PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, August 13, 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. Helen Caulton Harris, Dr. John Cunningham, Dr. Michèle David, Dr. Muriel Gillick, Mr. Paul J. Lanzikos, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Dr. Alan C. Woodward and Dr. Barry S. Zuckerman. Absent were: Mr. Harold Cox, Mr. Denis Leary, Dr. Meredith Rosenthal, Mr. Albert Sherman, and Dr. Michael Wong. Also in attendance was Attorney Donna Levin, DPH General Counsel.

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 further that docket item 4a (Project Application No. 2-3B23 of Mass. Bay Radiation Services was pulled from the docket due to lack of quorum on that item).

RECORDS OF THE PUBLIC HEALTH COUNCIL MEETINGS OF APRIL 9, 2008 AND MAY 14, 2008:

Dr. Alan Woodward made the motion to approve the **Record of April 9, 2008**. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the Record of the Public Health Council Meeting of April 9, 2008 as presented. The minutes had been distributed to the members prior to the meeting for review.

Dr. Alan Woodward made the motion to approve the **Record of May 14, 2008**. After consideration upon motion made and duly seconded, it was voted (unanimously) to approve the Record of the Public Health Council Meeting of May 14, 2008 as presented. The minutes had been distributed to the members prior to the meeting for review.

Proposed Regulations: Informational Briefing on Amendments to Regulations Governing the Testing of Newborns for Treatable Diseases and Disorders – 105 CMR 270.000:

Dr. Laurel Smith, Medical Director for the Department of Public Health presented the informational briefing on proposed amendments to 105 CMR 270.000. Dr. Roger Eaton of the New England Newborn Screening Program, University of Massachusetts Medical School accompanied Dr. Smith and answered questions for the Council.

Dr. Smith noted that the proposed regulations will update the requirements for the mandatory and optional screening provided by the Department of Public Health's newborn screening program. Dr. Smith provided the history and background of the program. She noted, "Pursuant to M.G.L. c.111, §§ 4E and 110A, the Department has established a newborn screening program to ensure that newborns are tested for treatable genetic, biochemical or infectious disorders or diseases. The disorders tested for are determined by the Commissioner of Public Health, at his discretion with the assistance of and "advisory committee on newborn screening". The Commissioner has the authority to mandate that newborns be screened for these disorders unless the parent(s) have a religious objection."

Staff's memorandum to the Council, from Dr. Smith and Ms. Sally Fogerty, Director, Family Health and Nutrition Bureau, dated August 13, 2008 notes that the Newborn Screening Program is operated by an interagency service agreement with the University of Massachusetts Medical School which runs the New England Newborn Screening Program. UMMS provides pre-test educational materials and infrastructure, tests the blood samples, reports test results, works with physicians, parents, and the Bureau of Family Health to ensure the necessary follow-up for repeat testing and care, and provides analyses and summary reports for the Department.

It was noted that from 1963 to 1999, disorders were added one at a time for mandated screening through amendment to the 105 CMR 270.000. In 1998, Massachusetts practiced statewide mandated screening for 9 disorders/diseases (more than any other state at the time). With the advent of a then-new technology, tandem mass spectrometry (msms) it became possible to test for several disorders with one blood sample and one multiplex assay so in 1999, Massachusetts increased the mandate to 10 disorders and began an optional program that allowed parents to access screening for an additional 20 disorders. This practice continued to the present time."

Chair Auerbach asked Dr. Smith to elaborate on the "distinguished chairperson of the Newborn Blood Screening Advisory Committee" which is current Council Member Dr. Barry Zuckerman. Chair Auerbach thanked Dr. Zuckerman for his "selfless contribution" on the advisory council. Dr. Zuckerman is the present Chair and has been since the inception of the advisory council in 1997, originally convened by Commissioner Howard Koh. The Committee met from December 1997 through June 1998 and developed guidelines/criteria for mandated screening and reviewed multiple additional metabolic disorders detectable by msms as well as cystic fibrosis. It was noted that the 1997/98 deliberations yielded recommendations that only one disease be added to the mandated list because not enough was known about the natural history or any effective

treatment for the other disorders. The Committee further recommended implementation of two pilot research studies on (1) 19 metabolic disorders and (2) cystic fibrosis (the additional 20 disorders mentioned above for optional screening). Following public hearings on the 1998 amendments, the Public Health Council adopted the regulations which became effective in February of 1999. Dr. Smith noted that in 2005, the Federal Health and Human Services Secretary's Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children recommended implementation of a national uniform newborn screening panel with the expansion of newborn screening to 29 conditions. This recommendation was endorsed by the Academy of Pediatrics and the March of Dimes as well as the American College of Medical Genetics. Massachusetts has been testing for all of these conditions since 1999 through the pilot studies but does not mandate screening for all of them.

It was noted in Staff's memorandum to the Council, dated August 13, 2008, that the newly reconvened Newborn Screening Advisory Committee met several times over the past year to consider and develop recommendations to the Department concerning:

1. Whether screening for certain additional disorders should be mandated based on additional information available since 1998, including those disorders which are the subject of the pilot studies listed in the 1998 regulations; and

2. Whether there are any conditions, either currently offered through the pilot study or not currently screened for, that should be offered through the pilot study.

