

MINUTES OF THE PUBLIC HEALTH COUNCIL

Meeting of October 21, 2015

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, October 21, 2015 9:00 AM

1. ROUTINE ITEMS:

- a. Introductions
- b. Updates from Commissioner Monica Bharel, MD
- c. Record of the Public Health Council Meeting September 16, 2015 **(Vote)**

2. DETERMINATION OF NEED (DoN)

- a. West Suburban Eye, LLC has filed a DoN for relocation and renovation of a licensed Freestanding Ambulatory Surgery Center ("FASC") . No. 3-4957 **(Vote)**

- b. Southshore Hospital, Inc, has filed a DoN for new construction of a Critical Care Unit. No. 4-3C42 **(Vote)**

3. PRELIMINARY REGULATION

- a. Informational briefing on 105 CMR 144.000 – *Licensure of Pine Street Inn Nurses Clinic*
- b. Informational briefing on 105 CMR 310.000 – *Transportation and Funerals of Persons Dead of Diseases Dangerous to Public Health*
- c. Informational briefing on 105 CMR 370.000 – *Prophylactic Remedy for Use in the Eyes of Infants*
- d. Informational briefing on 105 CMR 730.000 – *The Distribution of Biologic Products*
- e. Informational briefing on 105 CMR 731.000 – *The Sale of Surplus Biologic Products*
- f. Informational briefing on 105 CMR 921.000 – *Assuring Visitation at the Department of Public Health Hospitals for Patients Having a Relationship of Mutual Support*

4. FINAL REGULATIONS

- a. Request for Approval to Promulgate Final Regulations on Proposed Amendments to 105 CMR 700.000: *Controlled Substances Act* related to use of the Prescription Monitoring Program **(Vote)**

- b. Proposed Emergency Amendments to 105 CMR 164.000, *Licensure of Substance Abuse Treatment Programs* **(Vote)**

5. 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

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

Date of Meeting: Wednesday, October 21, 2015

Beginning Time: 9:13AM

Ending Time: 11:18AM

Attendance and Summary of Votes:

| Board Member | Attended | Item 1c Minutes of the September 16, 2015 Meeting | Item 2a Determination of Need No. 3- 4957 West Suburban Eye, LLC | Item 2b Determination of Need No. 4- 3C42 South Shore Hospital, Inc | Item 4a Request for Approval to Promulgate Final Regulations on Proposed Amendments to 105 CMR 700.000: <i>Controlled Substances Act</i> related to use of the Prescription Monitoring Program | Item 4b Proposed Emergency Amendments to 105 CMR 164.000, <i>Licensure of Substance Abuse Treatment Programs</i> | Roll Call Prior to Entering Executive Session |
|---------------------|------------------------|--|---|--|---|---|--|
| Monica Bharel | Yes | Yes | Yes | Yes | Yes | Yes | Present |
| Edward Bernstein | Yes | Yes | Yes | Yes | Yes | Yes | Present |
| Derek Brindisi | Yes | Abstained | Yes | Yes | Yes | Yes | Present |
| Harold Cox | Yes | Yes | Yes | Yes | Yes | Yes | Present |
| John Cunningham | Yes | Yes | Yes | Yes | Yes | Yes | Present |
| Michele David | Yes | Yes | Yes | Yes | Yes | Yes | Present |
| Meg Doherty | Yes; Arrived at 9:46AM | Absent at Time of Vote | Absent at Time of Vote | Absent at Time of Vote | Yes | Yes | Present |

| Board Member | Attended | Item 1c Minutes of the September 16, 2015 Meeting | Item 2a Determination of Need No. 3- 4957 West Suburban Eye, LLC | Item 2b Determination of Need No. 4- 3C42 South Shore Hospital, Inc | Item 4a Request for Approval to Promulgate Final Regulations on Proposed Amendments to 105 CMR 700.000: <i>Controlled Substances Act</i> related to use of the Prescription Monitoring Program | Item 4b Proposed Emergency Amendments to 105 CMR 164.000, <i>Licensure of Substance Abuse Treatment Programs</i> | Roll Call Prior to Entering Executive Session |
|----------------------|-----------------------------------|--|---|--|---|---|--|
| Michael Kneeland | Yes | Yes | Yes | Recusal | Yes | Yes | Present |
| Paul Lanzikos | Yes | Yes | Yes | Yes | Yes | Yes | Present |
| Denis Leary | Yes | Yes | Yes | Yes | Yes | Yes | Present |
| Lucilia Prates-Ramos | Yes | Abstained | Yes | Yes | Yes | Yes | Present |
| Jose Rafael Rivera | Yes | Yes | Yes | Yes | Yes | Yes | Present |
| Meredith Rosenthal | Absent | Absent | Absent | Absent | Absent | Absent | Absent |
| Alan Woodward | Yes | Yes | Yes | Yes | Yes | Yes | Present |
| Michael Wong | Absent | Absent | Absent | Absent | Absent | Absent | Absent |
| Summary | 13 members present | 10 members approved; 2 members abstained | 12 members approved | 11 members approved | 12 members approved | 12 members approved | 13 members present |

