MINUTES OF THE PUBLIC HEALTH COUNCIL

MEETING ON JULY 13, 2011

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

Updated Docket: Wednesday July 13, 2011, 9:00 AM

---

1. ROUTINE ITEM: No Floor Discussion

A. Compliance with Massachusetts General Laws, Chapter 30A, Section 11A ½ **(No Vote)**
B. Record of the Public Health Council Meeting of May 11, 2011 **(Vote)**

2. REGULATION: Floor Discussion (No Vote)

Informational Briefing on Proposed Amendments to *Licensure of Substance Abuse Treatment Programs* (105 CMR 164.000) Relating to Establishment of an Alternative Licensing Process for Accredited Opioid Treatment Programs, and Clarifications and Corrections

3. REGULATION: Floor Discussion (No Vote)

Informational Briefing on Proposed Amendments to the *Massachusetts Regulations for the Control of Radiation* (MRCR) (105 CMR 120.000)

4. REGULATION: No Floor Discussion (Vote)

Request for Final Promulgation of 105 CMR 225.000: *Nutrition Standards for Competitive Foods and Beverages in Public Schools* **(APPROVED)**

5. REGULATION: No Floor Discussion (Vote)

Request for Final Approval to Promulgate Proposed Regulations, 105 CMR 215.00: *Standards for School Wellness Advisory Committees* **(APPROVED)**

6. DETERMINATION OF NEED: CATEGORY 1 APPLICATIONS (Vote):

A. Project Application No 4-3B98 of Steward St. Elizabeth's Medical Center

New construction of a new one-story addition to the existing Connell Building to develop a 23-bed consolidated critical care until ("CCU") to replace the Medical Center's existing 27-bed CCU, which includes cardiac, surgical, respiratory and

neurology step-down units with shell space for five additional CCU beds if required by further increasing demand.

B. Project Application No 4-3B97 of Brigham and Women's Hospital

Addition of a part-time, Positron Emission Tomography ("PET") Scanner for clinical use in the Advanced Multimodality Image Guides Operating ("AMIGO") suite.

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 MEETING OVERVIEW

A regular meeting of the Public Health Council (M.G.L. C17, §§ 1,3) of the Massachusetts Department of Public Health was held on July 13, 2011. The meeting began at 9:00 a.m., in the Henry I. Bowditch Public Health Council Room, located at 250 Washington Street, Boston, Massachusetts on the second floor of the Massachusetts Department of Public Health Building. Please refer to the table below for council member attendance.

Council Member Attendance for PHC Meeting on July 13, 2011

PHC Members	**Present/Absent**	**Notes** (Late arrival times, etc.)
John M. Auerbach, Commissioner/Chair	**P**	
Helen R. Caulton-Harris	**P**	
Harold Cox	**P**	
Dr. John Cunningham	**Absent**	
Dr. Michèle David	**P**	
Dr. Muriel R. Gillick	**Absent**	
Paul J. Lanzikos	**P**	
Denis Leary	**Absent**	
Lucilia Prates Ramos	**P**	
José Rafael Rivera	**P**	
Dr. Meredith B. Rosenthal	**P**	
Albert Sherman	**P**	
Dr. Michael Wong	**P**	
Dr. Alan C. Woodward	**P**	
Dr. Barry S. Zuckerman	**P**	
15 Members of Council	**Total Present: 12** **Total Absent: 3**	

Chair Auerbach announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance. He noted changes to the order of the docket. Chair Auerbach asked for a vote on the minutes from the May 11th meeting. Mr. Sherman moved for approval. Minutes from the May 11th meeting were approved unanimously by the Council.

While waiting for Dr. Lauren Smith to arrive for the first regulation, Council Member Caulton-Harris took a moment to thank the members of the Council for their kind letters that they sent to her and the residents of Springfield, offering support after the recent tornado. Chair Auerbach thanked Council Member Caulton-Harris and welcomed Dr. Smith and thanked her for accommodating the change in schedule.

