PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, March 12, 2008, 9:00 a.m., at the Department of Public Health, 250 Washington St., Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Ms. Caulton-Harris, Mr. Harold Cox, Dr. John Cunningham, Dr. Michèle David, Mr. Paul J. Lanzikos, Mr. Denis Leary, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Dr. Meredith Rosenthal, and Dr. Michael Wong. Dr. Muriel Gillick, Mr. Albert Sherman, Dr. Alan C. Woodward and Dr. Barry S. Zuckerman were absent. Also in attendance was Attorney Donna Levin, General Counsel, Department of Public Health.

ROUTINE ITEMS AND ANNOUNCEMENTS:

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. In addition, Chair Auerbach noted that docket item #4 Previously Approved Project of Merrimack Valley Health Services, Inc. had been pulled from the docket and therefore would not be heard by the Council. He also introduced a new member of the Public Health Council, Mr. Denis Leary, a non-health care provider, recommended by the Secretary of Veterans' Services. Mr. Leary is Executive Director of Massachusetts Veterans Inc. in Worcester. Mr. Leary and the other members of the Council introduced themselves to the audience. Chair Auerbach spoke about Council Member Albert Sherman, noting that his kidney transplant operation was successful and that Albie Sherman was recovering and feeling good. And further, Chair Auerbach asked the Council to vote on a resolution to send best wishes and congratulations to Mr. Sherman verbally and in writing from the Council. Chair Auerbach moved for approval of his motion. After consideration, upon motion made and duly seconded, it was voted unanimously [Dr. David not present] to approve the resolution to send best wishes and congratulations to Council Member Mr. Albert Sherman.

RECORD OF THE PUBLIC HEALTH COUNCIL MEETING OF DECEMBER 12, 2007:

Records of the Public Health Council Meeting of December 12, 2007 were presented to the Public Health Council for approval. Council Member José Raphael Rivera moved for approval of the minutes of December 12, 2007. After consideration, upon motion made and duly seconded, it was voted unanimously [Dr. David not present] to approve said records as presented. The records were distributed to the members prior to the meeting for review.

Note: The proposed regulations on the Prescription Monitoring Program (105 CMR 700.000 was heard last

Note: Dr. Michele David arrived in time to hear the final regulations 105 CMR 650.000 below; however, she was not present to vote on the resolution for Mr. Sherman or the minutes of December 12, 2007 above.

FINAL REGULATION:

REQUEST FOR PROMULGATION OF AMENDMENTS TO BAN LEADED CHILDREN'S JEWELRY – 105 CMR 650.000 (HAZARDOUS SUBSTANCE REGULATIONS):

Ms. Suzanne Condon, Director, Bureau of Environmental Health, presented the request to ban leaded children's jewelry in Massachusetts. She said in part, "...I want to quickly review the proposed regulation, the summary of the Public Health process, our response to the public comments received, the proposed changes to the regulations that were made, and the next steps and then we will respond to questions by the Public Health Council."

Ms. Condon continued, "The proposed regulations means jewelry marketed to, or intended for use by children until fourteen years of age, that contains a concentration of lead that is either more than six hundred parts per million total lead content, as determined by the U.S. Consumer Product Safety Commission Screening Test for total lead, or similar methods, subject to the approval of the Department of Public Health, or would expose a child to greater than 15 micrograms of lead per day, over a chronic exposure period as determined by CPSC's acid extraction test. Children's leaded jewelry is jewelry that is manufactured, shipped or sold at retail, wholesale, indoors or outdoors, over the Internet or through catalogs, and includes but is not limited to jewelry sold in vending machines, toy stores, toy displays, toy departments, or toy sections, or that may use images otherwise designed or packaged to be particularly attractive to children."

Ms. Condon noted that the public hearings were held on November 6, 15th and 16th. Some of the comments made:

- That Massachusetts standards should be the same as the state of California's regulations;
- That a national standard is needed;
- That Massachusetts standards are too stringent and might not be feasible;
- That the proposed dual standard is not protective enough – that there is no safe level of exposure for lead;

- That Lead is a cumulative toxin, health effects are seen at blood levels less than ten micrograms per deciliter;
- The lead limit in jewelry should be 40 ppm;
- Children should be defined as six years old and younger;
- Children should be defined as twelve years old and younger;
- Toy jewelry and children's jewelry are not the same product;
- A request for exemptions for plated metals and certain other jewelry materials such as crystals;
- Small businesses and retailers need clarification and assistance on how to maintain compliance;
- There is potential for a damaging economic impact particularly without exemptions for certain jewelry metals and materials;
- That we should expand the regulations to include limiting lead content in all children's products, and parents stated their difficulty in ensuring safety and age-appropriate access to toys for young children.

Staff's response to these comments in brief:

- That the California standard (Proposition 65) is not protective enough. It takes into account only the average exposure that a product may bring and does not allow for worse case scenarios;
- Staff does support a national standard, and is encouraging other states to adopt the Massachusetts standard;
- The Consumer Product Safety data shows that many samples that they had tested were able to meet the Massachusetts standard, demonstrating the feasibility of proposed Massachusetts standard;
- Exemptions were not made for plated jewelry in which the base metal could expose a child to dangerous amounts of lead if the plated surface were damaged, or if the item were retained in the stomach for long periods of time;
- DPH did not receive any economic impact analysis from industry representatives that would have allowed DPH to make any more determinations on the effects of the proposed regulations on industry;
- A guidance document will be distributed to industry that will explain what is required of them and what compliance will entail and that will be released for a 30-day comment period;
- Staff believes the dual standard proposed is more protective than a single proposed standard of 40 ppm (parts per million);
- Children will be defined as less than 14 years old
- Enforcement of the regulation will be effective on June 13, 2008. This allows time for the public comment period on the guidance document and for posting in the Massachusetts Register and the proper time period for regulation to go into effect

- Violators will be subject o penalties as described in MGL Chapters 94B and 93A, the Hazardous Substance and Consumer Protection Act:
    - First Offense: $100.00 to $500.00 for having product on the shelves
    - Second Offense: $600.00 to $3,000.00. Fines may go up to $5,000.00 per violation.