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 October 21, 2015 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: Department of Public Health Commissioner Monica Bharel (chair); Edward Bernstein, MD; Derek Brindisi; Harold Cox; John Cunningham PhD; Michele David, MD; Meg Doherty; Michael Kneeland, MD; Paul Lanzikos; Denis Leary; Lucilia Prates-Ramos; Jose Rafael Rivera; and Alan Woodward, MD.

Absent member(s) were: Meredith Rosenthal, PhD; and Dr. Michael Wong, MD.

Also in attendance were Margret Cooke, General Counsel at the Massachusetts Department of Public Health and Jennifer Barrelle, Interim Deputy Chief of Staff for Policy and Regulatory Affairs at the Massachusetts Department of Public Health.

Commissioner Bharel called the meeting to order at 9:13AM and made opening remarks before reviewing the agenda. The Commissioner's remarks included the following items:

ROUTINE ITEMS

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

Commissioner Bharel gave several updates to Council members, including:

- The US Surgeon General's launching of the Step it Up campaign, a call to action on walking and walkable communities, and how the Mass in Motion initiative has been working with local communities and organizations on this issue. The Commissioner noted that the City of New Bedford was recently recognized by the White House for reaching five key health and wellness goals as part of a nationwide initiative to encourage movement and wellness.
- DPH held its first quarterly local board of health call, with over 100 municipalities participating. This call was an opportunity to update communities on DPH initiatives and also hear concerns from municipalities.
- As part of National Recovery Month in September, DPH held a DPH Celebrates Recovery event and participated with MOAR in Recovery Day at the State House. The Commissioner noted that October is National Substance Abuse Prevention Month.
- Commissioner Bharel provided an overview of testimony she provided at a Joint Hearing of the Committees on Elder Affairs, Mental Health, and Substance Abuse, including that 59% of Massachusetts residents over age 65 have four or more chronic diseases, 29% have been diagnosed with depression, and over 40% of those over age 55 admitted for substance abuse

treatment report prior mental health treatment. The Commissioner noted that DPH will continue work on this critical issue with the Executive Office of Elder Affairs.

Minutes

Commissioner Bharel asked if any members had any changes to be included in the September 16, 2015 meeting minutes. Hearing no request for changes, Commissioner Bharel requested a motion to accept the minutes.

Mr. Rivera made a motion to approve, and Dr. Bernstein seconded the motion. All approved, except Ms. Prates-Ramos and Mr. Brindisi who abstained as they were not present for the September meeting.

DETERMINATION OF NEED (DoN)

a. West Suburban Eye, LLC has filed a DoN for relocation and renovation of a licensed Freestanding Ambulatory Surgery Center ("FASC") . No. 3-4957 (Vote)

Commissioner Bharel invited Michael Sinacola, Interim Deputy Bureau Director for the Bureau of Health Care Safety and Quality, to present on the Determination of Need application filed by West Suburban Eye, LLC for relocation and renovation of a licensed freestanding ambulatory surgical center.

Upon conclusion of the presentation, Commissioner Bharel asked if members had any questions for Mr. Sinacola.

Mr. Lanzikos noted that the site is being relocated from an urban to a suburban location, and wanted to get a sense of the adequacy of transportation for patients who may not have their own vehicle.

Mr. Sinacola said this would be better answered by the applicant.

Mr. Rivera noted that generally there are conditions around Culturally and Linguistically Appropriate Services (CLAS) standards but that the conditions for this application seemed to refer only to language standards. He asked why CLAS standards were not referenced for this project.