REGULATION: REQUEST FOR FINAL PROMULGATION OF 105 CMR 225.000: *Nutrition Standards for Competitive Foods and Beverages in Public Schools*

Dr. Lauren Smith, Medical Director, Massachusetts Department of Public Health presented the proposed standards of 105 CMR 225.000 to the Council. Central to this bill is that it requires that DPH establish nutritional standards for "competitive foods and beverages" sold in public schools between 30 minutes prior to and after the school day. "Competitive foods and beverages" are those foods and beverages outside of the school breakfast and lunch program in public schools. Dr. Smith noted that DPH is required to update these standards every five years. Of note, 105 CMR 225.000 also promulgates that plain water be made available at no charge throughout the school day, along with the requirement that nutrition information be made available for non-prepackaged foods and that there be offerings of fresh fruits and non-fried vegetables at every food vendor in public schools, excluding vending machines.

Dr. Smith elaborated: "It also requires the establishment of regulations, or the promulgation of regulations to promote school wellness advisory committees, which Anne Sheetz is going to talk to you about, requires training of public school nurses for screening and referral for obesity, diabetes, and eating disorders, and establishes a Commission on School Nutrition and Childhood Obesity. These latter aspects, we are not really going to talk that much about today. It's really about the nutrition standards where we will spend most of our time".

Dr. Smith gave a summary of actions pertaining to the law that was signed on July 10, 2010. An interagency workgroup involving the Department of Elementary and Secondary Education, John Stalker Institute, Boston Public Health Commission, and Harvard School of Public Health was formed in the process of developing draft regulations. Dr. Smith noted that since the first presentation of 105 CMR 225.000 to the Council on February 9th, 2011, two public hearings (March 28; April 5, 2011) and a public comment period (through April 8th, 2011) were undertaken. The two public hearings were attended by more than 60 individuals, with 19 parties submitting oral testimony. The public comment period also brought in 91 written responses which were reviewed along with the 19 oral testimonies by the interagency workgroup.

Dr. Smith stated: "A number of public health organizations commented on this and supported the regulations as originally presented to you in February, and these are listed here, including the Boston Public Health Commission and the Healthy Foods in Northampton, as an example. We had other organizations that support the regulations but actually were asking for stronger qualifications, such as adding a fiber requirement, lowering sugar requirement, making the regulations apply twenty-four hours a day, seven days a week, and you will see those listed here". Dr. Smith then presented a thorough overview of comments and how the Department responded. Please see the transcript for a full account of her presentation.

There were several public comments asking for clarification of proposed definitions. Please see **Table I** below for a summary of additions and revisions to proposed definitions.

Table I. Additions and Revisions to Proposed Definitions of 105 CMR 225.000

Additions	Revisions

"An **item** is one serving of a product; packaged items can contain no more than one serving per package."	Revised (to include Healthier US terminology): "**Whole grains** mean grains or the foods made from them that contain all the essential parts and naturally occurring nutrients of the entire grain seed. For purposes of these regulations, whole grain should be the primary ingredient by weight, (i.e., whole grain listed first in the ingredient statement)."
"When applying the nutrition standards of 105 CMR 225.000, **the food product should be analyzed as a whole,** not by the individual ingredients that make up the product."	Revised (to clarify that guidelines apply to ALL the locations in and around the school) – food and beverages offered, sold or provided in: • school cafeterias offered as à la carte items • school buildings, including classrooms and hallways • school stores • school snack bars • vending machines • concession stands • booster sales • fundraising activities • school-sponsored or school-related events • any other location on school property
	Revised (for feasibility of implementation): "Fresh" means fresh, frozen, dried or canned without added sugar, fat, or sodium, for the purpose of these regulations."

Dr. Smith explained: "Implementing the nutrition information regulation, we knew that that was going to be tricky for schools, so we gave them an extra year to be able to do that. We are also going to be developing a support through a centralized approach and database so that each school won't have to do this individually. It doesn't make sense for three hundred and fifty-one school districts to have to do this on their own, and we want to support school districts in understanding how to do this in a financially successful way. Again, there are multiple ways to do that, and there's increasing evidence that schools can do this without financial downturn -- financial down side".

