

MINUTES OF THE PUBLIC HEALTH COUNCIL

Meeting of March 8, 2017

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

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

Docket: Wednesday, March 8, 2017 - 9:00 AM

1. ROUTINE ITEMS

- a. Introductions
- b. Updates from Commissioner Monica Bharel, MD
- c. Record of the Public Health Council February 8, 2017 Meeting **(Vote)**

2. PRELIMINARY REGULATIONS

- a. Informational briefing on proposed rescission of 105 CMR 515.000: *Action Levels for Poisonous or Deleterious Substances in Food.*

3. FINAL REGULATIONS

- a. Request for final promulgation of proposed amendments to 105 CMR 130.000: *Hospital Licensure. (Vote)*
- b. Request for final approval to rescind 105 CMR 701.000: *Regulations Adopted Jointly by DPH and the Board of Registration in Pharmacy. (Vote)*
- c. Request for final promulgation of proposed amendments to 105 CMR 721.000: *Standards for Prescription Format and Security in Massachusetts. (Vote)*
- d. Request for final promulgation of proposed amendments to 105 CMR 722.000: *Dispensing Procedures for Pharmacists. (Vote)*
- e. Request for final promulgation of proposed amendments to 105 CMR 700.000: *Implementation of M.G.L. c. 94C. (Vote)*

4. EXECUTIVE SESSION

The Public Health Council will meet in Executive Session as authorized by M.G.L. c. 30A, s. 21(a)(3) for the purpose of discussing strategy with respect to litigation, specifically Southcoast Hospital Group, Inc. v. The Massachusetts Department of Public Health, et al

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

Public Health Council

Attendance and Summary of Votes:

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

Date of Meeting: Wednesday, March 8, 2017

Beginning Time: 9:16AM **Ending Time:** 10:26AM

Board Member	Attended	Record of the Public Health Council February 8, 2017 Meeting (Vote)	Request for final promulgation of proposed amendments to 105 CMR 130.000: Hospital Licensure. (Vote)	Request for final approval to rescind 105 CMR 701.000: Regulations Adopted Jointly by DPH and the Board of Registration in Pharmacy. (Vote)	Request for final promulgation of proposed amendments to 105 CMR 721.000: Standards for Prescription Format and Security in Massachusetts. (Vote)	Request for final promulgation of proposed amendments to 105 CMR 722.000: Dispensing Procedures for Pharmacists. (Vote)	Request for final promulgation of proposed amendments to 105 CMR 700.000: Implementation of M.G.L. c. 94C. (Vote)
Monica Bharel	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Edward Bernstein	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Lisette Blondet	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Derek Brindisi	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Harold Cox	Yes	Yes	Yes	Yes	Yes	Yes	Yes
John Cunningham	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Michele David	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Meg Doherty	Yes	Not present at time of vote	Yes	Yes	Yes	Yes	Yes
Michael Kneeland	Yes	Abstain	Yes	Yes	Yes	Yes	Yes
Paul Lanzikos	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Lucilia Prates-Ramos	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Secretary Francisco Ureña	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Alan Woodward	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Summary	10 Members Present, 3 Members Absent	8 Members Approved, 3 members Absent, 1 Not present at time of vote, 1 abstain	10 Members Approved, 3 members Absent	10 Members Approved, 3 Members Absent	10 Members Approved, 3 Members Absent	10 Members Approved, 3 members absent	10 Members Approved, 3 Members absent

PROCEEDINGS

A regular meeting of the Massachusetts Department of Public Health's Public Health Council (M.G.L. c. 17, §§ 1, 3) was held on Wednesday, March 8, 2017 at the Massachusetts Department of Public Health, 250 Washington Street, Henry I. Bowditch Public Health Council Room, 2nd Floor, Boston, Massachusetts 02108.

Members present were: Monica Bharel, MD, MPH; Lissette Blondet; Harold Cox; John Cunningham, PhD; Meg Doherty; Michael Kneeland, MD; Paul Lanzikos; Lucilia Prates-Ramos; and Alan Woodward, MD.