The Newborn Screening Advisory Committee recommended the following changes (based on the sound criteria developed in 1998) to the regulations and the pilot study disorders. The basic requirements for a mandatory screen are:

- There is an accurate screening test;
- the disorder is treatable;
- early treatment is beneficial;
- there is a significant, life-challenging risk of morbidity if the disorder is untreated in newborns; and
- the positive benefits outweigh the risks and burdens of screening and treatment on newborns and relatives.

The Committee decided that the pilot study disorders should remain voluntary and still felt that not enough information was available about the natural history of the disorders or efficacy of treatment to mandate that parents have their

newborns screened for the disorders. However, the Committee thought that the study could provide enough information to know whether the disorders should be screened for in the future on a mandated basis. A brief discussion followed and Dr. Barry Zuckerman acknowledged Ms. Kathy Atkinson, Assistant Commissioner of Policy and Planning at the time and General Counsel Donna Levin for their work on the Advisory Board. He said in part, "...I take great pride in the work that the committee did....It's an interesting story. This firm developed the technology to do the testing and really pushed to have it. It was being done in Pennsylvania and one other state. The question became the ethical one, 'just because we can do it, should we?' It took about ten meetings to decide on the criteria and the conclusion of 'if you can't show that these things are treatable, we shouldn't do the testing.' I think we took a strong ethical position in the face of burgeoning technology that was really the right thing to do...We basically accomplished improving the public health through the method we do without violating that ethical concern..." Chair Auerbach acknowledged that it was breaking new ground at that time and further thanked Dr. Roger Eaton, Dr. Anne Comeau, and Sally Fogerty for their work. It was further noted that Sally Fogerty was retiring from the Department in September. She was thanked for her decades of work at the Department.

Dr. Muriel Gillick inquired about the religious objection, asking in part, "...Why would it be acceptable for parents to potentially deprive their infants of treatment?" General Counsel Donna Levin replied that it is a statutory requirement so it can't be altered by regulation. Dr. Roger Eaton replied that religious objections are rare – that they receive five or less a year.

<u>Proposed Amendments to the Regulations</u>:

1. Section 270.006 (A): Lists the disorders proposed for mandated screening. All of the new proposed disorders for mandated screening have been offered under the pilot studies since 1998.

2. Section 270.006 (B): Lists the disorders for which optional pilot studies will be conducted. These include 5 disorders currently offered in pilot study for which not enough information is known to determine whether they should be mandated, and a disorder new to the list – severe combined immune deficiency.

3. Section 270.006 (C): Lists those disorders that are not tested for directly, but that may be identified during the screening process. These "by-product conditions" do not currently meet the criteria for mandated screening, but if found, will be reported to the attending physician and infants would be followed (like the practice for pilot disorders).

4. Section 270.006: The changes in mandated and pilot disorders are effective February 1, 2009 in order to allow sufficient time for the NENSP to prepare for the change in screening.

5. Sections throughout the regulations: The program's name is changed from Newborn Screening Program to Newborn Blood Screening Program, and the testing is referred to as blood screening to distinguish it from newborn hearing screening.

6. Section 270.004: Includes new definitions for Mandated screening, Newborn Blood Screening Program and Pilot Study; and revised definitions for Attending physician, Screening and Specimen.

7. Section 270.006 (B) (3): Language is deleted that referred to the approval of a research protocol because it was approved and implemented in 1999 and continues today.

8. Section 270.007 (A): Clarification of instruction on time to take specimen.

9. Section 270.008: Clarification that for out-of-hospital births, parents receive the bill for the testing.

10. Section 270.010: New section on follow-up of newborn blood screening to require attending physicians to provide information on diagnosis and long-term outcomes for purposes of quality assurance, ongoing evaluation of the effectiveness of the program and the determination of those disorders that should be screened for.

11. Section 270.011 – New section on confidentiality that states the current policy of the program to maintain confidentiality of testing results.

In conclusion, Dr. Smith said that a public hearing would be held on the proposed regulations this fall and return to the Public Health Council for final promulgation in late fall or early winter. General Counsel, Attorney Donna Levin noted a typo correction on page 3, 105 CMR 270.006 (A) (29) the word "trype" should be "type".

NO VOTE / INFORMATION ONLY

DETERMINATION OF NEED PROGRAM:

COMPLIANCE MEMORANDUM:

PREVIOUSLY APPROVED PROJECT NO. 2-3A79 OF UMASS MEMORIAL MEDICAL CENTER:

Note: Council Member Dr. John Cunningham recused himself from discussion and vote on this item.

Ms. Joan Gorga, Director, Determination of Need Program, presented the UMass Memorial Medical Center application to the Council. Ms. Gorga noted in part, "...This request is for significant changes to its approved but not yet implemented DoN Project No. 2-3A79. The changes include increasing the maximum capital expenditure (MCE) from $22,698,493 (February 2005 dollars) to the maximum capital expenditure (MCE) of $39,199,697 (July 2008 dollars), an increase of 43% and adding 18 medical/surgical beds in 25,000 Gross Square Feet (GSF) of increased new construction. The 25,000 GSF of new construction is in addition to the 40,037 GSF of new construction and 3,500 GSF of renovation previously approved..."