Dr. Smith reminded the Council that these regulations go into effect on August 1st of next year, 2012, except for the following provisions which go into effect a year later: 1) the elimination of beverages with added sugars or sweeteners, and 2) the requirement to make nutritional information available to students. She continued: "The guidance document is currently being prepared by the interagency workgroup, again, to facilitate best practice implementations, and we are very fortunate that we had, as part of our workgroup, staff and representatives, key leaders from the Department of Elementary and Secondary Education, as well as the John Stalker Institute, who have already taken steps to incorporate the elements in this into their training programs and the TA that they already provide for school nutrition directors and

other appropriate school personnel, and I think, of note, they have been very helpful in contacting and thinking about the contracting and procurement implications of these standards, but schools will be prepared to incorporate this into their procurement approaches in advance of the implementation in August of 2012. So, we are very grateful for the partnership and the schools will benefit from the fact that we are thinking about this well in advance".

Dr. Smith concluded by acknowledging and thanking all of the individuals who are involved with this effort: "It certainly took a village to create this set of regulations, and I think that many of the people who were part of this work are in the audience today. I also want to particularly thank Howard Saxner from the General Counsel's Office, who is not here and we are going to miss him, but he was a tremendous asset to the development of these regulations".

Chair Auerbach clarified that Mr. Saxner in fact retired. He then thanked Lauren, noting the enormous amount of work this was for her and her workgroup. He stated: "I know this was an enormous amount of work for you and for the members of the workgroup because this is an incredibly detailed regulation, much more detailed than many of our regulations, and really required many different types of standards that have been used in different settings, and I think that an excellent job was done on balancing what was doable, given the restraints under which school systems operate, and what was optimally healthful for children, so just a terrific job and very clearly presented". Chair Auerbach apologized that he may have to cut discussion short due to scheduling difficulty in maintaining a quorum for voting. Questions were taken from Dr. Woodward, Mr. Sherman, Mr. Rivera, and then Mr. Lanzikos and Dean Cox.

A brief discussion followed. Of note, Dr. Alan Woodward stated that he was incredulous that there is not portable water across public schools already and further inquired as to the reasons. Dr. Smith informed the Council that there are an assortment of issues, one of which is related to the state of the water pipes (an issue for the Environmental Bureau). Currently, water is provided through bottled water supplies, among other mechanisms. Council member Paul Lanzikos then brought up the issue of what constitutes "fresh" and that perhaps adding a phrase to the definition regarding artificial preservatives may be important. A discussion amongst Dr. Smith and Council members concluded with Chair John Auerbach asking for the language to remain the same but for further investigation into the issue and a review of the wording. Please see the verbatim transcript for the entire presentation and discussion.

Mr. Sherman moved for approval and Helen Caulton-Harris seconded the motion. It was voted unanimously to approve the request for final promulgation of 105 CMR 225.000: *Nutrition Standards for Competitive Foods and Beverages in Public Schools*.

NO FLOOR DISCUSSION (Vote) (APPROVED)

REGULATION: REQUEST FOR FINAL APPROVAL TO PROMULGATE PROPOSED REGULATIONS, 105 CMR 215.00: *Standards for School Wellness Advisory Committees*

Proposed Regulations for School Wellness Advisory Committee: 105 CMR 215.000, mandated by Chapter 197 of the Acts of 2010 (M.G.L. c. 111 s. 223) were then discussed.

Director of School Health Services, Anne H. Sheetz, BSN, MPH, NEA-BC presented to the Council. She began, "Thank you for this opportunity and good morning to Members of the Council. My job was to work on the piece of Chapter 197 in the Acts of 2010 that mandated regulations for School Wellness Advisory Committees and, in some cases, the schools call them Health Advisory Committees. We were mandated to develop regulations that the Advisory Committees would help to develop policy and recommend School Wellness Policy, address nutrition education and physical activity, and we did this in collaboration with the Massachusetts Department of Elementary and Secondary Education".

