

## **PUBLIC HEALTH COUNCIL**

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Tuesday, January 23, 2007, 10:00 a.m., at the John W. McCormack Building, 21<sup>st</sup> floor Conference Rooms, One Ashburton Place, Boston, Massachusetts. Members present were: Chair Paul J. Cote, Jr., Commissioner, Department of Public Health, Clifford Askinazi, M.D., Atty. Jennifer A. Nassour, Ms. Maureen Pompeo, Mr. Albert Sherman, Gaylord Thayer, Jr., and Martin J. Williams., M.D. Absent were Ms. Soo J. Kim and Atty. Michael C. Hanson. Also in attendance was Attorney Donna Levin, General Counsel, Department of Public Health.

Chair Cote announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Bruce Cohen, Director, Division of Research and Epidemiology; Ms. Sally Fogerty, Associate Commissioner, Center for Community Health Services; Dr. Grant Carrow, Deputy Director, Center for Quality Assurance and Control; Ms. Donna Lazorik, Adult Immunization Coordinator, State Lab. Institute; Mr. Kevin Cranston, Assistant Commissioner, Director, HIV/AIDS Bureau; Ms. Joan Gorga, Director, Mr. Jere Page, Senior Analyst, Determination of Need Program; and the following Deputy General Counsels of the Office of the General Counsel of the Department of Public Health: Atty. Sondra Korman, Atty. James Ballin, and Atty. Tracy Miller.

### **STAFF PRESENTATION: "MASSACHUSETTS BIRTHS 2005", By Associate Commissioner Sally Fogerty, Center for Community Health Services, and Dr. Bruce Cohen, Director, Division of Research and Epidemiology**

Dr. Bruce Cohen, Director, Division of Research and Epidemiology, presented the "Massachusetts Births 2005" report to the Council. Some statistical highlights from the report follow:

- In 2005, the cesarean section delivery rate for Massachusetts was 32.3%, the highest rate ever reported, continuing an increasing trend since 1997.
- In 2005, 76,824 births occurred to Massachusetts residents, 2% fewer than in the previous year. The number of residents live births in Massachusetts had decreased by 17% since 1990 when it was 92,461 births.
- The Massachusetts teen birth rate in 2005 was 21.7 births per 1,000 women ages 15-19 compared with 22.2 births per 1000 women ages 15-19 in 2004. The teen birth rate has declined by 16% from 2000 (25.9 births per 1,000 women ages 15-19). Yet, the number of births to young teens (ages 10-14) increased for black non-Hispanic mothers, from 4 in 2004 to 17 in 2005.

- In 2005, the Massachusetts Infant Mortality Rate (IMR) was 5.1 infant deaths per 1,000 live births, compared with 4.8 deaths per 1,000 live births in 2004.
- The percentage of low birth weight (LBW) infants (less than 2,500 grams or 5.5 pounds) remained high, 7.9% compared with 7.8% for 2004, and it has increased by 36% since 1990 when it was 5.8%.
- Births to Laotian and Brazilian mothers have increased by more than 14% since 2004; however, these groups accounted for only 3% of all births in Massachusetts in 2005.
- The percentage of women who have reported smoking during pregnancy was 7.2% in 2005, compared with 7.4% in 2004. The percentage of women smoking during pregnancy has decreased by 62% since 1990, when it was 19.3%.
- The percentage of mothers who had their prenatal care financed through public programs increased by 7%, from 30.5% in 2004 to 32.6% in 2005. This rate increased by 11% for white non-Hispanic mothers (19.4% in 2004 vs. 21.5% in 2005).
- Disparities in birth outcomes by race, ethnicity, education and community persist:
  - The black non-Hispanic IMR was more than twice as high as the white non-Hispanic IMR (9.4 vs. 4.3 deaths per 1,000 live births).
  - The teen birth rate for Hispanics was almost 6 times that for white non-Hispanics (73.2 vs. 12.9 per 1,000 women ages 15-19).
  - Cambodian (55.1%), Other Central American (65.0%), and Other African (66.9%) mothers were less likely to receive prenatal care in their first trimester compared with mothers in other ethnicity groups (State average: 83.2%).
  - Among the 30 largest Massachusetts municipalities, Brockton (11.5%), Revere (10.9%), New Bedford (10.6%), Springfield (9.8%), and Boston (9.6%) recorded low birth weight percentages that were higher than the statewide average of 7.9%.
  - Mothers with a high school education or less were more likely to smoke during their pregnancies, more likely to deliver low birth weight infants, and less likely to receive adequate prenatal care.

