

MINUTES OF THE PUBLIC HEALTH COUNCIL

Meeting of May 11, 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, May 11, 2016 9:30 AM

1. ROUTINE ITEMS:

- a. Introductions
- b. Updates from Commissioner Monica Bharel, MD
- c. Record of the Public Health Council Meeting April 13, 2016 **(Vote)**

2. DETERMINATION OF NEED

- a. Shields Imaging, LLC (“Shields or Applicant) has filed a Determination of Need (“DoN”) for a mobile Positron Emission Tomography-Computed Tomography (“PET-CT”) service one day per week at Anna Jaques Hospital, LLC (#3- 4961) **(Vote)**
- b. Shields Imaging, LLC (“Shields or Applicant) has filed a Determination of Need (“DoN”) for a mobile Positron Emission Tomography-Computed Tomography (“PET-CT”) service one day per week at at Cooley Dickinson Hospital, LLC (#1- 4962) **(Vote)**
- c. Lawrence General Hospital, has filed a significant change to approved DoN Project No. 3-3C36 for renovation of shell space **(Vote)**

3. PRELIMINARY REGULATIONS

- a. Informational briefing on proposed regulatory amendments to 105 CMR 155.000 – Patient and Resident Abuse Prevention, Reporting, Investigation, Penalties and Registry, which sets forth standards for the prevention, reporting and investigation of patient and resident abuse, neglect, and mistreatment, and the misappropriation of property by individuals working in or employed by a facility, home health agency, homemaker agency or hospice program, and for sanctions and penalties
- b. Informational briefing on proposed rescission of 105 CMR 701: Regulations Adopted Jointly by the Department of Public Health and the Board of Registration in Pharmacy for the Implementation of [M.G.L. c.94C](#)
- c. Informational briefing on proposed regulatory amendments to 105 CMR 302: Congenital anomalies registry

5. PRESENTATIONS

a. Zika Update

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, May 11, 2016

Beginning Time: 9:36AM

Ending Time: 11:03AM

Attendance and Summary of Votes:

Board Member	Attended	Item 1c Minutes of the April 13, 2016 Meeting	Item 2a Determination of Need #3- 4961	Item 2b Determination of Need #1- 4962	Item 2c Amendment to Determination of Need #3-3C36
Monica Bharel	Yes	Approved	Approved	Approved	Approved
Edward Bernstein	Yes	Approved	Approved	Approved	Approved
Derek Brindisi	Absent	Absent	Absent	Absent	Absent
Harold Cox	Absent	Absent	Absent	Absent	Absent
John Cunningham	Yes	Approved	Approved	Approved	Approved
Michele David	Yes; Arrived at 9:38AM	Approved	Approved	Approved	Approved
Meg Doherty	Absent	Absent	Absent	Absent	Absent
Michael Kneeland	Yes	Approved	Approved	Approved	Approved
Paul Lanzikos	Yes	Approved	Approved	Approved	Approved
Denis Leary	Absent	Absent	Absent	Absent	Absent
Lucilia Prates-Ramos	Yes	Approved	Approved	Approved	Approved
Jose Rafael Rivera	Yes	Approved	Approved	Approved	Approved
Meredith Rosenthal	Yes	Approved	Approved	Approved	Approved
Alan Woodward	Absent	Absent	Absent	Absent	Absent
Michael Wong	Absent	Absent	Absent	Absent	Absent
Summary	9 Attended, 6 Absent	9 Approved, 6 Absent	9 Approved, 6 Absent	9 Approved, 6 Absent	9 Approved, 6 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, May 11, 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; John Cunningham, PhD; Michele David, MD; Michael Kneeland, MD; Paul Lanzikos; Lucilia Prates-Ramos; Jose Rafael Rivera; Meredith Rosenthal, PhD.

Absent member(s) were: Derek Brindisi; Harold Cox; meg Doherty; Denis Leary; Alan Woodward, MD; 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 9:36AM and made opening remarks before reviewing the agenda.

ROUTINE ITEMS

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

Dr. David joined the meeting at 9:38AM.

To open the meeting, Commissioner Bharel noted regulations to be heard were reordered, as follows: 105 CMR 155.000, 105 CMR 700.000, and 105 CMR 302.000. Next, she gave several updates to Council members.

The Commissioner indicated the Department was recognized in April by the Statewide Advisory Council for the Massachusetts Commissioner for Deaf and Hard of Hearing as Outstanding Organization of the Year for its work to ensure communication access for substance abuse; support for medical training for interpreters, consumers, and medical professionals; access to public meetings; and events and supporting development of a DVD in American Sign Language for SBIRT training.