Absent member(s) were: Edward Bernstein, MD; Michele David, MD; and Secretary Francisco Ureña

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

Commissioner Bharel called the meeting to order at 9:16 AM and made opening remarks before reviewing the agenda.

ROUTINE ITEMS

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

Commissioner Bharel began by sharing an update on the Baker Administration's proposed FY2018 Budget. She shared that this proposal maintains strong support for public health with a \$7M budget increase over FY17 spending, including more than \$144 million in funding for substance use disorders treatment and prevention. She then highlighted several key new policy provisions:

In order to continue and expand the Department's innovative Chapter 55 work beyond July 1st, the Governor's budget includes provisions that will allow DPH to perform data linkage studies on a long-term basis on critical public health issues. Providing a statutory framework to continue this work will allow Massachusetts to remain a national leader in precision public health. Additionally, the proposed budget adds three (3) new retained revenue accounts that build on several topics I know we have discussed here.

First, building off of our regulatory reform efforts, the budget proposes a new dedicated retained revenue account to support the Health Care Industry Plan Review and the Determination of Need programs. Successful passage of this funding will allow DPH to expedite our processes and enhance efficiency. By streamlining and aligning the timelines of DoN and facility licensure plan reviews, DPH can truly address longstanding provider concerns regarding a lack of process synchronization and unpredictable timelines. By minimizing delays and synchronizing reviews, this investment will result in significant savings for hospitals, community health centers, clinics, and long-term care facilities, while better supporting the Public Health Council in making critical DoN determinations.

Additionally, the Governor has proposed a dedicated Mobile Integrated Health or “MIH” retained revenue account to collect application fees to support implementation of the nation’s first statewide MIH law. This funding is paired with a targeted investment of \$900K for associated start-up costs. As we have discussed, MIH provides great promise for successfully incentivizing the development of new and innovative care delivery models that support patient needs within the community by utilizing community paramedics for pre- and post-clinical services. The introduction of these investments sends an important message to health care that we are supporting a public health-informed view of system transformation.

Finally, the Governor has also proposed licensure of the state’s home health agencies, bringing Massachusetts in line with most other states. This will be supported by a newly proposed retained revenue account included in the Governor’s budget. As we have dedicated ourselves throughout the regulatory review process, patient safety will continue to be our top priority and we look forward to working with you, patients, and the community alike in ensuring successful implementation.

The Commissioner then shared that the Governor has proposed a \$970K line item increase to support additional inspectors to help fulfill DPH’s responsibility to perform more than 1,000 (600 Hospital, Clinics, Rest homes; and 400 LTC) licensure surveys and respond to more than 14,000 complaints every year. She concluded by stating she would provide additional budget updates as they come.

In February, DPH released preliminary 2016 fourth quarter data for opioid-related deaths among Massachusetts residents. The report showed that death rates involving heroin continued to decline; however, those deaths have decreased at approximately the same rate that fentanyl-related deaths have increased with 75 percent of 2016 deaths indicating a toxicology screen showing a positive result for fentanyl.

The report also showed:

- A 15 percent decrease in 2016 in the number of prescriptions for schedule II & III opioids compared with 2015;
- A 47 percent increase in the total number of EMS incidents involving the overdose rescue drug naloxone in the first three quarters of 2016 compared with the same time period in 2015;
- And in 2015 – the last full year of data reported – that 80 percent of communities in Massachusetts (280 of 351) reported an EMS opioid-related transport, while naloxone was administered more than 12,000 times during EMS opioid-related incidents.

This data release underscored the need for the Commonwealth to continue our daily fight to bring this epidemic to an end.

Just last week, the Administration announced awards totaling \$1.75 million in new funding to residential substance use disorder treatment programs in three communities – Lowell, Salisbury, and Pittsfield.