Mr. Samuel Louis, the Coordinator for Health Care Institution Language Access Services for DPH's Office of Health Equity, joined the table to respond to Mr. Rivera's question. He noted that as part of the agreement with the applicant, CLAS is part of the language access condition and that the Office will ensure fully implemented as specified in the condition.

Seeing no further questions for Mr. Sinacola, Commissioner Bharel invited the applicant's representative, Dr. Andrew Gillies, to the table to make remarks and respond to member questions.

Dr. Gillies from West Suburban Eye, LLC, responded to Mr. Lanziko's question regarding transportation by referring to the applicant's current transportation model at its Waltham site and stated they anticipate this service being offered at the new site.

Mr. Lanzikos asked if that service was in place now.

Dr. Gillies affirmed the service is in place, as this new site will be under the same ownership umbrella.

Dr. Gillies noted that the applicant was very excited with the opportunity to serve residents of the Commonwealth with low cost, high quality service.

Seeing no further questions, Commissioner Bharel asked for a motion to accept the staff recommendation for approval of the Determination of Need for West Suburban Eye, LLC. Mr. Rivera made a motion to approve, Dr. Woodward seconded the motion. All approved.

b. Southshore Hospital, Inc, has filed a DoN for new construction of a Critical Care Unit. No. 4-3C42 (Vote)

Commissioner Bharel invited Michael Sinacola back to the table to present on the Determination of Need application filed by South Shore Hospital, Inc., new construction of a Critical Care Unit.

Dr. Kneeland recused himself, and left the room at 9:33AM.

Mr. Sinacola presented. Upon conclusion of the presentation, Commissioner Bharel asked the members if they had any questions for Mr. Sinacola.

Dr. Woodward noted that the applicant is delicensing 8 of its 24 ICU beds, while the summary notes that there is projected growth in the area. Dr. Woodward wanted to know whether there would be space in the new addition for additional licensed capacity, if necessary, moving forward.

Dr. Bernstein noted that the numbers on page two of the staff summary do not add up, specifically total old versus proposed new bed count, and wanted clarification on the numbers.

Mr. Sinacola referred these questions to the applicant.

Seeing no further questions for Mr. Sinacola, Commissioner Bharel invited the applicant's representative, Mr. Joseph Cahill, President and COO of South Shore Hospital, to the table to make remarks and respond to member questions.

In response to Dr. Woodward's question, Mr. Cahill noted South Shore Hospital is currently licensed for 32 critical care beds, and is in the process of delicensing eight of 32 beds through another project. He noted that these eight beds being delicensed have been out of service for a number of years. Mr. Cahill went on to say that the ICU beds will not need to be expanded, as this project creates intermediate care beds to better care for patients and will account for projected patient need.

Dr. Woodward asked if the shell space could be used for additional ICU capacity moving forward, if needed.

Mr. Cahill responded that yes, that space could be converted to more critical care space if necessary moving forward.

In response to Dr. Bernstein's question, Mr. Cahill noted that through this project South Shore Hospital's Messina and Pratt buildings will be connected. In building this connector, one medical/surgical bed will be lost when building this connector, meaning 24 medical/surgical beds will be added to the Messina Building.

Dr. Bernstein noted that moving into the future as we work to keep patients out of the hospital, their inpatient care needs will become more acute and more intensive care will be required.

Mr. Cahill noted that the proposed intermediate care beds will allow for that type of care and that the Hospital worked hard with their team and surgeons in determining the most appropriate approach.

Seeing no further questions, Commissioner Bharel asked for a motion to accept the staff recommendation for approval of the Determination of Need for South Shore Hospital, Inc. Dr. David made a motion to approve, Mr. Lanzikos seconded the motion. All members present approved.

Commissioner Bharel noted for the record that Meg Doherty joined the meeting at 9:46AM

Upon conclusion of the vote, Dr. Kneeland rejoined the meeting at 9:47AM.

PRELIMINARY REGULATION

a. Informational briefing on 105 CMR 144.000 – *Licensure of Pine Street Inn Nurses Clinic*

Commissioner Bharel invited Lauren Nelson, Director of Policy and Quality Improvement for the Bureau of Health Care Safety and Quality, to the table for an informational briefing on the proposed rescission of 105 CMR 144.000. Ms. Nelson joined by Sherman Lohnes, Director of the Division of Health Care Facility Licensure and Certification within the Bureau of Health Care Safety and Quality.