Next Steps:

Ms. Condon stated, "…In response to public comments and the Public Health Council comments last time we were here, staff has begun to investigate the potential for lead exposure from other children's products, to determine the need for additional regulations. To determine which children's products cause exposure risk would significantly delay implementation of these proposed regulations, which we believe address significantly greater health risks for children. Swallowing these jewelry items has shown, as you know, serious injury and death, and we felt it was important not to delay this process, but to move forward and then try to follow up immediately on addressing other children's product issues. An example would involve children's car seats…There is lead in the base of the seat, but the child cannot get to the lead in the base. So, is it appropriate to say you can't put that lead in the base? That is just an example of why we believe this is not such a quick solution and we do need more time to evaluate other products."

Ms. Condon further said, "Next steps are to engage multiple stakeholders in a process to propose additional regulations to protect children from lead in other children's products. We intend to conduct investigations into the potential for significant lead exposure and part of that will involve discussion groups that have already been planned for both industry and advocacy groups to determine products that pose the greatest public health threat to children."

She continued, "In terms of being clearer on the next steps, we tend to feel that there are key issues that additional regulations need us to focus on such as defining accessible lead. What is it that is most accessible to a child, that would put them at greater risk of lead exposure - that would be unacceptable? Defining appropriate laboratory methodologies; there are all sorts of methodologies out there. Many of them involve laboratories that are overseas, where some of the products originate. Therefore, we need to carefully evaluate which methods we believe will be sufficient to give us a comfort feeling such that children in Massachusetts won't be placed at risk. We have to evaluate compliance and enforcement strategies. Passing laws are important but ensuring effective compliance is equally important. We want to look at other state models and experiences…We have been communicating with other states and we want to look at what they have done and learn from their experience. Our goal is to

propose draft regulations later this year and we will return to the Council with some additional regulations."

Discussion followed by the Council. Dr. Michele David asked, "When you remove toy jewelry from the regulations – is that term subsuming under children's jewelry?" Ms. Condon replied in part, "Yes". Mr. Paul Lanzikos asked if children's jewelry given away at fast food outlets would be covered under this regulation. Mr. Roy Petre, Senior Policy and Regulatory Affairs Coordinator for BEH replied yes, because The Hazardous Substance Act prohibits giving away or even possessing for sale, or other distribution, banned substances. Ms. Martha Steele, Deputy Director, BEH, clarified for Dr. John Cunningham that accessibility is the same as absorption. Mr. Harold Cox asked staff how they intended to do the inspection process. Ms. Condon stated in part, "...We would be inviting local health officials to be our partner in helping us but not being unrealistic in terms of expectations...We have a variety of staff involved in Inspectional Services. We have interns that work with us throughout the year and during the summer months to increase our capacity. We will be going out to a variety of different venues across all areas of the State. Clearly, I think we will be focusing more intently on some of those areas of the state that we define as high risk communities, those 14 communities with elevated levels of childhood lead..."

Chair Auerbach added in part, "...We have talked with Ms. Condon and Dr. Dreyer about ensuring that when we pass regulations, we do have the capacity to enforce them and that raises the question of paying attention, as a Department, to having adequate resources within the regulatory agencies within DPH..."

Discussion continued and Mr. Lanzikos asked, "Items that are purchased through the Internet and catalogs, do the regulations cover out-of-state sources as well as those in state?" Attorney Susan Stein, First Deputy General Counsel for DPH, replied, "We would hope so. We have to work with the Attorney General's Office to determine the methodology for doing that, but I feel that we would be able to do that, yes."

Council Member José Rafael Rivera inquired about how families will be notified of the risk to their children, especially when they purchase products out of Massachusetts. Ms. Condon stated that her bureau has a strong Health Education component in their Childhood Lead Poisoning Prevention Program, which has the ability to develop materials before the regulations go into effect in appropriate languages for the high risk communities. Mr. Rivera noted that community health workers could be extremely helpful with that educational component and Ms. Condon agreed. Dr. David asked for clarification on preventing the Internet sales. Atty. Susan Stein noted that they would also work

with the Attorney General's Office on that issue to determine the method for doing it."

Dr. Wong made the motion to approve the proposed regulations. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the **Promulgation of Amendments to Ban Leaded Children's Jewelry – 105 CMR 650.000, the Hazardous Substance Regulations**; that a copy of the approved amendments be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as **Exhibit No. 14, 897.**

CATEGORY 2 DETERMINATION OF NEED APPLICATIONS:

For the record, due to conflict of interest DPH Deputy General Counsel, Donna Levin, stepped down as advisor to the Council on the two DoN applications. Atty. Susan Stein, First Deputy General Counsel for the Department, filled-in for her.

Dr. Michele David recused herself, "I want to avoid the appearance of conflict of interest so I am recusing myself from this."

PROJECT APPLICATION NO. 5-3B22 OF SOUTHCOAST HOSPITALS, INC. AND PROJECT NO. 2-3B25 OF DANA-FARBER CANCER INSTITUTE:

Mr. Jere Page, Senior Program Analyst, Determination of Need Program, presented the Southcoast Hospital application to the Council. He said, "...Southcoast Hospitals Group is before the Council with a proposal to establish a new radiation therapy service through acquisition of a megavoltage linear accelerator and new construction to accommodate the new unit at a satellite location, located at 200 Mill Road in Fairhaven. Southcoast is a group of three community hospitals in Southeastern Massachusetts that includes Charlton Memorial, Fall River, St. Luke's Hospital, New Bedford, and Tobey Hospital, in Wareham. The proposed new radiation therapy service in Fairhaven will serve cancer patients residing in the combined primary and secondary service areas of the hospitals."