Staff's memorandum to the Council, dated August 13, 2008, further states, "The holder is requesting approval of changes to the approved MCE for new construction and renovation as a result of the planned build-out of inpatient beds in the shell space originally associated with the Radiology Project. The holder has included an allocation of the original core and shell costs for this space....The inpatient costs of the Radiology Project were less than the capital expenditure threshold when originally planned so no DoN was filed for this space. The holder is requesting an inflation-adjusted increase of $11,859,101 (July 2008 dollars), the net effect of a $244,854 decrease in renovation costs and a $12,103,955 increase in new construction costs for the cost of building out the 18 beds."

Staff indicated further, "In its submission, UMMC has described the need for additional medical/surgical beds. The holder indicates that it has experienced a significant increase in inpatient volume which has exacerbated its shortage of medical surgical beds in private rooms. These beds are necessary to place patients for infection control, or to address gender or other medical requirements or specialized staffing needs. Patients are now boarded in the emergency department and its adjacent hallways while awaiting beds. On average, four to six patients per day are waiting for private beds. The flow of surgical patients is adversely impacted by a shortage of beds for patients scheduled for an operating room procedure. Patients remain in the Post

Anesthesia Recovery Unit (PACU) because there are not enough medical/surgical or step down beds available for them."

Staff's memorandum further explains, "UMMC expects to use the beds primarily for cardiovascular cases and stroke patients and as part of the Project will relocate existing cardiac diagnostic testing equipment and respiratory therapy to space adjacent to the unit. The space which has windows and exterior views, is the only available location which satisfies both space and design requirements to meet the clinical need for additional beds. In determining the reasonableness of the requested capital expenditure, staff reviewed the cost/GSF for new construction. Based on the requested 25,000 GSF for new construction, the requested cost/GSF is $481.00 (July 2008 dollars). Staff has compared the requested new construction cost to the most recent Marshall & Swift Valuation Service ("Marshall") class A "Excellent" base cost/GSF (November 2007) under its General Hospital designation... The cost for new construction for this project is lower than the Marshall recommendation. The $481.00/GSF is also within the range of costs for previously approved projects which ranged from $350-800/GSF...Staff has determined that the requested changes in the GSF and maximum capital expenditure (MCE) were reasonable in light of past decisions." Ms. Gorga noted a correction to the staff summary, "...in the last sentence of the first paragraph in the staff analysis. Staff stated incorrectly that there was an increase in renovation costs. It is really a slight decrease ($244,854). The staff recommendation for the total MCE and the conditions on Page 4 are not affected by this correction."

Dr. Alan Woodward made a motion to approve the request. After consideration, upon motion made and duly seconded, it was voted (unanimously) [except for Dr. Cunningham who recused himself] to approve the significant change to approved but not yet implemented **DoN Project No. 2-3A79 of UMass Memorial Medical Center, Inc.** to increase the maximum capital expenditure from $22,698,493 (February 2005 dollars) to $39,199,697 (July 2008 dollars), an increase of 43% and adding 18 medical/surgical beds in 25,000 Gross Square Feet (GSF) of increased new construction. The 25,000 GSF of new construction is in addition to the 40,037 GSF of new construction and 3,500 GSF of renovation previously approved. This amendment is subject to the following conditions:

1. The total GSF for this project is shall be a total of 68,537 GSF: 65,037 GSF for new construction to replace eight existing Ors, add two new Ors, add space for pre/post-operative recovery and a PACU and add 18 medical/surgical beds; and, 3,500 GSF for renovation to expand two existing surgical suites.

2. The holder shall provide approximately $825,060 over five years ($165,012 per year) for community programs according to the following:

   a. Funding Allocation

   - Approximately $30,000 annually to support Common Pathways operations

   - Approximately $135,012 to be granted to community projects through a Request for Proposal process following the current UMass Memorial Common Pathways DoN Committee process that was established through the original Level 2 Operating Room DoN Project No. 2-3A79

   - The Request for Proposals decision-making process will be under the guidance of the UMass Memorial Common Pathways DoN Committee which is comprised of 10 individuals, of which 5 are members of the UMass Memorial Community Benefits Advisory Committee and 5 are Common Pathways members.

   5. Reporting

   - An annual written report on the RFP process, grantees, and program outcomes will be submitted by the UMass Memorial Common Pathways DoN Committee to the Office of Healthy Communities at the Massachusetts Department of Public Health

   - All grantees, including Common Pathways, will submit a written report on their program goals and outcomes to the UMass Memorial Common Pathways DoN Committee

3. All other conditions attached to the original and amended approval of this project shall remain in effect.

A representative of UMass Memorial Medical Center was present but the Council had no questions. Chair Auerbach added for the record that lack of questions by the Council doesn't mean this application wasn't taken seriously; that the Council Members reviewed the application thoroughly.

Project Application No. 2-3B53 of Heywood Hospital, Inc.:

Note: Council Member Josè Rafael Rivera recused himself from participating in the discussion and vote on this item.