Director Sheetz provided an overview of the issue at hand: "Now we, in School Health, have had long experience with School Wellness Advisory Committees. We made it a requirement of our Essential School Health Service Programs in 1993, so we have been around a bit, for eighty districts, and then we added it, we have partner schools. Each of the eighty districts is required to mentor two other school districts in health, and so, we have an additional hundred and twenty-six districts. We also included the guidelines in our School Health Manual that we published in 2007, and the goal of these regulations is really to promote some consistency across the Commonwealth for all school districts, all public school districts; although, because of our work with private schools, they will, in many cases, affect them also. The key features of the regulations are that the superintendent needs to appoint a School Wellness Advisory Committee. They should, these committees should have school health and health related disciplines, and that can be school nurses, school physicians, food service directors, athletic directors, etc. There should be emergency -- or community providers and agencies on the committee; students, very important, and parents".

When these regulations are passed, Director Sheetz will be sending the standards to every school district, and every school nurse in the Commonwealth so that they can be shared with these committees. Director Sheetz noted in relation to parents: "… this is the year that we are implementing the total State and BMI regulations and the few parents, I have had about five unhappy parents call, and I talked them down, and suggested that they be part of these committees, and all agreed to do that, which I thought was very interesting. They had some good ideas". For a full account of Director Sheetz's presentation to the Council, please refer to this meeting's transcript.

Director Sheetz concluded: "The next step will be completing the guidelines for implementing the School Advisory or Wellness Committees, and that will be handled by the Department of Elementary and Secondary Education, with our assistance, and they will be doing regional conferences and, again, what I will do after these are passed, both this week and in September, we will send copies of the standards that were just promulgated to all of the school nurses because they are integral in providing the leadership to allow these committees. So, thank you very much".

Chair Auerbach opened the floor for Council member questions. Helen Caulton-Harris inquired if bylaws would be established by each district, which she was informed was correct. Please see the verbatim transcript for the entire presentation and discussion. Dr. Michael Wong moved for approval of the regulations for promulgation. Albert Sherman seconded the motion. The Council unanimously voted to approve the request for final promulgation of the proposed regulations, 105 CMR 215.000, Standards for School Wellness Advisory Committees.

NO FLOOR DISCUSSION (Vote) (APPROVED)

DETERMINATION OF NEED: CATEGORY 1 APPLICATIONS (Vote):

A. Project Application No 4-3B98 of Steward St. Elizabeth's Medical Center
New construction of a new one-story addition to the existing Connell Building to develop a 23-bed consolidated critical care unit ("CCU") to replace the Medical Center's existing 27-bed CCU, which includes cardiac, surgical, respiratory and neurology step-down units with shell space for five additional CCU beds if required by further increasing demand.

Ms. Joan Gorga, Director, DoN Program at the Department of Public Health: "I am just going to more or less introduce the two applications by saying that they are both modest and unique, and the first one for a Critical Care Unit at St. Elizabeth's will replace a twenty-five year old, four unit Critical Care Unit, which is inefficient, with one Critical Care Unit, that will be much more versatile, and the second application is for what is called an AMIGO suite, which will be for clinical use of what has previously been a research grant from NIH, and it will be for part of a unit, one quarter time increment. Jere will begin with the St. Elizabeth's project".

Mr. Jere Page, Senior Program Analyst, DoN Program introduced the project: "… this is a project on the St. Elizabeth's Medical Center campus in Boston, which will involve construction of a new one-story addition to the existing Connell Building at the Medical Center, to develop a 23-bed consolidated Critical Care Unit, otherwise known as a CCU. This will replace the Medical Center's existing 27-bed CCU, which right now includes cardiac, surgical and respiratory and neurology step-down units. The project also includes a little bit of renovation to connect the new CCU to the existing Emergency Department, as well as shell space for five additional CCU beds if further demand would require. All of this is intended to respond to the multitude of physical and operational deficiencies in St. Elizabeth's existing CCU. The existing units I just mentioned are scattered around in three different buildings and, as Joan said, this is not very efficient and creates a lot of problems, as well as additional cost for the hospital".

Mr. Page noted that the project's expected completion date was set to January of 2013. He continued: "The recommended MCE, capital expenditure is just over eighteen million dollars. It will be funded with a hundred percent cash equity provided by the Applicant's parent, Steward Health Care System, LLC".