Mr. Page explained, "To determine need for the new service, staff has reviewed actual U.S. Census data, and Massachusetts Institute of Social and Economic Research population projections for towns and cities in each of the primary and secondary service areas of St. Luke's and Tobey Hospitals and cancer cases reported in those same cities and towns. This data is in the staff summary. It was then used to determine a cancer incidence rate for the cities and towns and project total new cancer cases for the year 2010, as well as to determine the number of radiation therapy services needed in the area."

Mr. Page continued, "The recommended maximum capital expenditure for Southcoast is $7.5 million dollars, which will be funded through a 100% equity contribution from Southcoast's available unrestricted funds. Southcoast has agreed to contribute $375,000 over five years, for the greater New Bedford Community Health Network Area, CHNA #26. These funds will be used for a community health outreach and education project that addresses racial and ethnic health disparities in the area, with particular attention to cancer screening and prevention provided by community health workers..."

There were three Ten Taxpayer Groups (TTGs) registered in connection with this project. The Beth Greenspan and Mark Taylor TTGs registered in connection but did not submit written comments. The Robert Motha TTG submitted written comments in support of the project which are noted in the staff summary. No public hearings were requested.

Dr. Ronald Goodspeed, CEO, Southcoast Hospital Group addressed the Council, "...I will be brief and that is easy because the detailed analysis and recommendation of the Department actually factually and rationally speaks for itself. Southcoast is a large community of non-teaching hospitals in the southeastern region of Massachusetts. We have three acute care hospitals and forty outpatient sites in that region. We serve a population of more than 700 thousand people. Southcoast has the highest uninsured volume of community hospitals in the state, and our Emergency Department volume is among the highest in the country. We are the Commonwealth's largest community hospital Medicaid provider. Our patient population is older, sicker and poorer than anywhere else in Massachusetts. As the sole community hospital provider in the Greater New Bedford and Greater Wareham communities, Southcoast is committed to meeting the needs of the population we serve. The service area for this DoN application experiences a substantially higher cancer incidence rate than Massachusetts overall, and the disparity is highest in the eastern portion of the service area, where the proposed linear accelerator will be located. Southcoast seeks approval for a linear accelerator to support a comprehensive cancer program. Southcoast currently diagnoses the majority of all cancer cases in the region. We already offer inpatient and outpatient medical oncology services, surgical oncology services, including the region's only dedicated thoracic surgeon, performing advanced, minimally invasive lung cancer surgery. We have advanced imaging and diagnostic testing with PET CT coming on line this May. We have home care and hospice services and many other support services for cancer patients, and Southcoast has the demonstrated and documented ability to implement new complex care programs that are of high quality and patient safe from the start. Our current oncology program received Accreditation with Commendation from the American College of Surgeons during its most recent survey. With the addition of radiation therapy, this continuum of

care will ensure coordinated, high quality, easy access and efficient care for cancer patients and their families. It is imperative that Southcoast have a full service cancer program to meet the needs of our community and ensure local access to dedicated cancer therapies. The data clearly show our service area is under-served for radiation therapy. Southcoast urges your approval of this DoN application in order to meet the demonstrated community need to have high quality and safe cancer care…"

Discussion followed by the Council. Dr. John Cunningham, Council Member asked Dr. Goodspeed, CEO of SouthCoast Hospital, "This regards condition #5 on page 15 of the staff summary. It states that you seek Accreditation from the American College of Radiology and if you don't get accredited, you will notify the Program Director. Would you be opposed to a language that states, "You will not offer radiation therapy services if you are not accredited, besides just notifying us that you didn't get accredited?" Dr. Goodspeed responded, "I think that it is a matter of how long that process takes and the need to be able to provide the service to patients as soon as possible. If that is a requirement that is held out for other radiation therapy services in the State, we would obviously agree to that." Ms. Joan Gorga, Director, Determination of Need Program, informed the Council that the condition is a requirement of the DoN Guidelines and it is routinely put on applications and the applicant informs DoN when they receive their accreditation. She said, "No one has ever been unable to get the accreditation." Ms. Gorga said further that if anyone should ever tell them they did not receive the accreditation, the matter would be referred to the licensing authority which is the Bureau of Health Care Safety and Quality. Ms. Gorga agreed to notify the Council if an applicant does not receive accreditation so that the Council can attend to the issue.

Mr. Bernard Plovnick, Consulting Analyst, Determination of Need Program presented the Dana Farber Cancer Institute Application to the Council. He said, "…Dana Farber Cancer Institute today seeks DoN approval for substantial change in service that would permit the acquisition of a megavoltage linear accelerator for the establishment of a radiation therapy service on the campus of Milford Regional Medical Center in Milford, Massachusetts. If approved, the service will operate on the first floor of Milford Regional's new Cancer Center building that opened earlier this year. The service will be a collaborative effort of Dana Farber, Brigham & Women's Hospital Physician Organization and Milford Regional Medical Center. The proposed service in Milford is located thirty miles southeast of Worcester and forty miles southwest of Boston. It will provide more convenient access to cancer treatment for inhabitants of the Blackstone Valley area, who would otherwise be required to travel well in excess of thirty minutes to the nearest existing radiation oncology service. Our analysis found Dana Farber's proposed project to be in full compliance with the review factors of the DoN Guidelines for megavoltage radiation and therapy services, and the

Guidelines estimated need for up to eight additional linear accelerators statewide by the year 2010. As a result, the Guidelines support the approval of both Southcoast and Dana Farber applications. We recommend approval with conditions of Dana Farber's application with a maximum capital expenditure of $5,922,485 (October 2006 dollars). The recommended conditions include a provision for Dana Farber to contribute a total of $296,124 dollars to fund community health initiatives in Community Health Network Area 6 and also improvements to medical interpreter and outreach services to patients with limited English proficiency, and a requirement that, within two years, the service be accredited in radiation oncology by the American College of Radiologists. There were two Ten Taxpayer Groups registered for this application, neither of whom submitted comments."