Commissioner Bharel then gave a brief presentation of recently released data showing rates of unintentional/undetermined opioid-related deaths, broken down by age, gender, and race; the quantity of opioid prescriptions annually by county; and provided an update of the Baker Administration's efforts to combat the opioid epidemic.

Dr. Bernstein asked what the data showed for the first quarter of this year.

Commissioner Bharel noted that for the first time ever DPH was able to report information through March of 2016 and is available on the Department's website. She noted that because there are still a lot of open cases, many of those represent the predictive numbers but January, February, and March of 2016 look similar to that time period in 2015.

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

1. ROUTINE ITEMS

c. Minutes

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

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

2. DETERMINATION OF NEED

a. Shields Imaging, LLC (“Shields or Applicant) has filed a Determination of Need (“DoN”) for a mobile Positron Emission Tomography-Computed Tomography (“PET-CT”) service one day per week at Anna Jaques Hospital, LLC (#3- 4961) (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 #3-4961, and invited the following representatives of the applicant to the table:

Tom Shields, Jr. – President of Shields

Mark Goldstein – President and CEO of Anna Jacques Hospital

Kevin Kilday – Vice President and CFO of Anna Jacques 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 representatives.

Ms. Prates-Ramos asked about the community assessment completed for the Community Health Initiative funds.

Mr. Sinacola responded that it is a work in progress and several options for use of the funds are on the table.

Dr. Bernstein asked for a description of the oncology services being provided by Anna Jacques Hospital.

Mr. Goldstein indicated Anna Jacques Hospital is a community hospital and has a clinical affiliation with Beth Israel Deaconess Medical Center. He added that the cancer center at Anna Jacques is also affiliated with Beth Israel, and offers infusion and full service radiation therapy in partnership with a third party.

Dr. Bernstein noted that this project would allow patients to stay in the community for these services versus traveling long distances.

Mr. Goldstein responded that is correct, and that the project will allow for better integration.

Mr. Lanzikos asked if there were any changes in the implementation of the project if it would come back before the Council.

Mr. Sinacola responded that, depending on the nature of the change, there would be potential for the project to come back to the Council.

Mr. Lanzikos asked for an example of such a change.

Mr. Sinacola indicated falling below required volume minimums as established by DoN guidelines could indicate further review by the Council, at the discretion of the DoN program.

Seeing no further questions, Commissioner Bharel asked for a motion to approve this application for a mobile Positron Emission Tomography-Computed Tomography ("PET-CT") service one day per week at Anna Jaques Hospital, LLC (#3- 4961).

Seeing no further questions, Commissioner Bharel asked for a motion to accept the staff summary for Project #3-4961 and recommendation for approval of the application.

Dr. David made a motion to approve the application; Dr. Bernstein seconded the motion. All approved.

b. Shields Imaging, LLC ("Shields or Applicant) has filed a Determination of Need ("DoN") for a mobile Positron Emission Tomography-Computed Tomography ("PET-CT") service one day per week at Cooley Dickinson Hospital, LLC (#1- 4962) (Vote)

The Commissioner invited Mr. Sinacola and Ms. Rodman staff to remain at the table for presentation of the DoN staff summary for Project #1-4962, noted Mr. Shields would remain at the table, and invited Anthony Scibelli, Vice President of Operations and Chief Administrative Officer of Cooley Dickinson Hospital, to the table.

Mr. Lanzikos asked if the current vendor is providing service one day every other week.

Mr. Scibelli noted that the current vendor provides services every other week.

Mr. Lanzikos asked if the once per week schedule would present any issues based on the current operating schedule.

Mr. Scibelli responded that the current every other week schedule presents scheduling challenges that the hospital hopes will be mitigated by offering the service once weekly.

Dr. Bernstein asked who's responsible for the quality of the reading of the PET scans.

Mr. Scibelli indicated that physicians at the hospital read and interpret the scans.

Mr. Bernstein asked if those clinicians had a minimum number of scans to read annually.

Mr. Scibelli indicated it was his understanding that these clinicians were required to meet certain continuing education requirements to indicate a degree of specificity in this area of medicine.

Seeing no further questions, Commissioner Bharel asked for a motion to approve this application for a mobile Positron Emission Tomography-Computed Tomography (“PET-CT”) service one day per week at at Cooley Dickinson Hospital, LLC (#1- 4962).