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

Mr. Lanzikos asked if the underlying statute is still on the books.

Ms. Nelson noted it is on the books, and is for a pilot program.

Mr. Lanzikos further asked if having the statute on the books would be confusing or create a conflict, and if it should be repealed.

Ms. Nelson responded that repeal of the statute is one option; however the statute does not mandate the Department to have regulations for this purpose.

Ms. Doherty noted that initially this was about supervision of registered nurses who initially were providing care as volunteers, and asked if that is still the case and, if so, if those nurses bill for services.

Mr. Lohnes noted that review of the Pine Street Inn's website indicated the Inn is primarily concerned with housing while clinical care is provided by Boston Healthcare for the Homeless, which is licensed as a clinic by DPH and follows all requirements.

Ms. Doherty confirmed that since the statute and regulation went into effect, the nature of the clinic has changed and this regulation is no longer necessary.

Mr. Lohnes affirmed this, and again noted the Pine Street Inn's housing focus.

Seeing no further questions, the Commissioner thanked Ms. Nelson and Mr. Lohnes for their presentation.

b. Informational briefing on 105 CMR 310.000 – *Transportation and Funerals of Persons Dead of Diseases Dangerous to Public Health*

Commissioner Bharel invited Kevin Cranston, Director of the Bureau of Infectious Disease, to present an informational briefing on the proposed rescission of 105 CMR 310.000.

Upon conclusion of the presentation, Commissioner Bharel asked Council members if they had any questions for Mr. Cranston.

Dr. Bernstein asked how Ebola transmission via cadavers would be affected by rescinding this regulation.

Mr. Cranston noted that modern funereal practices and infectious disease clinical guidance issued by the Centers for Disease Control and the World Health Organization inform safe procedures when dealing with those dead from Ebola.

Dr. Woodward read some outdated procedures within the regulation, including enforcement of cadaver envelopment by a sheet, to reinforce the case for rescission.

Seeing no further questions, Mr. Cranston moved to the next presentation.

c. Informational briefing on 105 CMR 370.000 – *Prophylactic Remedy for Use in the Eyes of Infants*

Commissioner Bharel invited Kevin Cranston to present an informational briefing on the proposed rescission of 105 CMR 370.000.

Upon conclusion of the presentation, Commissioner Bharel asked Council members if they had any questions for Mr. Cranston.

Seeing no questions, Mr. Cranston moved to the next presentation.

d. Informational briefing on 105 CMR 730.000 – *The Distribution of Biologic Products* and 105 CMR 731.000 – *The Sale of Surplus Biologic Products*

Commissioner Bharel invited Kevin Cranston to present an informational briefing on the proposed rescission of 105 CMR 730.000 and 731.000.

Upon conclusion of the presentation, Commissioner Bharel asked Council members if they had any questions for Mr. Cranston.

Seeing no questions, the Commissioner thanked Mr. Cranston for his presentations.

e. Informational briefing on 105 CMR 921.000 – *Assuring Visitation at the Department of Public Health Hospitals for Patients Having a Relationship of Mutual Support*

Commissioner Bharel invited Sandra Akers, President of the Governing Body for Public Health Hospitals, to the table for an informational briefing on the proposed rescission of 105 CMR 921.000.

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

Mr. Rivera asked if federal hospitals fall under the same regulation.

Ms. Akers noted that while DPH does not oversee federal hospitals, those hospitals would also be required to follow the same CMS visitation standards.

Seeing no further questions, Commissioner Bharel thanked Ms. Akers for her presentation.

FINAL REGULATIONS

a. Request for Approval to Promulgate Final Regulations on Proposed Amendments to 105 CMR 700.000: *Controlled Substances Act* related to use of the Prescription Monitoring Program (Vote)

The Commissioner invited Lauren Nelson to return to the table to request approval to promulgate final regulations on proposed amendments to 105 CMR 700.000: *Controlled Substances Act*, related to use of the Prescription Monitoring Program (PMP). She was joined by Jonathan Mundy, who will be providing a PMP data update to Council members, as requested at the August Public Health Council meeting.

Upon conclusion of Ms. Nelson's and Mr. Mundy's presentations, Commissioner Bharel asked if the Council members had any questions about the proposed regulation.