Ms. Anne Levine, Vice-President of External Affairs, of Dana Farber Institute was present at the meeting but did not address the Council. She thanked the Determination of Need staff for their support of the application.

Council Member Harold Cox inquired to why the applications are considered together as comparable? Ms. Gorga explained, "The Determination of Need Regulations allow for what we call Comparability. When applications are received in the same filing cycle, on the same day, they are deemed comparable. The applications came in on the same day and so are therefore comparable." Ms. Gorga further noted, "I should note that the service area for radiation therapy services is statewide. So, technically, they are comparable. However, they are not comparable in terms of geography, sharing service area, etc. So, they are comparable in name only for regulatory purposes."

Council Member Cox made the motion to approve the Southcoast application. After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Project Application No. 5-3B22 of Southcoast Hospitals Group, Inc.**, based on staff findings, with a maximum capital expenditure of $7,512,000 (October 2006 dollars) and first year estimated operating costs of $3,253,000 (October 2006 dollars). A copy of the staff summary is attached and made a part of this record as **Exhibit No. 14, 898**. As approved, the application provides for establishment of a new radiation service through acquisition of a linear accelerator and new construction to accommodate the proposed unit at a satellite location at 200 Mill Road in Fairhaven. This Determination is subject to the following conditions:

1. Southcoast shall accept the maximum capital expenditure of $7,512,000 (October 2006 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. Southcoast shall contribute $7,332,000 in equity (October 2006 dollars) toward the final approved MCE.

3. Southcoast shall agree to operate radiation therapy equipment that has pre-market approval by the Food and Drug Administration (FDA).

4. Southcoast shall not consider ability to pay or insurance status in selecting or scheduling patients for the radiation therapy service.

5. Southcoast shall seek accreditation by the American College of Radiology prior to licensure of the new unit at Fairhaven. If Southcoast does not receive accreditation, it shall promptly notify the DoN Program Director.

6. Southcoast has agreed to provide a total of $375,621 (October 2006 dollars) over a maximum of five years to fund the community health service initiative described previously in Section H: Community Health Initiatives.

7. With regards to its interpreter service, Southcoast shall:

   Continue to post signage that informs patients of the availability of interpreter services at no charge in the Emergency Department and at all key points of entry into the Hospital, as required by Federal guidelines. Signage must be available in the primary languages identified by the Hospital's language needs assessment.

   Develop a plan to ensure the inclusion of LEP patients in surveys and mechanisms that measure patient satisfaction.

   Develop a detailed plan for training for clinical, support and administrative staff on the appropriate use of interpreters.

   Continue to include the Director of Interpreter Services Director in all decision-making processes that have an impact on communities that are racially, ethnically, and linguistically different.

   Use only trained interpreters to provide medical interpretation and/or logistical support.

   Identify how the patient data on race and ethnicity will be used to improve patient care and eliminate health disparities.

Provide a supplemental progress report on the most current DoN conditions as part of the annual Interpreter Progress report.

Continue to obtain the language patient prefers to discuss health related concerns at referrals and/or during admission.

Continue to assess the quality of Interpreter Services and monitor the availability of interpreter competence of interpreters, inclusive of employees.

Continue to provide yearly a Language Needs Assessment ("LNA"). (Guiding principles developed by OHE are a recommended source.)

Southcoast shall submit a plan to address these interpreter service elements to the Office of Health Equity (OHE) within 60 days of DoN Approval, and shall provide Annual Progress Reports to OHE within 45 days of the end of its Federal Fiscal Year. Southcoast shall also notify OHE of any substantial changes to its Interpreter Services Program, as well as follow recommended National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health Care.

Staff's recommendation was based on the following findings:

1. Southcoast is proposing to establish a new radiation therapy service through acquisition of a linear accelerator and new construction to accommodate the proposed unit at a satellite location located at 200 Mill Road in Fairhaven.

2. The health planning process for the project was satisfactory.

3. Need was found for the proposed new radiation therapy service, as discussed under the Health Care Requirements factor of the staff summary.

4. The project, with adherence to a certain condition, meets the operational objectives factor of the DoN Regulations.

5. The project, with adherence to a certain condition, meets the standards of compliance factor of the DoN Regulations.

6. The recommended maximum capital expenditure of $7,512,000 (October 2006 dollars) is reasonable compared to similar, previously approved projects.

7. The recommended operating costs of $3,253,000 (October 2006 dollars) are reasonable compared to similar, previously approved projects.

8. The project is financially feasible and within the financial capability of Southcoast.

9. The project meets the relative merit requirements of the DoN Regulations.

10. The proposed community health service initiatives, with adherence to a certain condition, are consistent with the DoN Regulations.

11. The Beth Greenspan Ten Taxpayer Group (TTG), representing New England Medical Center, and the Mark R. Taylor TTG, representing New England Neurological Associates, both registered in connection with the proposed project. The Robert Motha TTG, representing present and former patients of the Southcoast Hospitals Group registered in support of the project and submitted written comments. The Greenspan and Taylor TTGs did not submit written comments.

