adjourn; Mr. Rivera seconded the motion. All approved.

The meeting adjourned at 11:17AM.

LIST OF DOCUMENTS PRESENTED TO THE PHC FOR THIS MEETING:

* Minutes of the Public Health Council Meeting May 11, 2016
* Copy of staff memo and recommendation for Norwood Hospital’s request for approval of significant change to project scope and maximum capital expenditure Approved DoN Project No. 4-3C16
* Copy of regulation and presentation discussing proposed regulatory amendments to 105 CMR 700.000: Implementation of M.G.L. c. 94C
* Copy of regulation and presentation discussing proposed regulatory amendments to 105 CMR 721.000: Standards for Prescription Format and Security in Massachusetts
* Copy of regulation and presentation discussing proposed regulatory amendments to 105 CMR 722.000: Dispensing Procedures for Pharmacists
* Copy of proposed amendments to 105 CMR 335.000: Treatment of Persons Exposed to Rabies
* Copy of proposed amendments to 105 CMR 360.000: Tuberculosis Treatment Unit Standards for Admission, Treatment and Discharge
* Copy of proposed amendments to 105 CMR 365.000: Standards for Management of Tuberculosis outside Hospitals
* Copy of informational presentation regarding DPH’s campaign ”Big Tobacco is Sweet Talking Our Kids”

Commissioner Monica Bharel, Chair