Mr. Page concluded: “The total funding for community initiates associated with this project is, over five years, is nine thousand -- nine million -- I'm sorry, nine hundred thousand four dollars, and Cathy O'Connor is here if you have questions about that. So, in brief, we have recommend approval of this project with the conditions detailed on Page 15 and the head of the hospital, John Polanowicz, is here to address the Council”.

Chair Auerbach thanked Mr. Page and noted that Doctors Wong and Zuckerman would be recusing themselves from both the discussion and vote. Questions were then taken from Council members. Please refer to the verbatim transcript for a full account of the presentation and discussion.

Chair Auerbach asked for a vote. Dean Cox motions. Mr. Sherman seconds. Doctor’s Wong and Zuckerman recused themselves. The Council unanimously voted to approve the Project Application No 4-3B98 of Steward St. Elizabeth’s Medical Center.

B. Project Application No 4-3B97 of Brigham and Women’s Hospital

Addition of a part-time Positron Emission Tomography ("PET") Scanner for clinical use in the Advanced Multimodality Image Guided Operating ("AMIGO") suite. Mr. Bernie Plovnick, Senior Analyst with the DoN Program, presented the staff recommendation for DoN Project No. 4-3B97, filed by Brigham and Women's Hospital.

Mr. Plovnick began: “The Brigham seeks approval of a substantial change in service to provide interoperative PET CT services at its main campus in Boston. Two days ago, Brigham was granted a research exemption under Section 100.230 of the DoN regulations, to acquire and operate a PET CT Scanner, a new state-of-the-art suite, funded through a grant from the National Institutes of Health. The AMIGO suite, the acronym stands for Advanced Multimodality Image Guided Operating Room, has been designed to study the benefits of employing imaging modalities in the operating room, including PET CT and MRI, to guide surgical decisions. Brigham anticipates that the availability of real time multimodality imaging capability in the operating suite will improve their quality of surgical outcomes and will significant reduce the incidence of repeat surgeries”.

Mr. Plovnick concluded: “It is Staff's opinion that the potential benefits to patient care are sufficient to merit approval of this application for a part-time clinical PET CT under Section 100.534 as a promising alternative to existing methods of health care delivery. Staff recommends approval, with six conditions, of Brigham's application, to devote twenty-five percent of the capacity of this interoperative research PET device, or an average of twenty-one hours per week, to clinical care. The conditions, as enumerated on Page 9 of the Staff Summary, include a requirement for reporting annually to the DoN Program on the clinical use of this PET CT Scanner, as well as the stipulation that the use of the interoperative PET CT may not exceed twenty-five percent of operating capacity without additional DoN approval. The Applicant is represented this morning by Mairead Hickey, Executive Vice-President and Chief Operating Officer of Brigham and Women's Hospital”.

Chair Auerbach opened the floor to questions from the Council. Please see the verbatim transcript for a full account of the presentation and discussion.

Of note, Dr. Rosenthal posited the following question: "I am curious what we know to date so far about the comparative effectiveness and comparative cost effectiveness of this new technology relative to the existing standard of care and, second, I am also wondering about reimbursement, the extent to which Medicare will reimburse for surgery in this context, differentially from surgery in other context, or whether there has been some progress in getting this new code, essentially, through Medicare".

Victor Berbaudo, Director of Nuclear Medicine and Molecular Imaging at the Brigham and Women's Hospital and the Medical School, was introduced to respond to Dr. Rosenthal's question: "To answer her question, I think that the cost effectiveness of PET in the clinical setting, being diagnostic and monitoring response to therapy is a proven fact. In the setting of a surgical suite, I believe that is what you are trying to address, I will recommend you actually read two of my publications in the setting, not necessarily the surgical but treatment-wise, radio frequency and biopsies, and what we have found so far, with the limited data that we have, remember that this is seventy-five percent … is that we are minimizing sampling error in the biopsy setting and, therefore, we are minimizing cost by not having to resample; and, in the setting of surgical procedures, what we are actually thinking is that, by the fact that we are able to establish and understand what the margins of that lesion are, especially in the setting where there is some congruency between anatomy and function in cancer. It is very difficult to target the margins of the tumor in the brain, in the breast, for example, just with anatomic imaging. If we do have metabolic information, we are able to then target that and what we are suspecting is going to happen is that we are going to be minimizing the number of surgical procedures a patient will have to undergo. This will have an impact on increasing recurrence and, therefore, increasing progression-free survival and general overall survival".