Dr. Cunningham asked for an explanation of what is happening regarding total prescriptions out of state.

Mr. Mundy noted that there are a number of out of state prescriptions reported to the PMP, including mail order patients going out of state, and that there are nuances to the data that do not allow for an apples to apples comparison.

Ms. Doherty asked if all out of state prescriptions are prescribed by a Massachusetts prescriber.

Mr. Mundy responded that could be the case, or it could be through a mail order pharmacy sending a medication into Massachusetts.

Ms. Doherty suggested it may be helpful to take a look, by county, at the number of hospice agencies and the physicians responsible to those agencies for writing those prescriptions and whether that accounts for a bump in the total prescriptions for a county.

Mr. Mundy responded that when pulling the county by count data together, those prescriptions are excluded from the total.

Dr. Bernstein asked if the PMP tracks e-prescribing.

Mr. Mundy responded that PMP data does reflect e-prescriptions for Massachusetts patients receiving a prescription in state.

Dr. Woodward suggested looking at solid quantity or number of prescriptions per person or prescribed by zip code may be helpful.

Mr. Mundy noted that today's data presentation is a macro-level look at the data. He said that part of the PMP is the Medical Review Group and indicated that concerns are brought before the Group, who reviews data to see if there is a prescriber of concern and, if so, forwards the issue to the appropriate professional board.

Dr. Woodward asked if we were confident the boards are following up on concerns.

Mr. Mundy said that while he does not know the disposition of the cases, he does know that the boards request information from the PMP when reviewing a case

Commissioner Bharel asked if Mr. Mundy could speak to PMP email alerts regarding patients.

Mr. Mundy responded that when a patient falls into a prescribing history category of concern, prescribers who have had an encounter with that patient are sent alerts regarding this concern. He noted that once the alert is sent, a follow up survey is conducted and the program receives good feedback.

Dr. Bernstein asked why the solid quantity for methadone stands out.

Mr. Mundy said that methadone prescriptions are interesting, in that the drug is available in five to 10 milligram tablets while the patient receives very high doses; because it is a small milligram strength, the dose and prescribed quantity are high.

Dr. Bernstein additionally asked how differences between specialists, based on the nature of practice, are accounted for.

Mr. Mundy noted that the PMP does track physician specialty, and is able to review prescribing by those specialist categories.

Mr. Rivera asked if there are conversations are happening around the availability of Narcan in certain counties is commensurate to the number of prescriptions per county, and noted that this would be something helpful to compare.

Mr. Mundy offered to follow up on this, and indicated that he is aware programs are active at the local level to ensure there is access to Narcan and that the Drug Control Program ensures these groups have all requirements in place, and has been actively doing so over the past 12 months.

Mr. Lanzikos asked if the PMP data can be aggregated by health system or provider group.

Mr. Mundy said right now this is not a possibility, but that the program would welcome the ability to group data in that way.

Commissioner Bharel clarified that at this time the system does not collect information on practice site.

Dr. David asked for an update on progress around integration of the PMP system within electronic health records.

Mr. Mundy noted that this is moving forward.

Commissioner Bharel added that there are two ongoing pilots working to evaluate this and while there is not an update at this time, Department staff can work to bring an update. Additionally, the Commissioner noted that the new PMP system is under procurement, and that this is a priority of that process.

Mr. Lanzikos noted that that there were no comments on the regulation, and whether or not that was due to smaller pharmacies not being aware of the comment period.

Ms. Nelson indicated that the BHCSQ did extensive outreach to pharmacies and that the majority submit their information within the next business day or within a similar timeframe. She also stated that BHCSQ has been reaching out to pharmacies not currently submitting information in this way, and these pharmacies understand this is on the horizon.

Dr. Woodward asked about current compliance with this reporting, and whether there pharmacies currently out of compliance with the seven day reporting period.

Ms. Nelson responded that there are some pharmacies that do not currently submit data every 24 hours, but there are no outliers for the current seven to 10 day reporting requirement.

Mr. Rivera asked if gender data is captured based on observation or on how the patient identifies.

Mr. Mundy affirmed that this information is collected based on patient identification.

Dr. Bernstein indicated that instituting reporting and programs like this may bring more attention to the data and certain trends.

Ms. Nelson noted that PMP is one tool being used to address the opioid epidemic, and does not indicate causation through the data presented, as any changes can be due to multiple factors.