These contracts will fund 60 long-term residential treatment slots that will serve approximately 240 women each year. Expanding residential treatment in Massachusetts has been a priority for the Administration with increased spending on addiction services by 50 percent (to more than \$180 million), while adding more than 500 substance use treatment beds to the Commonwealth's recovery system in the last two years. It is our hope that these new programs will add to the strong foundation Massachusetts is building to help prevent, treat, and support the recovery of those suffering from addiction.

Also last week, Commissioner Bharel celebrated with BMC President Kate Walsh and the BMC staff, the Governor, Secretary Sudders, and many others, on Boston Medical Center's announcement of a \$25 million gift from Eilene and John Grayken to intensify BMC and our Commonwealth's fight against the current opioid epidemic.

As both the largest gift in BMC's history and the nation's largest aimed towards SUD treatment in the last decade, this unprecedented investment will create the new BMC Grayken Center for Addiction Medicine, focused on research, treatment – including the development of more advanced data analytics and the establishment of new outcome measures – training, and prevention.

Commissioner Bharel then announced that Kick Butts Day is on Wednesday March 15, 2017 (rescheduled for Wednesday April 26, 2017). Kick Butts Day is a national day of activism that empowers youth to stand out and speak up against the tobacco industry in their communities. Over 200 young people, representing over half of the state's 84 Chapters, will be coming to Boston for this event. This is a powerful and energetic day and the Commissioner invited members to join her at the State House to support these inspiring young people who are working to make a change within their communities. Staff will send details to each of you following today's meeting.

Finally, the Commissioner gave updates on awards and accolades.

The U.S. News & World Report named Massachusetts the best overall state in their inaugural report. The best state ranking evaluates all fifty states in various categories, with Massachusetts ranked the #1 overall state, #1 in health care and health care access, #2 in education and among the top ten for economy and crime and corrections. Governor Baker appeared on *CBS This Morning* to discuss the recognition and included in his remarks what the state is doing to address opioids – and specifically called out the Department's work around core competencies and prescriber education.

She also shared that the Association of Immunization Managers (AIM) has selected Pejman Talebian, Director of our Immunization Program, to receive the Natalie J. Smith, MD Award for Excellence in Program Management. Pejman is immediate past chair of AIM and a well-respected national leader among immunization program directors. This award recognizes accomplishments and visionary leadership that have had a significant impact on achieving city, state, and national vaccine-preventable disease goals. Pejman's dedicated leadership has enabled Massachusetts, among many other notable accolades, to reclaim our universal childhood vaccination status and maintain our standing as a national leader in the fight against vaccine-preventable disease.

Commissioner Bharel noted she is very proud of the Department's work in fighting the stigma of substance use disorder. One of the important components of DPH's anti-stigma work is disseminating the message of treating substance use disorder as the medical disease it is and decreasing stigma. To that end she announced that the Department was the recipient of a 2017 Platinum AVA Digital Award for our #statewithoutstigma campaign, given for excellence in digital marketing. This is the latest in several national awards we have received for this important health campaign.

Before proceeding, the Council was asked if they had any questions on the updates. Seeing none, she proceeded with the agenda.

Mr. Lanzikos arrived at 9:25am.

1. ROUTINE ITEMS

c. Record of the Public Health Council February 8, 2017 Meeting (Vote)

Commissioner Bharel asked if any members had any changes to be included in the February 8, 2017 meeting minutes.

Seeing none, the Commissioner asked for a motion to approve the minutes.

Dr. Woodward made a motion to approve, and Ms. Blondet seconded the motion. Dr. Kneeland abstained from the vote as he was not present at the February 8th meeting. All present members approved.

2. PRELIMINARY REGULATIONS

a. Informational briefing on proposed rescission of 105 CMR 515.000: Action Levels for Poisonous or Deleterious Substances in Food.

Ms. Doherty arrives at 9:31am.

Commissioner Bharel invited Mike Moore, Director of the Food Protection Program within the Bureau of Environmental Health and Kay Doyle, Deputy General Counsel for the Department, to the table for an informational presentation on the proposed rescission of 105 CMR 515.000: Action Levels for Poisonous or Deleterious Substances in Food.