In closing, Dr. Cohen said, "...We are indeed fortunate in Massachusetts to be able to collect and use information such as this to guide our policies and identify areas for intervention. We need to recognize the importance of the data from the birth certificate and from the death certificate for developing programs such as newborn screening, high risk infant identification, and immunization tracking, as well as for research and surveillance. It is extremely important that all physicians, other medical professionals, and hospital administrators sustain their efforts to provide timely data of the highest quality to our Registry of Vital Records and Statistics, which does a tremendous job compiling all these data and making them available for use in DPH and throughout the Commonwealth for all these important purposes...."

Associate Commissioner Sally Fogerty responded to a question by Council Member Thayer in which he asked why the Department has been so successful. Ms. Fogerty said, "...Within the Department of Public Health, particularly over the last five to six years, we have moved forward to make sure that we are using our data to drive our programs and to really integrate that with our program efforts. In doing that, we are targeting to a much greater extent our programs and our dollars. We have also been working to coordinate our programs across one another and, in doing that, working with communities, such as Springfield and Worcester, to look at the data, look at the multiple programs they have within those communities, and how do we coordinate and integrate them to target the populations most at risk. We have also moved from just looking at pregnancy. We have really adopted a lifespan approach. We are focusing both on the pre- and the intra-conception period, making sure we are addressing issues such as smoking, substance abuse, such as precursors for chronic disease prior to pregnancy and between pregnancies. We have been quite successful and one example is, if you go back and look at the information around smoking. We have been using our tobacco dollars to really target communities that have higher smoking rates for pregnant women, and we have been able, in several of those communities, to begin to bring those numbers down. We expect to continue this effort and also to continue to work from the community up because that is what it is all about." **No Vote/Information Only**

**MISCELLANEOUS: REQUEST FOR ADOPTION OF MAGISTRATE'S RECOMMENDED DECISION AS THE FINAL AGENCY DECISION IN THE MATTER OF DPH (OFFICE OF EMERGENCY MEDICAL SERVICES) V. PAUL O'GRADY:**

Attorney Sondra Korman, Deputy General Counsel, Department of Public Health, presented the EMS vs. Paul O'Grady matter to the Council for consideration. Atty. Korman said in part, "In January of 2006, Paul O'Grady filed an application with OEMS to renew his EMT-Basic certification. He disclosed that he had a criminal conviction for Operating Under the Influence. After further investigation, OEMS determined that on July 6, 2004, O'Grady pled guilty to motor vehicle homicide, operating under the influence. Under Massachusetts law, a guilty plea is equivalent to a criminal conviction. He received a 2 ½ year House of Correction sentence to be followed by three (3) years on Supervised Probation. Currently, O'Grady is serving his probationary sentence. Additionally, based on his driving history, O'Grady's driver's license has been placed on

“Lifetime Revocation” status in accordance with the regulations of the Registry of Motor Vehicles.”

Attorney Korman continued, “On or about March 30, 2006, OEMS issued a proposed Agency Action notifying O’Grady of its decision to refuse to renew his EMT certification. O’Grady filed a timely request for hearing and the matter was submitted to DALA for further proceedings. The Department submitted a Motion for Summary Disposition in an effort to dispose of this case without the necessity of an evidentiary hearing. O’Grady, through his counsel, did not oppose this motion. On December 20, 2006, the Magistrate issued a decision in the Department’s favor. O’Grady has not filed objections to the Magistrate’s decision. By granting the Department’s motion, the Magistrate agreed that O’Grady’s actions demonstrate a failure to adhere to the high standards of public trust required of all EMTs and constitute sufficient grounds for the proposed agency action. Specifically, his actions directly relate to the performance of his duties as an EMT as set forth in 105 CMR 170.940 (E) and demonstrate a pattern of conduct that endangers the public health and safety as set forth in 105 CMR 170.940(F).”