Mr. Bernard Plovnick, Consulting Analyst, Determination of Need Program, presented the Heywood Hospital application to the Council. He said in part, "Heywood Hospital is a 134-bed acute care community hospital located at 242 Green Street in Gardner, serving a primary service area comprised of eight Central Massachusetts towns. Heywood has filed a Determination of Need application for substantial capital expenditure to replace and expand exiting facilities. The proposed project involves the construction of a three-story building encompassing 72,000 gross square feet adjacent to the existing inpatient facility. The project would not result in new services or additional bed capacity. Rather, the project would replace and upgrade antiquated and substandard facilities for core clinical services and also free up space for other clinical and support services that currently occupy inadequate space. The scope of new construction includes expansion/renovation of the lobby and relocation of the emergency department on the first floor; relocation of 25 beds, including the existing intensive care (ICU) and telemetry units on the second floor; and construction of shell space for future relocation of 25 adult medical/surgical beds. The project also would involve relocation of imaging services, including CT scan and MRI, to space adjacent to the new emergency department on the first floor."

Mr. Plovnick noted further, "The project would not result in any new services or additional bed capacity. AS discussed in the staff summary, the uppermost floor of the building would be constructed as shell space to accommodate the replacement of an additional 25 existing beds in the future. Construction of shell space has been permitted on a case-by-case basis in a select number of previously approved projects, such as the one we just discussed, UMass Medical Memorial, including applications also submitted by Baystate Medical Center, Cape Cod Hospital and Massachusetts General Hospital. Staff analyzed Heywood's shell space proposal and found it to be reasonable and consistent with the previous approvals mentioned. In all other respects as well, the proposed project conformed to DoN Guidelines and to similar previously approved projects. Staff is recommending approval of this project with five conditions, as detailed on pages 9 through 11 of the staff summary and the recommended maximum capital expenditure of $34,952,586 (February 2008 dollars) and the applicant will be contributing $1,720,000 over nine years in funding support for Healthy Communities programs in the greater north central Massachusetts area."

The applicant, Daniel P. Moen, President/CEO of Heywood Hospital addressed the Council briefly. He said in part, "...Just a few comments on the project. Obviously, it is a very important one for Heywood. We are looking to improve quality, safety, patient experience through new facilities for our most important services, emergency room, med, surg, ICU. The financing is in place and is ready to go as is the design. We also have had a review of our interpreter, multi-cultural program, which I think is a very

strong program and we are looking to go forward and make that even stronger in the future…"

Council Member Dr. Muriel Gillick asked, "I note in the staff summary that it indicates that over the last three years utilization of the telemetry beds has been averaging 60 percent and the ICU beds 25 percent, which seems a little on the low side. Is there an expectation that with upgrading of the facilities that the ICU bed occupancy in particular will increase?" Mr. Moen replied, "We believe that is a distinct possibility with new facilities. We are also actively recruiting new positions to the community as well. The other interesting thing is as a smaller hospital, the averages don't tell the whole story. We have spikes in volume that get us to capacity at times, so it is important for the community to have that available especially in the event that there is a significant flu epidemic or the like in upcoming seasons."

Ms. Lucilia Prates Ramos made a motion to approve the Heywood Hospital application. After consideration, upon motion made and duly seconded, it was voted unanimously [except for Mr. Rivera who recused himself] to approve **Project Application No. 2-3B53 of Heywood Hospital, Inc.**, with a maximum capital expenditure of $34,952,586 (February 2008 dollars) and first year incremental operating costs of $2,311,776 (February 2008 dollars). A staff summary is attached and made a part of this record as **Exhibit No. 14, 908.** As approved, this application provides for construction of a three-level, 72,000 GSF addition to its existing facility to accommodate its intensive care and telemetry units, emergency department, imaging services, and shell space for the future relocation of existing inpatient beds. This Determination is subject to the following conditions:

1. Heywood Hospital shall accept the maximum capital expenditure of $34,952,586 (February 2008 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. The total gross square feet (GSF) for this project shall be 72,000 GSF of new construction, including 16,000 GSF of shell space.

3. Heywood shall contribute equity in the amount of $8,952,586 (February 2008 dollars), representing 26% of the final approved MCE.

4. With regards to its Medical Interpreter Service, Heywood shall maintain the following elements of a professional medical interpreter service:

    a. Written policies and procedures that consistently

        - Provide interpreter services at no cost;
        - Affirm the use of only trained interpreters to provide medical interpretation and/or logistical support;

- Prohibit the use of minors; and
- Discourage the use of family members and friends as medical interpreters.

b. Signage posted at all points of entry informing patients of the availability of interpreter services at no charge.

c. Ongoing training for all hospital clinical staff on the appropriate use of interpreter services, including telephone services.

d. Assessment and assurance of the quality of staff and contracted vendors that function as trained interpreters.

e. Use of patient data on race and ethnicity to improve patient care and eliminate health disparities.

f. Submission of an Annual Progress Report to OHE within 45 days of the end of the federal fiscal year (September 30).

g. Notification of OHE in the event of any substantial changes to interpreter services program.

h. 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).

i. Inclusion of the Director of Interpreter Services in all matters affecting the accessibility of populations that are racially, ethnically, and linguistically different.

j. Submission of a plan for improvement addressing the above items to OHE within 45 days of DoN Approval.