Commissioner Bharel thanked Ms. Nelson and Mr. Mundy for their presentations, and asked members for a motion to approve amendments to 105 CMR 700.000.

Dr. Bernstein made a motion to approve, Mr. Rivera seconded the motion. All approved.

b. Proposed Emergency Amendments to 105 CMR 164.000, *Licensure of Substance Abuse Treatment Programs* (Vote)

Commissioner Bharel invited Erica Piedade, Director of Quality Assurance and Licensing for the Bureau of Substance Abuse Services, to present on proposed emergency amendments to 105 CMR 164.000. Ms. Piedade was joined by Alison Mehlman, Deputy General Counsel for the Department.

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

Mr. Rivera asked if Section 35 requires a Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnosis.

Ms. Piedade responded that the law states that someone who is considered a danger to self or others can be civilly committed. The commitment process requires the person or individual to appear before a court where the individual will be assessed by a forensic clinician completes the assessment and generally a DSM-5 is used for the summary diagnosis.

Mr. Rivera said the reason he asked was because the statute includes the term alcoholism, and asked how that is determined versus alcohol abuse.

Ms. Piedade responded that the Section 35 law is an old law, and at the time it was passed the term was alcoholism.

Mr. Rivera suggested this language should be revisited.

Ms. Piedade responded that it is an old law, but through this process DPH is trying to ensure that those who are civilly committed are afforded adequate diagnosis and adequate treatment.

Mr. Leary asked for a summary of the process to be committed under Section 35.

Ms. Piedade noted that while her role is regulatory, her understanding of the process is that a family member or clinician or someone concerned with someone's ability to be safe and not harm him or herself can petition the court for that person to be civilly committed. At that time, the person is assessed by a forensic clinician, and the diagnosis is presented to a judge who makes the final decision.

Mr. Leary suggested opportunities to streamline this process with the justice system could be examined, as he imagines a warrant of some sort has to be issued which may be very hard for families to consider.

Ms. Piedade responded that the Governor's administration is looking for ways to streamline across different state agencies that could help in that process.

Commissioner Bharel noted that part of the Governor's recommendations is looking across agencies within the administration to try and bring the pieces together. She also stated that Section 35 is one way to enter the system now, and that most entries are voluntary.

Dr. Bernstein noted that he would like to see some clinical assessment of the patient prior to this commitment, instead of a subjective assessment. He also noted that through his experience with the process a warrant was required. He stated that for hospitals to be involved in this there has to be a more clear-cut way of doing this. Dr. Bernstein stated that he does think there are times where involuntary commitment is warranted, but he cautioned that we must make sure there is no bias or disparity when implementing this as well as adequate treatment, standards of care, and follow up post-discharge.

Commissioner Bharel thanked Dr. Bernstein for his input and welcomed his expertise on this moving forward.

Dr. Woodward asked if the data on the number of civil commitments could be broken down by the substance being misused to show commitments due to alcoholism versus other substance misuse.

Ms. Piedade said that she believes the data is available, and that the Department will follow up. She stated that for individuals in substance abuse treatment overall that over 50% have a primary or secondary diagnosis of opioid use disorder and would imagine it may break down similarly for civil commitments.

Mr. Lanzikos asked what the likelihood is that the death data adequately captures the actual number of deaths. He noted that, anecdotally, there is an increase in young people dying unexpectedly and he suspects this could be due to drug use and wanted to know if these cases are collected appropriately.

Ms. Piedade said that while this is not her area of expertise, it is her understanding that DPH has been working to get real time, accurate data from across the state.

Commissioner Bharel noted that until quarterly reporting began in February, this data was reported with a two year delay. She stated we are able to report on a quarterly basis through work with the medical examiner's office. DPH is now receiving more timely data and more validation. DPH has been able to work with the hospital and provider community engaged in regular reporting and highlighting individuals with risk of dying.

Mr. Lanzikos said that he's seeing an increase in the number of death notices including the cause of death as drug related.

Commissioner Bharel said that, while anecdotal, it is an important note as we work to combat stigma and an opportunity to educate.

Mr. Lanzikos asked what would happen once this amendment is passed, and if there are any anticipated responses from civil liberty groups.