Council Member Cox made the motion to approve the Dana Farber application. After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Project Application No. 2-3B25 of Dana-Farber Cancer Institute,** based on staff findings, with a maximum capital expenditure of $5,922,485 (October 2006 dollars) and first year estimated operating costs of $3,890,396 (October 2006 dollars). A copy of the staff summary is attached and made a part of this record as **Exhibit No. 14, 899**. As approved, the application provides for establishment of a radiation therapy service in Milford through acquisition of a linear accelerator. The unit will be located in leased space at the Milford Regional Medical Center campus at 20 Prospect Street, Milford. This service is intended to support state of the art cancer care to be provided at Milford Regional's new cancer center. This Determination is subject to the following conditions:

1. Dana-Farber shall accept the maximum capital expenditure of $5,922,485 (October 2006 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. Dana-Farber shall contribute 100% in equity, or $5,922,485 (October 2006 dollars) to the final approved maximum capital expenditure.

3. For Massachusetts residents, Dana-Farber shall not consider ability to pay or insurance status in selecting or scheduling patients for radiation

therapy services.

4. Dana-Farber shall operate only radiation therapy equipment that has received pre-market approval from the United States Food and Drug Administration.

5. Within two years of approval the applicant shall submit to the DoN Program Director evidence of accreditation in radiation oncology by the American College of Radiology.

6. To ensure optimal and timely provision of competent medical interpreter services and outreach to the limited and non-English proficient (LEP) patients at the proposed radiation therapy clinic, Dana-Farber must have in place:

    a) A comprehensive strategy identifying the specific roles and responsibilities of the contracted party (Milford Regional) that will be providing services at the radiation clinic.

    b) Policies and procedures that establish written protocols to assist staff in readily accessing interpreter services; emphasize the availability of interpreter services at no cost, affirm the use of only trained interpreters, prohibit the use of minors and refrain from requiring, suggesting or encouraging patients to use family members or friends as interpreters.

    c) An annual language needs assessment of the service area with input from community-based organizations, and which includes identification of those languages for which notices shall be posted. (Guiding principles developed by OHE are a recommended source before conducting and LNA.

    d) Training and assessment process for both interpreters and hospital staff who will be working with LEP patients.

    e) Establishing and publicizing grievance procedures regarding access to interpreter services.

    f) Signage at all points of contact and public points of entry informing patients of the availability of interpreter services at no charge.

    g) A reliable and valid system to schedule and track request and monitor completed interpreting sessions, inclusive of the use of

employees;

h) A plan to assess the quality of Interpreter Services and monitor the competence of interpreters, inclusive of employees.

i) A detailed plan for training clinical, support and administrative staff on the appropriate use of interpreters.

j) A comprehensive strategy to inform referral sources and LEP community members about the availability of interpreter services as part of the radiation therapy services.

k) A plan to ensure the inclusion of LEP patients in satisfaction survey.

l) Adherence to recommended National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health Care (materials available online at http://www.omhrc.gov/templates/browse.aspx?1v1=2&1v1ID=15),

m) Notification of the Office of Health Equity of any substantial changes to its Interpreter Services Program and provide an Annual Progress Report to the Office of Health within 45 days at the end of the Federal Fiscal Year.

n) A plan for improvement addressing the above is to be submitted within 60 days of DoN's approval of the Office of Health Equity.

7. Pursuant to DoN Factor 9, Dana-Farber shall do the following:

a) Dana-Farber shall contribute $59,224 annually for a period of 5 years, a total of $296,124, or 5% of the maximum capital expenditure for this project to fund community health initiatives in the Milford area.

b) Dana-Farber shall work with Community Partners for Health (CHNA 6) and Milford Regional Medical Center to design community health programs consistent with the area's targeted health priorities based on the community assessment and strategic planning process based on the healthy communities' principles to be conducted in 2008 by CHNA 6. The programming can include, but is not limited: (1) an annual conference on identified health concern (2) health promotion campaigns targeted at the schools and the community at large and (3) mini-grants to local agencies. A portion of the DoN funds will be allocated to CHNA program support and evaluation of

the programs it undertakes.

c) Dana-Farber and CHNA 6 shall provide the Office of Healthy Communities with yearly reports regarding community health initiatives undertaken including detailed budgets and program outcomes. CHNA 6 will determine the fiscal agent for the funds.

Staff's recommendation is based on the following findings:

1. Dana-Farber Cancer Institute has filed for a DoN for a substantial change in service to acquire a linear accelerator and establish a radiation therapy service in collaboration with Milford Regional Medical Center (Milford Regional) on the Milford Regional campus at 20 Prospect Street, Milford, MA 01757

2. The project was designated a comparable application to that of Project #4-3B22 filed by Southcoast Hospitals Group, Inc.

3. The health planning process was satisfactory and compliant with the Guidelines.

4. The project meets the health care requirements provisions of the Guidelines.

5. With adherence to certain conditions, the project meets the operational objectives requirements of the Guidelines.

6. The project meets the Factor Four standards of the Guidelines.

7. The proposed and recommended expenditure for equipment is reasonable relative to similar, previously approved projects.

8. The proposed and recommended incremental operating costs are reasonable relative to similar, previously approved projects.

9. With adherence to a condition, the project is financially feasible and within the financial capability of the applicant.

10. The project meets the relative merit requirements of the Guidelines.

11. The proposed community health initiative is consistent with the Guidelines.

STAFF PRESENTATION: OVERVIEW OF REGIONALIZATION IN MASSACHUSETTS, BY Geoff Wilkinson, Senior Policy Advisor to the Commissioner and Attorney James Ballin, Deputy General Counsel

Some excerpts from Mr. Wilkinson's Powerpoint presentation follow:

"I am part of a workgroup and a team that has been, for close to two years, been looking at developing a regional system for Public Health in Massachusetts. This is an initiative that was started by Local Public Health Officials around the Commonwealth and has grown to involve a number of stakeholders in and out of government."