Council member Ms. Caulton-Harris inquired about the comments from the Office of Health Equity: "It seems that you need to have, thirty days from today, a plan in place that talks about medical interpreting. At least, that is what I am reading in the document, and then it says that, at the end of the federal -- there are forty-five days before the end of the federal fiscal year, there has to be another implementation plan. Those seem like the same dates to me, or are we talking about another the following year?"

Mr. Samuel Louis from the Office of Health Equity was brought forward to respond to Ms. Caulton-Harris's questions: "I met with the Applicant for the approval of the implementation plan. That plan was discussed comprehensively with them at the time of the assessment so they understand what needs to happen. The second part of your question about the forty-five days annual report, this is an existing annual report that they must produce regularly. So, that is different. These two reports are different. The first one is based on the conditions that are attached, also looking at previous conditions that they have, to ensure that there is continuous report and that existing conditions are not being overlooked, and that they are being implemented as well as new conditions. The second report looks at the overall operation of interpreter services for the entire hospital".

Council member Jose Rafael Rivera moved for approval, Albert Sherman seconded. Doctors Wong and Zuckerman recused themselves. After consideration of motion, it was voted unanimously to approve the **Project Application No 4-3B97 of Brigham and Women's Hospital**.

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO THE MASSACHUSETTS REGULATIONS FOR THE CONTROL OF RADIATION (MRCR) (105 CMR 120.000)

Ms. Suzanne Condon, Associate Commissioner, Director, Bureau of Environmental Health first recognized Robert Gallagher, who is the Director, Acting Director of our Radiation Control Program, and Jim Ballin, Deputy General Counsel, who worked tirelessly in trying to address many of the issues they would be presenting. She additionally recognized Karen Farris and Margaret Foster from the X-ray and Healing Arts Unit of the Radiation Control Program. Karen and Margaret were present to help address any questions the Council may have, and importantly the partnership across the agency. Ms. Condon also noted that both Sally Graham and Joelle Stein were present from the Division of Professional Licensure, Board of Registration in Physician Assistants.

Ms. Condon provided a brief outline of her presentation: "I am going to briefly review the Radiation Control Program's regulatory authority, specific need for changes to our regulations today, what those proposed regulatory amendments are our efforts to coordinate regulatory requirements with other regulatory bodies, both within DPH and outside, and then just a brief summary".

Ms. Condon continued: "The specific need for regulatory amendments today, and the reason that we are here, is, the major issue is to address the issue of physician assistants desire to expand their practice to include the use of fluoroscopic equipment; also to adopt national standards for the use of radiation producing machines reflecting technological advances in equipment, consistent with recommendations from an entity called the Conference on Radiation Control Program Directors, a working group that they have pulled together to address technological advances, to require a quality assurance program consistent with national standards for diagnostic imaging equipment, and then, minor changes have been made to sections that we presented to you some time back, but then, in NRC realized that they had omitted some definitions and changes, so here we are trying to be consistent with NRC. So, why is radiation training, safety training and curriculum important for physician assistants? Primarily because the general curriculum for physician assistants includes really no training at all in radiation safety and/or procedures, important procedures such as positioning, and such training is obviously critical in reducing the potential for radiation risk, and this is just an example of the kinds of radiation burns that can occur when things don't go right".

Ms. Condon noted that: "What we are proposing for physician assistants to perform fluoroscopic procedures is successful completion of the didactic and clinical training, of passing a written certification exam as developed by the American Registry of Radiologic

Technologists, and documentation from the supervising physician, verifying the PA's competency to perform fluoroscopic procedures".