Ms. Piedade noted that this amendment would not require someone to do anything, but rather removes a prohibition and provides the option and tool to substance abuse treatment programs while also ensuring adequate treatment is provided.

Ms. Mehlman noted that the statute already allows for this commitment, so there is no change in civil liberties.

Commissioner Bharel noted that the intent of this amendment is to provide capacity so women can be moved from MCI Framingham and establish capacity within the treatment system to provide adequate treatment.

Mr. Lanzikos stated that is an important distinction and important to include when discussing this, in order to affirm that this is not designed to curtail civil liberties.

Ms. Doherty noted that the PMP data presentation showed a decrease in opioid prescriptions while we have seen a rise in opioid deaths, and that the cost of these medications versus heroin and heroin use in the state should be looked at and taken seriously.

Dr. Bernstein requested that we look at capacity and affirm that no capacity will be removed from the system. He stated that not all people need commitment so all options need to be available, and treatment should be provided with the least restrictive means because people can come out of these programs at more risk for overdose or suicide. Dr. Bernstein said this vote will require explaining to the public, and added that while the Council should support this that this is not the answer but the extreme.

Ms. Piedade thanked Dr. Bernstein for his comment and noted that the Governor and Commissioner are looking at this as one tool in the tool box addressing the opioid epidemic as well as substance abuse. She also included that this would give BSAS the tools to ensure that civil liberties are not being violated because at this point in time if someone goes into the penal system the focus is on criminality and not on treatment. She concluded by saying that this approach would allow individuals to be provided treatment services in a substance abuse treatment program and allow clinicians to assess when someone is ready to return to the community and provide appropriate supports to do so This amendment provides another tool to address substance use disorder.

Dr. Bernstein thanked Ms. Piedade for her comments.

Commissioner Bharel requested a motion for final promulgation of the proposed emergency amendments to 105 CMR 164.000. Mr. Leary made a motion to approve, seconded by Ms. Doherty. All approved.

Commissioner Bharel noted that the Council will now 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.

Dr. Cunningham made a motion to enter Executive Session, seconded by Dr. David.

Following the motion, a roll call of all members was conducted, and the Council moved into Executive Session at 11:05AM.

5. 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

Dr. Cunningham left the meeting at 11:08AM and did not return.

Mr. Cox left the meeting at 11:09AM and did not return.

Mr. Brindisi left the meeting at 11:14 and did not return.

At the conclusion of the Executive Session, the Council meeting adjourned at 11:18AM.

LIST OF DOCUMENTS PRESENTED TO THE PHC FOR THIS MEETING:

1. Docket for the meeting
2. Minutes of the Public Health Council meeting held September 16, 2015
3. Determination of Need (DoN) Pending Projects

4. DoN Staff Summary for DoN Project No. 3-4957
5. DoN Staff Summary for DoN Project No. 4-3C42
6. Copy of the existing regulation, Council memo, and PowerPoint presentation for the informational briefing on 105 CMR 144.000 – *Licensure of Pine Street Inn Nurses Clinic*
7. Copy of the PowerPoint presentation for the informational briefing on 105 CMR 310.000 – *Transportation and Funerals of Persons Dead of Diseases Dangerous to Public Health*
8. Copy of the existing regulation, Council memo, and PowerPoint presentation for the informational briefing on 105 CMR 370.000 – *Prophylactic Remedy for Use in the Eyes of Infants*
9. Copy of existing regulation, Council memo, and PowerPoint presentation for the informational briefing on 105 CMR 730.000 – *The Distribution of Biologic Products*
10. Copy of the existing regulation, Council memo, and PowerPoint presentation for the informational briefing on 105 CMR 731.000 – *The Sale of Surplus Biologic Products*
11. Copy of the existing regulation, Council memo, and PowerPoint presentation for the informational briefing on 105 CMR 921.000 – *Assuring Visitation at the Department of Public Health Hospitals for Patients Having a Relationship of Mutual Support*
12. Copy of the proposed regulation, Council memo, and PowerPoint presentation for request for approval to promulgate final regulations on proposed amendments to 105 CMR 700.000: *Controlled Substances Act* related to use of the Prescription Monitoring Program
13. Copy of the proposed regulation, Council memo, and PowerPoint presentation for proposed emergency amendments to 105 CMR 164.000, *Licensure of Substance Abuse Treatment Programs*

Commissioner Monica Bharel, Chair