5. Heywood shall provide a total of $1,720,000 over a nine year period to fund community health service initiatives in its service area and the greater North Central Massachusetts region in the following manner:

   a. The funds shall be allocated as follows:

Joint coalition on Health (34%)	$584,800 over 7 years
CHNA #9 (26%)	$447,200 over 9 years
Collaborative Funding (40%)	$688,000 over 9 years

b. Payment shall be made as follows:

Joint Coalition on Health	$83,543 per year for seven years beginning in 2010
CHNA 9	$30,000 per year for two years, beginning in 2008, and seven years of funding at $55,314 per year beginning in 2010
Collaborative Funding	$20,000 per year for two years, beginning in 2008, and seven years of funding at $92,571 per year beginning in 2010

c. Funding support (as designed in the above chart) shall begin within 30 days following DoN Approval. In its allocation and expenditure of these funds, Heywood shall adhere to the processes described in its revised Factor 9 submission dated July 29, 2008 and attached to the DoN Staff summary. Heywood, in collaboration with the CHNA and the Joint Coalition on Health shall submit an annual report to the Office for Healthy Communities describing the programs established and supported through this funding, the level of funding support for each, and a measure of program impact, as indicated by process or outcome measures.

This application was approved based on the following staff findings:

1. Heywood Hospital, Inc. has proposed construction of a new 72,000 square foot acute care building to replace its existing ICU, telemetry unit, and emergency service. This includes the construction of 16,000 GSF of shell space for the future relocation of existing acute beds.

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

3. The applicant has demonstrated need for the proposed project.

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 compliance factor of the DoN regulation.

6. The recommended maximum capital expenditure of $34,952,586 (February 2008 dollars) is reasonable compared to similar, previously approved projects.

7. The recommended operating costs of $2,311,776 (February 2008 dollars) are reasonable compared to similar, previously approved projects.

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

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.

Project Application No. 6-3B55 of Northeast Hospital Corporation/Beverly Hospital:

Note: Donna Levin, General Counsel for the Department of Public Health stepped down on the Northeast Hospital Corporation application; Attorney Susan Stein, First Deputy Counsel for DPH filled-in as General Counsel.

Mr. Jere Page, Senior Analyst, Determination of Need Program, presented the Northeast application to the Council. He said in part, "...Northeast Hospital Corporation/Beverly Hospital has filed a DoN application to expand its magnetic resonance imaging (MRI) service through acquisition of two MRI units. One unit, a mobile MRI housed in a self-contained trailer with a permanent building connector, will be located on the main campus of Northeast Hospital Corporation/Beverly Hospital at 86 Herrick Street in Beverly. The second unit is a fixed MRI unit that will be located at NHC/BH's ambulatory care facility at 480 Maple Street in Danvers. NHC/BH is a 223-bed acute care community hospital located in Beverly, which also includes other acute care facilities: Addison Gilbert Hospital in Gloucester, BayRidge Hospital in Lynn, Beverly Hospital in Danvers, and the Beverly Hospital Hunt Center in Danvers. NHC is also the acute care division of the Northeast Hospital System, which is among the largest providers of health and human services in Essex County.

It was noted in the staff summary dated August 13, 2008 and by Mr. Page at the meeting "that NHC/BH and North Shore Medical Center was part of a joint venture doing business as the North Shore Imaging Center (NSMIC) to provide diagnostic imaging services, including MRI services, originally approved in August of 1984. Since that time NSMIC has received DoN Approval to operate a total of six MRI units. In September of 2007 NSMIC ceased the operation of MRI services so that each entity could more efficiently and cost-effectively provide MRI services individually. In October of 2007, The DoN Program Director approved NHC/BH's 308 exemption request (requested in September 2007) to acquire and operate two MRI units, one mobile unit

on the Beverly Hospital campus and one fixed unit at the Hospital's ambulatory facility site on Maple Street in Danvers. Consistent with the terms of the DoN Exemption letter of approval, the present NHC/BH DoN application has been filed within six months of the Section 308 exemption approval date, requesting final approval to expand it's MRI service by acquiring and operating two MRI units, one mobile and one fixed. It was further noted that the revised MRI guidelines adopted by the Public Health Council on August 19, 1997, allocate MRI units on a statewide basis, and recommends that applicants with existing licensed MRI services be allowed to expand their existing services provided that the applicant's present units operate at 90% capacity for the past year, evidenced by the number of scans performed annually and the hours of operation. NHC/BH submitted information demonstrating that in FY 2007, both their mobile and the fixed unit operated beyond the 90% capacity requirement of the Guidelines."

Mr. Page said further, "The recommended maximum capital expenditure is $3.8 million, include the fair market value which is $750,000 of the leased mobile MRI van and unit at Beverly Hospital. This will not be included in the applicant's equity contribution for the project. As a result, the equity contribution in this case will be 3.1 million which is 100 percent of the applicable recommended MCE for the project. With regard to the community initiatives, staff notes that the two proposed MRI units are considered to have previously funded community initiatives and therefore, there are no new initiatives recommended for this project, for either of these units."