Upon the conclusion of Mr. Moore's presentation, Council members were asked if they had any questions or comments.

Dr. Cunningham inquired if there needed to be a new action level in the future, is there a time advantage in adding it on to the current regulation rather than creating a new one.

Ms. Doyle responded that it will take the same route regardless and will not save any time.

Commissioner Bharel then asked if there were any further questions from the group, seeing none she proceeded with the agenda.

3. FINAL REGULATIONS

a. Request for final promulgation of proposed amendments to 105 CMR 130.000: Hospital Licensure. (Vote)

At this time Commissioner Bharel invited Lauren Nelson, Director of Policy and Regulatory Affairs for the Bureau of Health Care Safety and Quality; Sherman Lohnes, Director of Health Care Facility Licensure and Certification within the Bureau; Kate Fillo, Director of Clinical Quality Improvement for the Bureau; and Rebecca Rodman, Deputy General Counsel for the Department, to the table to present proposed amendments to 105 CMR 130.000: Hospital Licensure and request approval of these changes from the Council.

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

Dr. Cunningham asked for an infant on CPAP, if there was an increased risk for the neonatologist to be elsewhere in the hospital rather than the bedside.

Ms. Fillo replied that after conferring with experts they do not believe there is an increased risk. Once the infant is put on CPAP the nurse/respiratory therapist is also at the bedside caring for the infant; this enables the neonatologist to attend to things such as calling report to the receiving hospital where the infant is being transferred. Ms. Fillo noted that they believe it is a better reflection of what some of the neonatologist responsibilities might be in terms of transfer of the infant.

Mr. Lanzikos asked in regards to the community benefits, what constitutes publication and how does the partner know if it has been submitted and published according to the Attorney General's requirements.

Ms. Rodman responded that these are public reports once they've been accepted by the Attorney General. The Department is aware of publication and has the ability to review the plans.

Mr. Lanzikos then asked if the community benefits plans will be added to the Department's website.

Ms. Rodman replied that the community benefits plans that are sent for DoN purposes will be on the website.

Ms. Cooke, general counsel, added that community benefit plans are posted on the Attorney General's website.

Mr. Lanzikos asked about an active notification for publication.

Ms. Rodman replied that the hospital will have to inform us as to whether it has been accepted and published to say that they have met the qualification.

Dr. Woodward asked if there is still a provision for the hospital to supply vaccinations to patients, particularly the elderly.

Ms. Fillo stated that hospitals follow the federal guidelines for influenza vaccinations; the recommendation is that any individual who is 6 months and older receive the vaccination, not just individuals over the age of 65. Vaccinations are tracked at the state level through the MIIS and it is a regulatory requirement that healthcare providers enter information there.

Dr. Woodward replied that he understands the tracking but would like to know if there is a requirement that they offer flu vaccine to inpatients.

Ms. Fillo informed him that the Centers for Medicare and Medicaid Services publicly reports the percentage of patients that are assessed and receive the influenza vaccination on their Hospital Compare website.

Dr. Woodward asked if that since they have to report on it does it indicate they are offering it.

Ms. Fillo replied that is correct. She further added that they have overwhelmingly seen that hospitals provide and offer flu vaccinations for their patients.

Ms. Doherty asked if getting rid of the paper copies of the bylaws implies that the review of that, online etc., now becomes a part of the process internal to DPH.

Mr. Lohnes replied that is something they started a few years back as the Secretary of State's website has it publicly available and it is more efficient to validate it on the website.

With no further questions, the Commissioner asked for a motion to accept the amendments to 105 CMR 130.000.

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

3. FINAL REGULATIONS

b. Request for final approval to rescind 105 CMR 701.000: Regulations Adopted Jointly by DPH and the Board of Registration in Pharmacy. (Vote)

Then Commissioner then asked James Lavery, Director for the Bureau of Health Professions Licensure which houses the Office of Prescription Monitoring and Drug Control, to join Lauren and Rebecca at the table for presentations on four regulations. The first presentation will request the Council's approval to rescind 105 CMR 701.000: Regulations Adopted Jointly by DPH and the Board of Registration in Pharmacy.