Mr. Rivera made a motion to approve the application; Dr. Rosenthal seconded the motion. All approved.

c. Lawrence General Hospital, has filed a significant change to approved DoN Project No. 3-3C36 for renovation of shell space (Vote)

The Commissioner invited Mr. Sinacola and Ms. Rodman staff to remain at the table for presentation of the DoN staff summary for significant amendment Project #3-3C36, and invited the following representatives of the applicant to the table:

Deborah Wilson – Chief Financial Officer and Executive Vice President for Finance and Transformation at Lawrence General Hospital

Felix Mercado – Vice President for Finance for Lawrence General Hospital

Dennis Ingram – Facilities Manager for Lawrence General Hospital

Seeing no questions, Commissioner Bharel asked for a motion to approve this significant change to approved DoN Project No. 3-3C36 for renovation of shell space.

Mr. Lanzikos made a motion to approve the significant amendment to approved DoN Project #3-3C36; Dr. Cunningham seconded the motion. All approved.

3. PRELIMINARY REGULATIONS

a. Informational briefing on proposed regulatory amendments to 105 CMR 155.000 – Patient and Resident Abuse Prevention, Reporting, Investigation, Penalties and Registry, which sets forth standards for the prevention, reporting and investigation of patient and resident abuse, neglect, and mistreatment, and the misappropriation of property by individuals working in or employed by a facility, home health agency, homemaker agency or hospice program, and for sanctions and penalties

Commissioner Bharel invited Lauren Nelson, Director of Policy and Quality Improvement within the Bureau of Health Care Safety and Quality, Sherman Lohnes, Director of the Division of Health Care Facility Licensure and Certification 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 155.000 – *Patient and Resident Abuse Prevention, Reporting, Investigation, Penalties and Registry*.

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

Mr. Lanzikos asked if the regulations pertain to an individual other than a nurse aide, home health aide, or homemaker engages in misconduct or patient abuse.

Mr. Lohnes responded that if the individual is licensed by a professional board, the individual is referred to the respective board. He added that in all instances of findings the individual is referred to the Office of the Attorney General for violation of the patient abuse law.

Mr. Lanzikos asked if the Department had any information on how frequently administrative staff or unlicensed individuals are reported to the Office of the Attorney General.

Mr. Lohnes responded that in all instances the individual is reported to the Office of the Attorney General. He added the Department would have to take a look at the referrals for more detailed understanding of the individuals referred.

Mr. Lanzikos asked if there was a way for members of the public to file a complaint and, if so, a way to do so anonymously.

Mr. Lohnes responded that the Department has a toll free number for complaints and added that individuals can report anonymously.

Dr. Bernstein asked if this regulation applies to assisted living facilities, particularly those providing Alzheimer's care.

Mr. Lohnes responded that presently the statute does not extend to assisted living facilities, and added that the statute and regulation would extend to a dementia special care unit within a licensed nursing home.

Mr. Lanzikos added that assisted living facilities are under the jurisdiction of the Executive Office of Elder Affairs and noted he would be happy to connect Dr. Bernstein with resources.

Mr. Lanzikos then added that at the April meeting he raised some questions about DoN oversight of long term care, and noted a proposed project for a 90 bed facility when there appears to be no unmet need for long term care services. He indicated that facilities providing short term services on a Medicare-only basis are disruptive to the system and delivery of long term care in Massachusetts.

The Commissioner thanked Mr. Lanzikos for his comments and indicated the Department would take them under consideration, as it has previous comments relative to long term care and DoN, as it moves through the regulatory review process.

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

b. Informational briefing on proposed rescission of 105 CMR 701.000: Regulations Adopted Jointly by the Department of Public Health and the Board of Registration in Pharmacy for the Implementation of M.G.L. c.94C

Commissioner Bharel invited Lauren Nelson, Director of Policy and Quality Improvement within the Bureau of Health Care Safety and Quality, and Rebecca Rodman, Deputy General Counsel, to remain at the table for an informational briefing on proposed rescission of *105 CMR 701: Regulations Adopted*

Jointly by the Department of Public Health and the Board of Registration in Pharmacy for the Implementation of M.G.L. c.94C. She also invited Jonathon Mundy, Director of the Drug Control Program within the Bureau of Health Care Safety and Quality, to the table.

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

Mr. Lanzikos asked if the provision of this regulation noted to be moved to 105 CMR 721.000 was on track for amendment or if there would be a gap in regulatory oversight as a result of this proposed rescission.