In conclusion, Ms. Condon summarized: "… the additions we are requesting for the x-ray and healing arts regulations will enable us to meet standards set forth by the US Food and Drug Administration and used nationwide. The Department has been working with our sister agency and our sister bureau to develop regulations that will allow PA's to legally perform fluoroscopy under the supervision of a licensed physician. Registrant of diagnostic x-ray imaging equipment will now be required to have a quality assurance program for diagnostic imaging equipment, and then, minor changes have been made to sections of the regulations related to omissions that were previously made by the NRC".

Chair Auerbach thanked Ms. Condon. He then noted that: "… this will go out now for public comment, and then come back to Council probably sixty to ninety days for a vote". Chair Auerbach then open the floor for questions from the Council. Please refer to the verbatim transcript for a full account of the presentation and discussion. Chair Auerbach concluded by noting the Council is looking forward to getting the public comment and to their return in a few months.

NO VOTE/INFORMATION ONLY

Informational Briefing on Proposed Amendments to *Licensure of Substance Abuse Treatment Programs* (105 CMR 164.000) Relating to Establishment of an Alternative Licensing Process for Accredited Opioid Treatment Programs, and Clarifications and Corrections

Ms. Hilary Jacobs, Deputy Director, Bureau of Substance Abuse Services and Lisa Snellings, Deputy General Counsel presented the proposed amendments to the licensure of substance abuse treatment programs, 105 CMR 164.000. These proposed amendments were not to be voted on at this meeting.

Ms. Jacobs began: "The Bureau of Substance Abuse Services is a single state authority on substance abuse treatment and contract and fund prevention, treatment, and case management and recovery support services. We license and inspect treatment facilities, somewhere in the neighborhood of several hundred treatment facilities. We license addiction counselors, around two thousand of them. We have overall responsibility for the quality of care of the substance abuse treatment system, including complaint investigations and resolutions".

Ms. Jacobs described the reasoning for the current amendments to these regulations: "…we had always anticipated that we would need to make some minor amendments to these -- provisions to these regulations. What we did in December of 2008, when these were promulgated, is that we took seven sets of regulations and two sets of guidelines that were promulgated at various times, some of them twenty plus years old, and tried to pull them into one consistent document. So, we ended up with eighty-eight pages of regulation, and we had

no belief that we would get it all exactly right, regardless of the amount of -- we did very extensive vetting; and so, we had always anticipated that this process would be necessary. The purpose of the initial regulation revision was, as I said, to update regulation chapters and to reflect best practices, to eliminate redundancies and inconsistencies. What we are here to achieve today is -- we also thought that, while we were here to make those kinds of changes, we wanted to respond to a long time provider request from the Methadone Treatment Program community, which I will refer to as Opioid Treatment Programs, or OTP's, to look a deemed status or an alternate licensing provision for them. We are also here to do clarifications leading to common misunderstandings of the intention of the original regulations, and to correct sections where key information was missing and there have been some things that have changed, that we reference, and I can give you some examples of that later, since the promulgation of these regulations in 2008".

Ms. Jacobs concluded: "In terms of timeline, we expect to go to public hearing on August 12th. We are going to return here for request for promulgation in October or November and, because we do not see these as significant changes, we don't think that we need a lot of time to implement them, so we would like to promulgate them one month after the vote. So, we are here for any questions".

Chair Auerbach thanked them for the presentation. There were no questions. Chair Auerbach noted the Council was looking forward to their return in a few months in which time the Council would hear comments if there were any and would then vote on the proposed amendments.

NO VOTE/INFORMATION ONLY

GENERAL BUSINESS

Mr. Lanzikos took a moment to raise a point: "We reviewed the list of pending projects that we get in our packet. And I am noting that, especially now, with the disposal of the two capital projects that we heard this morning, that there are -- the only capital projects that are on this list are involving renovations of long term care facilities. In the last twelve months, there have been eight files, total capital cost of 57.6 million dollars, involving almost eleven hundred beds, and I note that the processing (business) is happening off-line, but there has been a real spike in these applications in the last couple of years. I know that there's a number of applications that have already been approved, and while I actually believe that we need to improve the quality of nursing facility care in the Commonwealth, I am concerned that it is happening sort of under the radar. It is not consistent; the standards that are being used are essentially standards that have been in place for several decades, not consistent with the Commonwealth's current policy of community first, putting an emphasis on providing long term services support in the community whenever possible, that virtually all of the proposed renovations are currently in suburban locations, that there is a … of long term care facilities in suburban locations. In fact, the closest we come to an urban location in the eight that have been filed in the last year is Brookline. There's a lack of local input to the process even with