Upon the conclusion of Ms. Nelson's presentation the council was asked if they had any questions or comments.

Dr. Woodward asked why did it take so long to bring back rescission that had no public comments.

Ms. Nelson responded that they had planned to bring all 700 regulations at once before the council.

With no further questions, Commissioner Bharel asked for a motion to approve rescission of 105 CMR 701.000

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

3. FINAL REGULATIONS

c. Request for final promulgation of proposed amendments to 105 CMR 721.000: Standards for Prescription Format and Security in Massachusetts. (Vote)

Commissioner Bharel then asked the group to remain at the table to present proposed amendments to 105 CMR 721.000: Standards for Prescription Format and Security in Massachusetts and request approval of these changes from the Council.

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

Dr. Woodward stated that from his knowledge if they give an emergency prescription orally in the middle of the night and there isn't a prescription within 72 hours there is an automatic report to the DEA. He then asked if there was a provision for an emergency prescription, a reminder from the pharmacist to the physician.

Ms. Nelson stated that the pharmacist and the prescribers are in contact frequently on these things so they would rely on their robust communication efforts.

Mr. Lavery stated there is no requirement. If the prescription is called in orally the prescriber must follow up within 72 hours with a written prescription.

Dr. Woodward replied that sometimes physicians may forget during the middle of the night emergency, it might be helpful to have a reminder set to avoid unnecessary reports to the DEA.

Ms. Nelson responded that part is a DEA rule. However, when they do these regulations they provide guidance, in that guidance they can certainly make sure pharmacist follow-up with prescribers.

Ms. Rodman replied that the guidance that Ms. Nelson mentioned is jointly put out by the Pharmacy Board and the Drug Control Program so that they have pieces of it in both places.

Commissioner Bharel stated that she believes Dr. Woodward is asking that it be clarified in the guidance so that is understandable on both ends.

Dr. Kneeland agreed with Dr. Woodward's suggestion.

With no further questions or comments, the Commissioner asked if there was a motion to accept the amendments to 105 CMR 721.000.

Dr. Cunningham made the motion, Ms. Prates Ramos seconded it. All present members approved.

3. FINAL REGULATIONS

d. Request for final promulgation of proposed amendments to 105 CMR 722.000: Dispensing Procedures for Pharmacists. (Vote)

The Commissioner then asked the group to present proposed amendments to 105 CMR 722.000: Dispensing Procedures for Pharmacists, which we propose be renamed Dispensing Procedures for Clinic and Hospital Pharmacies, and request approval of these changes from the Council.

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

Seeing none, Commissioner Bharel asked a motion to accept the amendments to 105 CMR 722.000.

Dr. Woodward made the motion, Ms. Prates Ramos seconded it. All present members approved.

3. FINAL REGULATIONS

e. Request for final promulgation of proposed amendments to 105 CMR 700.000: Implementation of M.G.L. c. 94C. (Vote)

Commissioner Bharel then asked the group to present their final presentation: proposed amendments to 105 CMR 700.000: Implementation of M.G.L. c. 94C, and request approval of these changes from the Council.

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

Seeing none, the Commissioner asked for a motion to accept the amendments to 105 CMR 700.000.

Mr. Lanzikos made the motion, Dr. Cunningham seconded it. All present members approved.

4. EXECUTIVE SESSION

The Public Health Council will meet in Executive Session as authorized by M.G.L. c. 30A, s. 21(a)(3) for the purpose of discussing strategy with respect to litigation, specifically Southcoast Hospital Group, Inc. v. The Massachusetts Department of Public Health, et al.

Commissioner Bharel requested a motion from Council members to enter Executive Session.

Dr. Woodward so moved, seconded by Ms. Blondet. Commissioner Bharel then completed a roll call of Council members.

Commissioner Bharel indicated that the next meeting will be held April 12th, and indicated the meeting will be adjourned upon conclusion of the Executive Session.

The meeting adjourned at 10:26AM.