The purpose of this project is to strengthen our Massachusetts Public Health system by creating a state-funded regional structure so that we can have equal delivery of public health services across the Commonwealth."

Massachusetts's Statistics:

- Population: 6.3 million
- 351 towns and cities
- 13th in nation for population
- 44th in nation for land area
- 1st in nation for number of local public health depts. (351)
- No county system
- No statewide public health mutual aid system

Local Health Responsibilities (required by state regulation):

- Health Care and disease control
- Food protection
- Housing and dwellings
- Hazardous and solid waste; septic systems (Title V)
- Pools and Beaches
- Camps, motels, mobile home parks
- Nuisances, pesticides, smoking, tattoo parlors, etc.
- Record Keeping and reporting

Top Ten Local Public Health Activities in MA (CLPH/ICH survey, 191 communities, 2006):

- Food Service regulation/inspection (95%)
- Tobacco Retailers regulation/inspection (84%)
- Septic tank installation (92%)
- Solid waste haulers regulation/inspection (77%)
- Housing inspection (91%)

- Food Safety Education (73%)
- Smoke free ordinances (89%)
- Infectious disease surveillance (73%)
- Swimming pools (public)
- Adult immunization (71%)

Programmatic Challenges:

- Pandemic flu
- Emergency Preparedness
- Surge capacity
- Obesity/Diabetes
- Chronic Disease
- Racial & Ethnic Health Disparities
- (Re) Emerging Diseases
- Substance Abuse
- Environmental health
- Uneven healthcare delivery systems

Other Statistics:
67% of reporting cities & towns failed to meet food inspection requirements in 2006
17% of western MA towns kept no records of reportable diseases (2004)
Over 70% of local health officials report that they do not have enough staff to consistently fulfill their responsibilities to the public (CLPH Study, 2006)
Budgets vary dramatically: $200 to $900,000 for towns less than 40,000 population
Competition for limited municipal dollars
No direct state support
Regional disparities
No education, certification or experience requirements for local public health directors in MA.
18% of local health officials eligible to retire in next two years (CLPH/ICH study, 2006)

Benefits of Regionalization:
Increases capacity to provide for the equitable delivery of public health services across state
Allows communities to combine expertise and resources
Clarifies roles and responsibilities at local, regional, and state levels through an integrated system
Establishes standards of performance for agencies and staff
More efficient use of limited resources

Mr. Wilkinson noted that the working group on regionalization of Massachusetts consists of local public health officials, the Coalition for Local Public Health (Professional & Advocacy Organization): MA Health Officers Association, MA Environmental Health Association, MA Association of Health Boards, MA Association of Public Health Nurses, MA Public Health Association), legislators (Public Health and Health Care Financing), State Agencies (EOHHS, MDPH, MDEP) and Academics.

Mr. Wilkinson stated in regards to Council Member Harold Cox, "Harold has really been the Project Leader for this work, starting with his work at the Cambridge Health Department, and then taking leadership of the project to BU School of Public Health. He has been able to help raise money from the Robert Wood Johnson Foundation and the National Association of County and City Health Officers (NACCHO)."

He continued, "We have broad participation from local public health officials around the state, those five local health organizations that I mentioned, a strong leadership and support from the Chairs, especially of the Public Health Committee, Senator Fargo and Representative Koutoujian, and we have the Executive Office of Health and Human Services, and Environmental Protection at the table, as well as DPH."

Mr. Wilkinson stated further, "This work has gone on for a long time, building public support, not just an inside research effort. We have had a lot of meetings. This working group has met at least monthly, often more than that. We have had statewide meetings of different configurations of groups, several published progress reports, statewide meetings, filed a bill as a placeholder and it is being flushed out right now. It is a very broad process. We have articulated principles to guide our work and these have gained support statewide. All residents of the Commonwealth deserve equal access. Your protection of public health services should not depend on where you live, but, in fact, it does now. We have to respect the existing legal authority of Local Boards of Health, which is very broad. We have a strong, even back to the Colonial days, tradition of Home Rule in Massachusetts. The Local Boards of Health are able to set policy and manage at the local level, and they are not about to give that up and we think, in fact, there are some benefits to that. The workplace smoking ban started locally and probably wouldn't have happened in Massachusetts statewide without this Home Rule authority. It has to be voluntary.

Communities need to buy into this or we could see the whole initiative go down the drain. One size does not fit all, and we have defined several models that we think could be used to create districts. It is going to require new and sustained state funding to work, and the intention is to augment the existing workforce, not to replace it, which of course has been a concern of local health…"

Critical Elements of Plan
Provide the ten essential public health services to all residents of Massachusetts
Through an integrated public health system that offers legal foundation, governance structures, and financial incentives for forming districts
Clarify roles and responsibilities at local, regional, and state agency levels
Establish performance standards, including workforce credentials and agency performance measures
Recommend system to routinely deliver comprehensive training for the local public health workforce

Work Group Recommendations
Form Public Health Districts within DPH Regions
Strengthen DPH Regional Public Health Operations

Features of A Regional Health System with Districts
Member cities & towns of each district retain home rule authority
Finances, workforce management, and policy-making within districts to be specified in district governance agreements, backed by statute
District boards guarantee compliance with uniform state performance standards to be established
Qualified districts receive new, sustainable state funding
Current districts (7) to be grandfathered

Mr. Wilkinson described the four models that could be used to form districts:

1. A single entity would be created with its member communities receiving all the services that they need, shared through the district.
2. The Limited Services Model would provide a limited model that all member communities would share in kind. For example, tobacco education, epidemiology, emergency and preparedness. Their local statutory responsibilities they would attend to on their own.
3. A cafeteria model would be where the district would have the capacity to offer whatever services the member communities would need, and different communities would choose what they needed; and

4. A standalone model, for instance Boston and Springfield, and several other communities that have sufficient resources to do what they need to do and provide the essential ten services to their combined population.