Mr. Page continued, "The Margaret O'Malley and Steven Goldin Ten Taxpayer Groups were registered in connection with the proposed project and requested a public hearing which was held on June 3 in Beverly. The O'Malley taxpayer group believes that there's an access problem for Cape Ann residents seeking MRI services and recommended that the proposed mobile MRI unit at Beverly be available to provide MRI services at least one full day each week at Addison Gilbert Hospital in Gloucester. Staff did not find compelling information that would indicate an access problem for Cape Anne residents. Staff notes, however, that the applicant has agreed, as a condition of approval, to provide free transportation to residents with transportation hardship in Gloucester, Manchester, Essex and Rockport, essentially Cape Ann, and are referred for MRI services at the applicant's facilities in Beverly, Danvers and Peabody. In conclusion, we are recommending approval of this project with the conditions indicated on pages 10 and 11 of the staff summary as well as the attachment 1, which provides further detail on condition No.5..."

Mr. Denis Conroy, CEO of Beverly Hospital addressed the Council. Ms. Christine Aiello, Director of Radiology at Beverly Hospital joined him to answer questions by the Council Members, including a question by Council Member Paul Lanzikos, who inquired about transportation between the facilities for the patients of Cape Ann that will have to travel for MRI services to the facilities in Beverly, Danvers and Peabody. He acknowledged the Determination of Need staff for their work and support of the application. Ms. Aiello and Mr. Conroy agreed that they could provide free transportation for the hardship

patients between the facilities and further that they would put the transportation availability information in writing for the patients as well as include it in their financial counseling group process.

Mr. Conroy noted briefly, "Just to focus on one matter, keep in mind that this is just a redistribution of the six units that are presently in the joint venture, three going to Beverly and three going to Salem Hospital. It's technically an expansion under the DoN rules, but there is not really an expansion of units in the Commonwealth or on the North Shore. With regard to the condition on transportation, we already offer a program similar to this. The DoN staff is asking us to formalize it and we are quite comfortable doing that."

Chair Auerbach noted that State Senator Bruce E. Tarr of the First Essex and Middlesex District, submitted a letter, which staff noted arrived after the deadline so the letter is not considered part of the official record. However Chair Auerbach had copies of the letter handed out to the Council Members and Senator Tarr's concerns were discussed. Please see verbatim transcript for full discussion. In brief, Senator Tarr's letter indicated he had concerns about the hospital not communicating with the community and being responsive to the health care needs of the community and further about availability of services at Addison Gilbert Hospital including surgical and MRI services and finally about adequate capital investment and staffing at AGH. As noted in the above paragraph, the hospital representatives assured the Council that community health needs were being addressed and met at their facilities and at the Addison Gilbert Hospital in Gloucester. In response to Senator Tarr's comments, Mr. Conroy said he felt that they were responsive to the community and that they try to be. He said that they are very committed to the Addison Gilbert Hospital. He noted that they operate a 24-hour hospital based emergency room at the Addison campus, maintain 24/7 hospitalist coverage, maintain two physicians 24/7, have electronic order entry to reduce medical errors there, and they are putting millions of dollars into building suites for specialty services to enhance capabilities there. He said they helped launch a community health center across the street from the hospital and that they have Cape Ann residents on the NHC Board on all their committees. And further that their CEO meets with the Gloucester City Council and the Rockport Board of Selectmen on an annual basis. In response to the inquiry by Council Member José Rafael Rivera, Mr. Conroy said his organization is in communication with the local Community Health Network Area (CHNA).

For the record, the two Ten Taxpayer Groups did not testify at the Public Health Council meeting.

Council Member Helen Caulton-Harris moved for approval of the application as presented by staff. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve **Project Application No. 6-3B55 of Northeast Hospital Corporation/Beverly Hospital** with a maximum capital expenditure of

$3,865,044 (March 2008 dollars) and first year incremental operating costs of $2,828,080 (March 2008 dollars) at the Danvers site and $1,739,528 (March 2008 dollars) at the Beverly site. A staff summary is attached and made a part of this record as **Exhibit No.14,909.** As approved, this application provides for expansion of its Magnetic Resonance Imaging (MRI) service through acquisition of two MRI units. One unit, a mobile MRI housed in a self-contained trailer with a permanent building connector, will be located on the main campus of Beverly Hospital at 86 Herrick Street in Beverly. The second unit is a fixed MRI unit that will be located at Beverly Hospital's ambulatory care facility at 480 Maple Street in Danvers. This Determination is subject to the following conditions:

1. NHC/BH shall accept the maximum capital expenditure of $3,856,044 (March 2008 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. NHC/BH shall contribute $3,115,044 (March 2008 dollars) or 100% in equity of the applicable final approved maximum capital expenditure.

3. For Massachusetts residents, NHC/BH shall not consider ability to pay or insurance status in selecting or scheduling patients for MRI services.

4. NHC/BH shall agree to operate MRI equipment that has pre-market approval by the Food and Drug Administration.

5. NHC/BH shall provide free transportation to residents with transportation hardship who reside in Gloucester, Manchester, Essex and Rockport, and are referred for MRI services at Beverly Hospital, Beverly, Beverly Hospital in Danvers, and North Shore Magnetic Imaging Center in Peabody. Transportation hardship is defined as <u>one</u> of the following patients who are non-ambulatory, elderly; do not have access to transportation or with financial hardship. Further details of this condition are specified in <u>Attachment 1.</u>
6. With regards to its interpreter service, NHC/BH shall:

    - Develop interpreter policies and procedures that are direct and consistent to avoid individual interpretation.