Ms. Nelson responded that amendments to 105 CMR 721.000 are underway and that the rescission of 105 CMR 701.000 would be held until proposed amendments to 105 CMR 721.000 were finalized and promulgated.

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

c. Informational briefing on proposed regulatory amendments to 105 CMR 302.000: Congenital Anomalies Registry

Commissioner Bharel invited Marlene Anderka, Director of the Center for Birth Defects Research and Prevention within the Bureau of Family Health and Nutrition, Ron Benham, Director of the Bureau of Family Health and Nutrition, and Alison Mehlman, Senior Deputy General Counsel, to the table for an informational briefing on proposed amendments to *105 CMR 302.000: Congenital Anomalies Registry*.

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

Mr. Lanzikos asked about the relevance of passports to the regulation.

Ms. Anderka noted it was for the purposes of identification for certain individuals requesting access to data from the registry.

Mr. Lanzikos asked if the Department gathered data about some of the environmental exposures a mother could encounter.

Ms. Anderka indicated Center staff do work with the Bureau of Environmental Health relative to environmental health data and possible geocoding of trends.

Dr. Bernstein asked if staff has found any environmental linkages or patterns.

Ms. Anderka responded that the Registry's data is put into the Department's environmental health tracking portal, which links geocoded data to environmental data such as water source. She added that birth defects is one of the outcomes you can look at using that portal.

Mr. Rivera asked if information on second-hand smoke exposure by a coresident is collected.

M. Anderka responded that the Registry does not collect this information for each of its cases, but for cases enrolled in the National Birth Defects Prevention Study there is an extensive exposure survey that does assess this factor.

Seeing no further questions, Commissioner Bharel thanked Ms. Anderka, Mr. Benham, and Ms. Mehlman for their presentation.

5. PRESENTATIONS

a. Zika Update

Commissioner Bharel invited Dr. Catherine Brown, Deputy State Epidemiologist and State Public Health Veterinarian, and Kevin Cranston, Assistant Commissioner and Director of the Bureau of Infectious Disease and Laboratory Sciences, to the table for an informational presentation on the Massachusetts response to Zika virus.

Commissioner Bharel added that the state is very fortunate to have Dr. Brown here, and under Mr. Cranston's leadership, the State Public Health Laboratory moved very rapidly to add Zika testing to their work. She also noted the coordination with DPH's birth defects registry.

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

Mr. Rivera asked if we know the impact of Zika virus on those with compromised immune systems.

Dr. Brown responded that there have been some studies on this, and the data indicates that even immunocompromised individuals experience mild symptoms. She added that the CDC has an entire page devoted to Zika virus in HIV patients.

Dr. David asked that even though we're testing for Zika in Massachusetts we haven't documented a case in Massachusetts.

Dr. Brown indicated that case counting for Zika virus is very complex, but to date the state has reported 10 confirmed cases of Zika virus infection in Massachusetts residents contracted through travel. She added that this is an imported disease. She noted the CDC is establishing a registry for pregnant women that will include those pregnant women with some evidence of infection but not necessarily a confirmed case; she added that children born to those women will be followed so any effects can be observed.

Mr. Lanzikos congratulated Dr. Brown on her recent promotion to Deputy State Epidemiologist.

Dr. Bernstein asked if a case would need to show all of the symptoms discussed in the presentation.

She indicated that not all symptoms need to occur. She added that fever is the most common symptom in over 90% of cases, followed by rash in over 80%, and arthralgia and conjunctivitis in around 60%.

Dr. Cunningham left the meeting at 11:01AM and did not return.

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

Commissioner Bharel indicated that the next meeting will be held June 8th, and requested a motion to adjourn.

Dr. Kneeland made a motion to adjourn; Dr. David seconded the motion. All approved.

The meeting adjourned at 11:03AM.

LIST OF DOCUMENTS PRESENTED TO THE PHC FOR THIS MEETING:

- Minutes of the Public Health Council Meeting April 13, 2016
- Copy of regulation and presentation discussing proposed regulatory amendments to 105 CMR 155.000: *Patient and Resident Abuse Prevention, Reporting, Investigation, Penalties and Registry*
- Copy of regulation and presentation discussing proposed rescission of 105 CMR 701.000: *Regulations Adopted Jointly by the Department of Public Health and the Board of Registration in Pharmacy for the Implementation of M.G.L. c.94C*
- Copy of regulation and presentation discussing proposed regulatory amendments to 105 CMR 302.000: *Congenital Anomalies Registry*
- Copy of informational presentation providing an update on Zika virus

Commissioner Monica Bharel, Chair