Attorney James Ballin, Deputy General Counsel, Office of the General Counsel, Department of Public Health described the legal structure and changes that the workgroup is looking to make. He noted that most of the legal work was done by Cheryl Sbarra and Laura Richards. Atty. Ballin noted in part, "There are basically three sections of the General Laws that address Regional Health Districts. They are all in Chapter 111, Section 27A, 27B and 27C. 27A allows two or more towns to form a district for the purpose of appointing a health officer and any necessary assistants or clerks. Some of the concerns that have been addressed identified with this section. First of all, there is no board of Health involvement with either forming the districts or withdrawing from the district, and right now that authority rests with the governing body of the town. There is no means of adding, or at least it does address a process for adding additional towns to a district that is already formed; and this section applies only to towns not cities. 27B authorizes two or more cities or towns to form a Regional Health District. There is no public health involvement in forming the Regional Health Districts. That is left solely to the governing town or city body. The legal authority of the board of health is handed over to the Regional Health District…And Finally, 27C provides for reimbursement for health districts for initial expenditures at the rate of fifty cents per inhabitant of the constituent cities and towns. This only addresses start-up costs…And this is not currently being funded…"

Atty. Ballin noted other issues identified by the legal workgroup: (1) there is very little language with regard to protection of local public health officials, (2) credentialing of staff, (3) the need for standards for agency performance, and the need to clarify that Regional Health Districts are political subdivisions.

In his closing remarks, Mr. Wilkinson stated in part, "…After this year's work, the goal is to develop a final plan, that would be submitted in the first week of December 2008, for the next two year legislative session with a funding plan, and we hope that the administration will embrace this in future years…"

Council Member Harold Cox added in part, "…It is an important initiative. It is really simple. Local Public Health is in trouble and this is about providing the resources to Local Public Health, to provide the services that it needs. This is a long arduous process of trying to get buy-in, of trying to understand how you change the system, but I believe, ultimately, it is the right thing for us to be doing. So Kudos to all of the folks who have been working on this project and I am interested in the kinds of concerns and issues that may come up in this group."

Council Member Ms. Helen Caulton-Harris, Director, Division of Health and Human Services, City of Springfield said in part, "…I have always been thankful to Harold Cox and John Auerbach for starting this initiative. It is clear to me, that we on the local level lack the

resources to be able to do much of the work that we do, so regionalization is really an important initiative. I am grateful for it...There are a lot of details that need to be worked out. As an individual in a city who has participated in Region 1, in terms of Pandemic Planning, I understand the challenges of working with communities around you whose demographics, perhaps, and whose budgets and whose needs are completely different than your own, and trying to come to consensus around those issues are a challenge..."

Discussion continued around credentialing of the local health workforce and the agencies. Please see the verbatim transcript for full details. Chair Auerbach noted in regard to credentialing, "This is occurring within a national context, and the national context on the issue of credentialing is that the federal agencies that provide a good deal of funding to Public Health, the Centers for Disease Control, the Health Services and Resources Administration, have made it clear that their intention is, over the next several years, to actually require that State and Local Health Departments are able to verify that they can achieve essential public health goals, and there has been resistance to that at the state and local level, but we have been told, it's coming, and in fact, it is being rolled out on a pilot basis in a number of states now...Unless we begin to think about this now, we will be ill-equipped to respond to the Federal requirements and that will actually jeopardize funding."

Discussion continued by the Council Members. Council Member José Rafael Rivera, asked about racial and ethnic health disparities being addressed on the local level and if community health workers or community agencies were being utilized. Mr. Wilkinson replied in part that "very few local health departments are able to address health disparities in any kind of systematic way but most would like to do more." He also said that there was a large disconnect between contract services where you would find the community health workers and local public health, which is not contracting for those services.

It was noted during discussion that the amendments to the statute that the workgroup is proposing to the Legislature would bring Public Health Boards into the loop, consistent with powers that Public Health Boards have now, under statute, to determine policy and to govern their own employment practices. Attorney Ballin said, "It would not replace local city or town authority but add Board of Health authority, as well."

Chair Auerbach said in closing the discussion, "We are fortunate that we have seen other states who, in recent years, have been successful in terms of similar initiatives and in Connecticut, where there were a large number of locals without state or regional structure, where I think they have overcome some of those traditional municipal self-control issues by doing what the characteristics of our proposal would be, which would be voluntary. It is not coercive and there are incentives, primarily in terms of the possibility of acquiring additional resources, which wouldn't exist in the absence of a regional approach...There are several other states that are also in similar processes now, at various stages of the process to develop a regional structure...We are doing this because we see the local need, but also we are moving ahead on this because we will be so out of sync with the rest of the country in terms of being able to mandate that there is a consistent level of quality services that

are available to all people at the local level, that unless we make this initiative, we will be jeopardizing resources, and actually not serving well the residents of the Commonwealth, who are entitled to a level of quality services.

No Vote / Information Only

Proposed Regulations: Informational Briefing on Amendments to 105 CMR 700.000: Implementation of M.G.L.c.94C (Prescription Monitoring Program:

Chair Auerbach stated in part, "What we are doing today is, we are hearing about a proposal to make regulatory amendments. We won't be voting on this today. We are being informed about the effort to release these regulatory amendments for a public hearing process, but we are able, as a Council, to offer comments, suggestions to the staff that are making this recommendation."

