

MINUTES OF THE PUBLIC HEALTH COUNCIL

Meeting of September 19, 2012

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

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

Docket: Wednesday, September 19, 2012, 9:00 AM

1. ROUTINE ITEMS: No Floor Discussion

- a) Introduction **(NO VOTE)**
- b) Record of the Public Health Council Meeting of June 13, 2012 **(APPROVED)**

2. DETERMINATION OF NEED:

**Project Application Number 4-3C11 of Massachusetts General Hospital –
For expansion of proton beam therapy service (APPROVED)**

3. DETERMINATION OF NEED:

**Significant Change to Project #1-3B36 of Baystate Medical Center – for
build-out of shell space to accommodate 96 medical/surgical beds and to increase
the project's maximum capital expenditure (APPROVED)**

4. REGULATION:

**Request approval for emergency promulgation of amendments to 105 CMR 970.000,
Pharmaceutical and Medical Device Manufacturer Conduct (APPROVED)**

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.

Date of Meeting: Wednesday, September 19, 2012

Beginning Time: 9:24 AM

Ending Time: 10:13 AM

Attendance and Summary of votes

Board Member	Attended	Item 1b	Item 2	Item 3	Item 4
		Record of the Public Health Council Meeting of June 13, 2012	Determination of Need Project Application # 4-3C11 of Massachusetts General Hospital	DoN: Significant change to Project #1-3B36 of Baystate Medical Center	Regulation: Request approval for emergency promulgation of amendments to 105 CMR 970.000, Pharmaceutical and Medical Device Manufacturer Conduct
John Auerbach	Yes	Yes	Yes	Yes	Yes
Helen Caulton - Harris	No	-----	-----	-----	-----
Harold Cox	Yes	Yes	Yes	Yes	Yes
John Cunningham	Yes	Yes	Yes	Yes	Yes (2 nd)
Michele David	No	-----	-----	-----	-----
Muriel Gillick	No	-----	-----	-----	-----
Paul Lanzikos	Yes	Yes	Yes	Yes	Yes
Denis Leary	No	-----	-----	-----	-----
Lucilia Prates Ramos	No	-----	-----	-----	-----
Jose Rafael Rivera	Yes	Yes	Yes	Yes (M)	Yes (M)
Meredith Rosenthal	Yes	Yes	Yes	Yes (2 nd)	Yes
Albert Sherman	Yes	Yes (M)	Yes (M)	Yes	Yes
Michael Wong	No	-----	-----	-----	-----
Alan Woodward	Yes	Yes (2 nd)	Yes (2 nd)	Yes	Yes
Barry Zuckerman	No	-----	-----	-----	-----
Summary	8 members attended	Approved with 8 votes	Approved with 8 votes	Approved with 8 votes	Approved with 8 votes

(M): Made motion (2nd): Seconded motion

PROCEEDINGS

A regular meeting of the Massachusetts Department of Public Health's Public Health Council (M.G.L. C17, §§ 1, 3) was held on Wednesday, September 19, 2012 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: Chair John Auerbach, Commissioner, Department of Public Health, Dean Harold Cox, Dr. John Cunningham, Mr. Paul Lanzikos, Mr. Jose Rafael Rivera, Dr. Meredith Rosenthal, Mr. Albert Sherman, and Dr. Alan Woodward.

Absent members were Ms. Helen Caulton-Harris, Dr. Michele David, Dr. Muriel Gillick, Mr. Denis Leary, Ms. Lucilia Prates Ramos, Dr. Michael Wong, and Dr. Barry Zuckerman. Also in attendance was Attorney Donna Levin, General Counsel, Massachusetts Department of Public Health.

Chair Auerbach called the meeting to order at **9:24 AM** and reviewed the agenda.

ITEM 1b: Record of the Public Health Council meeting of June 13, 2012

Chair Auerbach asked if there were any changes to the minutes of the Public Health Council meeting of June 13, 2012. No changes were recommended. **Mr. Albert Sherman** made the motion to approve the minutes of June 13, 2012. After consideration, upon motion made and duly seconded by **Dr. Alan Woodward**, it was voted unanimously to approve the minutes as presented.

Voting in the affirmative were all **8** present members. There were no abstentions and no votes in opposition.

During the motion of the minutes, **Dr. Woodward** made a motion to recognize Chair Auerbach for the outstanding work he has done as Commissioner of the Department of Public Health. **Dr. Woodward** and **Mr. Cox** each addressed Commissioner Auerbach, praising his leadership of the Department. The Council voted unanimously to recognize the Commissioner for his "extraordinary intellect, knowledge, and commitment to public health, and his exemplary leadership of this Council and this Department and for the advocacy for the health and well being of all residents of this Commonwealth."