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

    - Discourage the use of family and friends as medical interpreters.

    - Provide timely, accurate, competent and culturally appropriate patient educational materials. The Guidelines developed by OHE on translating

materials are a recommended source.

- Provide ongoing training for all hospital clinical staff on the appropriate use of interpreter services, inclusive of telephonic services.

- Include the Director of Interpreter Services in all decision-making that may have an impact on communities that are racially, ethnically, and linguistically diverse.

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

- Prohibit the use of minors as medical interpreters.

- Post signage at all points of entry informing patients of the availability of interpreter services at no charge.

- Develop a policy to ensure the quality and competence of interpreters provided through contracted vendors.

- Submit a plan to OHE addressing the above requirements within 45 days of DoN Approval.

NHC/BH shall notify OHE of any substantial changes to its Interpreter Services Program, and progress reports shall be submitted annually to OHE within 45 days of the end of the federal fiscal year. Also, NHC/BH shall follow recommended National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health Care.

Staff's recommendation was based on the following findings:

1. Staff found that NHC/BH has engaged in a satisfactory health planning process.

2. Staff found the proposed NHC/BH project to be consistent with the DoN Health Care Requirement standards.

3. Staff found that with adherence to certain conditions, the NHC/BH MRI meets the operational objectives requirements of the Guidelines (revised August 19, 1997 DoN Guidelines for MRI).

4. Staff found the proposed maximum capital expenditure (MCE) of $3,865,044 (March 2008 dollars) to be reasonable, based on similar, previously approved

projects.

5. Staff found the proposed individual incremental operating costs for both the fixed and mobile MRI units to be reasonable compared to similar, previously approved projects. All operating costs are subject to review and approval by the Division of Health Care Finance and Policy and third party payers according to their policies and procedures.

6. Staff found the project to be financially feasible, consistent with the MRI Guidelines, and within the financial capability of NHC/BH.

7. Staff found that the project meets the relative merit requirements of the Guidelines.

8. There is no community initiative funding requirement at this time since four of the six MRI units licensed by NSMIC previously funded community health initiatives. Two remaining units of the NSMIC will be divided between NHC/BH and NSMC/SH, who each will file a DoN application for its unit. At that time each entity will be required to file community initiative proposals.

9. The Margaret A. O'Malley and Stevan Ten Taxpayer Groups (TTGs) registered in connection with the proposed project. At the request of the TTGs, a public hearing was held on June 2, 2008 at Beverly Memorial Building Auditorium in Beverly. The hearing was attended by 11 people, six of whom testified. Written comments were also received from NHC/BH, the Mayor of Gloucester, and the O'Malley TTG, representing Partners for Addison Gilbert Hospital, a citizens group formed in 1996, to advocate for the maintenance of acute care services at Addison Gilbert Hospital in Gloucester. The summarized comments are in the staff summary. After careful consideration of the public comments, staff continues to recommend approval of the NHC/BH application.

Staff Presentation: "Overview of Senate Bill 2863: An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care", by Mr. Daniel Delaney, Legislative Director, Department of Public Health and Dr. Paul Dreyer, Director, Bureau of Health Care Safety and Quality:

Mr. Daniel Delaney gave a brief overview and noted in part, "…Senate President Murray introduced the first iteration of this legislation in March of 2008 which was passed by the Senate in mid-April. The House version passed in July with significant difference from the Senate version. The Governor signed it into law just this past Sunday. The result of the process is a 55-page piece of legislation which addresses Health Care cost containment, reform and efficiency, access to care, enhanced transparency, and adoption of health information technology."

Mr. Delaney said further that the Legislation mandates three types of response from the Department of Public Health (1) Regulatory change (2) Programmatic & policy Development & Implementation (3) Collaboration, Assessment, and Reporting.

Dr. Paul Dreyer presented the piece that requires Public Health Council action. The areas that would fall under the Bureau of Health Care Safety and Quality and then be presented to the Public Health Council for final action would be (1) the requirement of regulations for hospitals to establish patient and family advisory councils; (2) requirement of regulations for acute care hospitals to develop a method for requesting immediate assistance for deteriorating patients (3) requirement of regulations for the reporting of HAIs and SREs (including serious adverse drug events); (4) a requirement for regulations prohibiting a health care facility from charging for services provided as the result of the occurrence of an SRE (serious reportable event); and (5) changes process by which hospitals and clinics may destroy medical records and time period for retention.

Dr. Dreyer further noted some of other mandates by the legislation:

- Mandates DPH to promulgate regulations by October 2012 that will require hospitals/CHCs to implement Computerized Physician Order Entry systems (CPOE)

- Mandates DPH to promulgate regulations by October 2015 that will require hospitals/CHCs to implement interoperable electronic health record systems

- Mandates regulations requiring the licensure and subsequent DoN for physician based ambulatory surgery

- Mandates regulations requiring a DoN filing for outpatient capital projects exceeding $25 million

- Mandates a “Gift Ban” : The department has been mandated to adopt a “standard marketing code of conduct for all pharmaceutical or medical device manufacturing companies that employ a person to sell or market prescription drugs or medical devices in the commonwealth”…regulations to be promulgated by January 1, 2009

Other pieces in the legislation were noted involving changes by the professional Boards; DPH being the lead agency for a pharmacy drug detailing program and a Health Care Workforce Center; a special commission on the Health Payment Reform to be co-chaired by DHCFP and ANF; an End of Life Care Initiative to be led by

EOHHS; action steps to address primary care shortages; and MassHealth promotion of medical home efforts.