what's been happening locally, the ones that have been approved. There's no requirement that they talk to the local communities. There's no sense of integration. There's no Public Health Council role. There's no community health initiative benefit. So, I am not being critical of the fact that these applications are coming in, but I am raising the fact that this is now emerging as sort of the new frontier in terms of, we have learned to be concerned about capital costs to the Commonwealth and Medicaid expenditures, that this is happening without any sort of revisiting of what our priorities are, what our standards are, and I would also note that most -- and I haven't seen these specifics proposals, but I know the ones that have been recently approved essentially reconstructing themselves from being long term care facilities to being short term rehab, sort of sub-acute facilities and, while those definitely meet -- they are going to be playing a role, in the future of health care delivery, we do need properly operated long term care facilities for those folks who will find the necessity of living in these types of environments. I would hope that, as these new facilities get approved, we are not then relegating people who, because they have chronic conditions, or capacities such as Alzheimers, to substandard facilities. So, I just address this. I know we are starting to look at this, and Alice Bonner was here, but she has left, and especially where we don't have a lot of acute capital projects before us, this may be a good time for this Council to start looking at this set of issues".

Chair Auerbach responded: "Thanks for raising this, Mr. Lanzikos. I know that Ms. Gorga is not here at this point, and I wish she was here to have heard you say that. We are fortunate that Dr. Biondolillo is here. What I would request, perhaps, is a conversation regarding your comments and questions that you have raised with either Dr. Biondolillo, or staff with the Bureau that she oversees so that we can ask for perhaps a presentation of the -- related to the issue that you are raising in a forum that would allow us to have a fuller discussion about it; and so -- and Dr. Biondolillo is not in on that. So, it's raising a lot of things and I think it is important for us to think about. I think we should prepare time and background information to allow us to do that".

Please refer to the verbatim transcript for a full account of the Council discussion.

The meeting adjourned at 11:00 a.m.

FOLLOW-UP ACTION STEPS:

Council member Paul Lanzikos:
-Concern with under-radar, poor standards, with regards to nursing homes
-Concern with long-term care improvements mainly in suburban communities; also no requirement for locals to be involved.
-If we are concerned with capital projects and medical expenditures, we need to think/address that we need properly functioning long-term care facilities.
-Wants to start looking at this issue of acute care.

Council member Dr. Alan Woodward suggested that we send out the power points a day prior to meetings.

LIST OF DOCUMENTS PRESENTED TO THE PHC FOR THIS MEETING:

- Docket of the meeting (July 13, 2011)
- Draft minutes of the Public Health Council for the meeting of May 11, 2011
- Copy of the meeting notices to A&F and Secretary of the Commonwealth
- Informational briefing memorandum and proposed draft amendments to *Licensure of Substance Abuse Treatment Programs* (105 CMR 164.000) Relating to Establishment of an Alternative Licensing Process for Accredited Opioid Treatment Programs, and Clarifications and Corrections
- Informational briefing memorandum and recommended final draft amendments to 105 CMR 225.000: *Nutrition Standards for Competitive Foods and Beverages in Public Schools*
- Informational briefing memorandum and recommended regulations to 105 CMR 215.00: *Standards for School Wellness Advisory Committees*
- Staff memorandum for determination of need for Category 1 Applications:
    - A. Project Application No 4-3B98 of Steward St. Elizabeth's Medical Center
    - B. Project Application No 4-3B97 of Brigham and Women's Hospital
- Determination of need pending projects table from Wednesday, July 06, 2011
- Public Health Council Memo: Semi-Annual Report on Adjudicatory Decisions

_____

Chair John Auerbach

LAST PAGE (S) SHOULD BE THE DOCKET FOR THE NEXT PHC MEETING