Dr. Grant Carrow, Deputy Director, Bureau of Health Care Safety and Quality and Director of the Drug Control Program, presented the proposed amendments to 105 CMR 700.000 to the Council. He was accompanied by Dr. James Wechsler, a board-certified Anesthesiologist with a sub-specialty in Pain Management at South Shore Hospital and South Shore Anesthetist Associates. Dr. Wechsler is also a longstanding member of DPH Medical Review Group and participated in a physician pilot project that DPH conducted.

Dr. Carrow noted that the Prescription Monitoring Program is only one of the initiatives in the Drug Control Program (DCP) whose mission it is to balance, ensuring that there are pharmaceuticals available for medical use for citizens of the Commonwealth, while at the same time working to prevent drug diversion, prescription fraud, elicit use and abuse of those pharmaceuticals…The DCP program is only one of the initiatives the Department undertakes to address the problem of prescription drug abuse and misuse.

Dr. Carrow further noted, "The Program collects data on Schedule II Drugs, which are narcotics, stimulants and sedatives. As you know, they have medical use, but they are highly sought for abuse and misuse and we collect information from community pharmacies, outpatient pharmacies and clinic pharmacies in the Commonwealth, and last year we collected records on 3.2 million Schedule II prescriptions. The data that DCP collects is reviewed and analyzed by the program and the Medical Review Group (consists of physicians, dentists, and pharmacists) who reviews the information and makes recommendations on the clinical aspects of the information and recommends release to appropriate authorities such as regulatory boards and state and law enforcement agencies…"

Dr. Carrow said, "What we are proposing is to change the current provision in which reports are only provided to law enforcement, to enable us to provide reports also to clinicians and to use this as a public safety tool and public health tool. In order to do that, we will need to collect additional fields of information. Further, staff would like to change

the current provision that only provides for a request for an ID on dispensing a Schedule II prescription and make that mandatory, with appropriate exceptions…We now provide reports to law enforcement regulatory agencies such as the Massachusetts State Police, the Medical Board, the Attorney General, and the DEA. We are proposing to provide this information to prescribers and dispensers."

Dr. Carrow noted further, "We anticipate that the information would be used by practitioners' to assist their patients who may be at risk, or are involved in prescription drug diversion or abuse, and we will talk more about providing practitioners with tools to be able to refer their patients to appropriate treatment and/or enter addiction, as needed." Dr. Carrow noted that staff developed a tool kit for practitioners', who receive the information from the program so they know how to interpret the data, what resources are available for managing patients and referral to treatment information.

Dr. James Wechsler addressed the Council. He said in part, "The pilot study that I undertook involved pulling charts from the pain clinic where I am part of the staff and comparing the chart data on prescriptions written against the PMP data to see how it correlated and to see if there were any glaring errors or problems. In fact, the charts followed the data that Grant presented to you. What I did come away with was the potential value of having this data, and the help that it would give a practicing physician who might have a question about prescribing Schedule II narcotics. With access to the database, he could reassure himself that he was prescribing something to someone who isn't seeking prescriptions from multiple prescribers, and I think that is a concern…A lot of primary physicians are afraid to prescribe schedule II narcotics to patients because they don't have any information about whether the patient is legitimate or not, whether the need is legitimate or not, and this kind of data helps them form the opinion."

Discussion followed, please see verbatim transcript for full discussion. Dr. Michael Wong, Council member asked if the data that the PMP collects – is it going to be in concert with Medicaid patient information he receives as a physician which details what prescriptions that are filled by these patients and paid for by Medicaid. Dr. Michele David, Council Member also asked for clarification on how physicians would receive the information. It was clarified that the PMP information would only be received by a physician if a determination was made by the Medical Advisory Board that this exceeded what would be considered to be understandable, appropriate, routine prescriptions of Schedule II drugs. The percentage of patient population for whom a letter would be generated would be a very tiny percentage of the patient population. The PMP data would show all patients not just Medicaid patients and also show Medicaid patients paying with cash. Council Member Denis Leary asked about the small amount of narcotics dispensed in emergency rooms to patients. It was noted that ER dispensing would probably not show up in this data base because there would be no prescription. Council Member Cunningham inquired about whether the proposed amendments take into account comments from the previous public hearing (February 2006) and from drug store chains. Dr. Carrow said, "Yes that they met

with the Massachusetts Medical Society and the National Chain Store Drug Council and others to ensure that the regulations address their concerns…"

Discussion continued and Council Member Paul Lanzikos asked if mail order prescriptions would be included in this PMP analysis. Dr. Carrow said they would only be able to include a Massachusetts mail-order pharmacy and there are none at this time. He noted that there is a separate effort funded by the U.S. Justice Department that will address sharing of information between states. Council Members Mr. José Raphael Rivera and Mr. Harold Cox voiced their concern about the protection and rights of the individual patients. Chair Auerbach replied in part, "…The vast majority of patients receiving Schedule II prescriptions will not be affected at all by this. It would be where we see a very large number of prescriptions in a given year, perhaps as many as a dozen to that many different pharmacies that it would raise the point that a clinician would say this seems to be so unusual that we need to take the rather unusual step of contacting the clinicians involved to let them know. We clearly hear your concern and where we set that threshold needs to be mindful of protecting patient rights and we will be doing that."

Council Member Lanzikos asked if problematic behaviors by prescribers are included in the PMP. Dr. Carrow noted that this information is already collected by the PMP for law enforcement. Dr. Carrow stated in part, "…The requirement to have an ID will actually deter a lot of prescription fraud, possibly including elicit prescribing. That might be an expected benefit." Dr. David asked for clarification on the ID requirement would this still allow family members and others to drop-off and pick-up prescriptions for patients. The answer was yes, the ID does not have to be the patients.

In closing, Chair Auerbach noted in part, "…We look forward to hearing the public comments from the hearing and the vote in a couple of months…"

No Vote / Information Only

The meeting adjourned at 11:45 a.m.

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John Auerbach, Chair

LMH