Discussion followed by the Council. Please see the verbatim transcript for full discussion. Rapid Response Teams were discussed. Dr. Zuckerman questioned the necessity of them. Council Member Lucilia Prates Ramos explained how this piece of legislation came about, "This was actually part of the bill that Health Care for All drafted, and I was part of that process in my role as the President of the Consumer Health Quality Council, and our intent was that when an individual or family members go in to see their relative and they are quickly deteriorating, you call the nurse or you call the doctor, and there really isn't a response, or they are busy with another patient… There would be somebody else that you could call upon, you know, a team, a rapid response team, to come. And so I think it's going to take some crafting on our part but that was the intent. It wasn't that you would immediately call this response team – that there would be a process that you would call the nurse, the doctor, and if there was no response, then you would go to the rapid response team." Dr. Zuckerman noted that Rapid Response Teams have been shown to actually improve outcomes particularly in intensive care units. Dr. Alan Woodward added, "I think the concept is what is going to be the appropriate trigger. It isn't going to be an anxious family member brings a whole team from all over the hospital to the bedside of a patient but we need to get a nurse involved immediately, and then if it is appropriate, we have to have appropriate backup mechanisms, and not all hospitals yet have rapid response teams…The evidence is overwhelming that they are beneficial and probably cost effective, and certainly improve patient safety and patient outcome…I think the intent in the legislation is based on or is coming from multiple studies that indicate this kind of intervention is appropriate and should be in place." Ms. Helen-Caulton Harris asked Dr. Dreyer if the Department planned on using just the explicit language in the legislation for hospitals to follow and therefore develop their own criteria or would the Department put together criteria for the hospitals to follow? Dr. Dreyer said, "They usually try to give more guidance and develop more explicit criteria for hospitals." Ms. Prates Ramos added that patients need to be aware that the mechanism exists at the hospitals once it is in place so they can use it.

Chair Auerbach added in part, "Given that there is clearly both interest and expertise on the Council in terms of this particular regulation. I would suggest that in the development of this, before we finalize it for release in a draft version, we might incorporate a discussion and commentary period in the preparation of the regulation…Dr. Dreyer responded that he could send out a draft to Council Members to solicit their input and comment."

Discussion continued around hospitals not being able to charge insurers or consumers for their serious reportable events (SREs). Please see verbatim transcript for full discussion. Chair Auerbach noted the goal of the legislation on the SREs "is

to prevent these occurrences from happening at all and the hope is that by creating a financial disincentive that a good deal more resources will be spent to the prevention of these kinds of events…" The council posed questions around: How does a new physician called in to fix the SRE get reimbursed, who pays, what if the physician who made the mistake, fixes the mistake – does the legislation allow him to bill? What happens if the event necessitates a transfer to another medical facility, who pays then? Dr. Dreyer noted that the Department will have to define SREs very carefully and will probably rely on the National Quality Forum (NQF) which, has been recognized as essentially an arbiter for setting standards in these areas. The NQF has identified 28 events as serious reportable events.

Discussion continued, Dr. Dreyer noted that the new legislation provides for outpatient capital projects over $25 million to be reviewed by DoN. Dr. Gillick stated, "This is one part of the legislation that seems to specifically address cost containment. Will it be as the existing ones are that one can consider cost but not effectiveness? Chair Auerbach responded in part, "We may ask the Legislature, did you mean for us to consider elements which we have been excluded from considering by other Legislative bills or not?" Dr. Dreyer responded in part, "…The one thing that is clear is that the DoN Factors will apply and one of the Factors is duplication of service. I'll put need in quotes from the point of view of duplication of service…"

Dr. Alan Woodward said in part, "…I think it would be reasonable to assume that there should be some different criteria. These are different facilities in different settings, staffed differently, et cetera, and I would think probably we would want to think about some different criteria. I don't think there is anything that would exclude that discussion in the legislation…" Discussion continued; see the verbatim transcript for further details.

Mr. Daniel Delaney made concluding remarks, noting in part, "All in all, this is a comprehensive piece of legislation that addresses much of what the first iteration of health care reform was unable to address. The Department's share of the workload is significant. We are hopeful the General Court will continue to provide support to the Department as we endeavor to fulfill our mandates…"

Chair Auerbach noted the lead persons for some of the mandates here at DPH: Andy Epstein for the Drug Detailing Program. Dr. Auerbach said he will have Andy Epstein back another day to talk more about the issue and how they are approaching it. The Council will be given Andy's telephone and email address so they can give her any advice on the matter. He noted that Steward Landers and Donna Johnson are working on the Health Care Workforce Center which includes the primary care medical school loan program and the Council will be given their contact information so they can reach them. Dr. Gillick mentioned that the IOM Report came

out with a report on manpower needs for our aging society and geriatricizing the workforce and Chair Auerbach asked her to provide a link to staff on the report.

No Vote / Information Only

The meeting adjourned at 11:10 a.m.

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John Auerbach, Chair

LMH