ITEM 2: DON: Project Application # 4-3C11 of Massachusetts General Hospital – For expansion of proton beam therapy service

Mr. Jere Page, Sr. Program Analyst for the DoN Program presented DON Application #4-3C11 of Massachusetts General Hospital. Mr. Page described the proposed expansion, summarized in the written staff summary as the "expansion of the existing proton beam radiation therapy service through acquisition of a second proton beam unit

and associated renovation to accommodate the new unit at Massachusetts General Hospital's main campus in Boston."

Mr. Page described proton beam therapy, including its medical uses, how many there are in the United States and the status of the applicant's proton beam service, including how often it is in operation, how old the unit is and the applicant's rationale for expansion.

Discussion followed by members of the Council with input from Dr. Peter Slavin, President of Massachusetts General Hospital and Dr. Jay Loeffler, Chief of Radiation Oncology for the hospital. Topics discussed included justification for the additional proton beam service, how the system accommodates downtime, and maintenance of the units. Please see transcript for full discussion.

Mr. Albert Sherman made the motion to approve Application # 4-3C11 of Massachusetts General Hospital with conditions as noted. After consideration, upon motion made and duly seconded by **Dr. Alan Woodward**, it was voted unanimously to approve the application as presented.

Voting in the affirmative were all **8** present members. There were no abstentions and no votes in opposition.

ITEM 3: DON: Significant change to Project #1-3B36 of Baystate Medical Center – For build-out shell space to accommodate 96 medical/surgical beds and to increase the project's maximum capital expenditure

Mr. Bernard Plovnick, Director of the DoN Program presented Project #1-3B36 of Baystate Medical Center, which is an amendment to a DoN originally approved by the Council in November 2007.

Mr. Plovnick summarized the application "Bay State seeks today in its amendment to build out 80,116 growth square feet of previously approved shelf space to accommodate the replacement of 96 existing adult medical surgical beds currently operating in outdated facilities, as well as a number of support and ancillary service improvements." The adjusted maximum capital expenditure (MCE) would be \$359,423,474 in June 2012 dollars. Mr. Plovnick continued describing the justification for the request, recommending approval of the application and outlining three conditions attached to the application. Please see transcript for verbatim discussion.

Mr. Jose Rivera made the motion to approve a significant change to Project #1-3B36 of Baystate Medical Center with conditions as presented. After consideration, upon motion made and duly seconded by **Dr. Meredith Rosenthal**, it was voted unanimously to approve the application as presented.

Voting in the affirmative were all **8** present members. There were no abstentions and no votes in opposition.

ITEM 4: REGULATION: Request approval for emergency promulgation of amendments to 105 CMR 970.000, pharmaceutical and medical device manufacturer conduct

Mr. Iyah Romm, Director of Policy, Health Planning, and Strategic Development for the Bureau of Health Care Safety and Quality and Attorney Carol Balulescu, Deputy General Counsel presented the proposed emergency amendments to the Council. Mr. Romm described the amendments which implement recent changes in state law that “now allows meals to be offered at non-continuing medical presentations for healthcare practitioners outside of the office or hospital setting. Previous law restricted pharmaceutical and medical device manufactures from directly providing meals to healthcare practitioners, except in office or hospital settings.”

Mr. Romm further described the process for writing the amended regulations, including comparing definition of modest meals and refreshments by the federal government, other states and industry codes of conduct. The Commonwealth also reviewed state and federal law. He presented the main change of the regulation, namely the definition of “modest meals and refreshments” saying in part “we propose that the definition of modest meals and refreshments not include a specific dollar amount, but rather be consistent and compliant with ... Pharma, AdvaMed, and AMA codes, which requires that meals and refreshments be “similar to what a healthcare provider might have purchased when dining or his or her own expense as judged by local standards.””

Further discussion included a summary of the public hearing schedule and rationale for emergency amendments.

Discussion followed by members of the Council. Topics discussed included questions from **Dr. Rosenthal** on enforcement, from **Mr. Rivera** on whether alcohol should be addressed and from **Dr. Woodward** about whether there would be criteria for the events to be considered educational. **Mr. Lanzikos** asked for a presentation on how the current regulations compare to other states and trade codes of conduct when the subject comes back for a final vote. Please see transcript for full discussion.

Mr. Jose Rivera made the motion to approve the emergency promulgation of amendments to 105 CMR 970.000. After consideration, upon motion made and duly seconded by **Dr. John Cunningham**, it was voted unanimously to approve the emergency amendments as presented.

Voting in the affirmative were all **8** present members. There were no abstentions and no votes in opposition.

LIST OF DOCUMENTS PRESENTED TO THE PHC FOR THIS MEETING:

1. Docket of the meeting
2. Public Health Council Meeting Minutes from June 13, 2012
3. Determination of Need Pending Projects List
4. Staff Summary for Determination of Need by the Public Health Council – MGH proton beam expansion.
5. Memo for Determination of Need Project #1-3B36 Baystate Medical Center
6. Regulation: 105 CMR 970.000: Pharmaceutical and Medical Device Manufacturer Conduct
7. Copies of all power point presentations (emailed upon conclusion of the meeting)

Chair John Auerbach