Staff proposes that O’Grady’s EMT certification not be renewed until:

- (1) he provides the Department with official documentation from the Court reflecting the termination of his court-ordered probation in Commonwealth v. O’Grady, Norfolk Superior Court, Docket # CR 030262001-2005 and
- (2) until the Department receives a written assessment, deemed satisfactory by the Department, from his supervising probation officer or, alternatively, a Department-approved qualified mental health professional (licensed psychiatrist, psychologist, clinical social worker), that O’Grady does not pose an unacceptable risk to the public.

For the record, Chair Cote asked if Mr. O’Grady was present and if so would he like to address the Council. There was no response.

Mr. Sherman moved approval. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the **Affirmation and adoption of The Magistrate’s Recommended Decision as the Final Agency Decision in the Matter of DPH (Office of Emergency Medical Services) v. Paul O’Grady**. This Determination includes the two conditions proposed by staff above.

**REGULATIONS:**

**REQUEST FOR FINAL PROMULGATION OF EMERGENCY AMENDMENTS TO 105 CMR 150.000: LICENSING OF LONG TERM CARE FACILITIES, RELATED TO EMPLOYEE INFLUENZA VACCINATIONS:**

Dr. Carrow, Deputy Director, Center for Quality Assurance and Control, presented the request for final promulgation of Emergency Amendments to 105 CMR 150.000 to the Council.

Staff's memorandum, dated January 23, 2007 (Issued January 16, 2007) states in part, "Epidemiological data suggest that health care workers can spread highly contagious influenza to patients in their care. Unvaccinated care workers can be a key cause of influenza outbreaks in health care settings. There is broad recognition of the seriousness of this issue among health care-related professional organizations and government agencies (National Foundation for Infectious Diseases).

Estimated rates of influenza-associated pulmonary and circulatory-related deaths are highest among people  $\geq 65$  years of age. Deaths in older adults account for 90% of deaths attributed to pneumonia and influenza (CDC.MMWR 2005;54 (No.RR-8); 1-40). It is currently estimated that fewer than 40 percent of health care workers are vaccinated against the influenza virus each year. The Joint Commission on Accreditation of Health Care Organizations (JCAHO) has recently approved a new infection control accreditation standard, to be implemented beginning January 1, 2007, for Critical Access Hospital, Hospital and Long Term Care accreditation programs. Under this standard these organizations must offer influenza vaccine to all staff, including volunteers, and licensed independent practitioners with close patient contact. However, JCAHO accreditation is voluntary and not all health care facilities seek this accreditation.

The Department of Public Health provides influenza vaccine for all long term care facility residents. To protect the employees and residents in long term care facilities and avoid influenza outbreaks as much as possible, the Department therefore through emergency promulgation of the amendments in November, requires that all long term care facility employees be offered annual vaccination against the influenza virus. The amendments also include language regarding the provision of information to every employee regarding the risks and benefits of the vaccine, recordkeeping, the opportunity for an employee to refuse vaccination and, in the case of such a refusal, documentation that the employee has received information about the vaccine and declined to receive the vaccine. In November, the Department provided facilities with information about the new requirement, including links to the CDC's website for more information about influenza and sample forms the facility might use to track vaccination status."

Dr. Carrow noted that the emergency amendments became effective in November, though the flu vaccine requirement will not be in effect until the 2007-2008 flu season. He indicated that the emergency promulgation was necessary to allow long term care facilities sufficient time to plan and order vaccine for the next flu season. Dr. Carrow

said further that a public hearing was held on December 18, 2006 and that public comments were accepted through December 26. He noted that the Massachusetts Association of Residential Care Homes and the Massachusetts Extended Care Federation testified at the public hearing in support of the applications, however, they both had concerns about the costs of the vaccine to the facilities. Dr. Carrow said that although there would be an initial upfront cost to the facilities -- in the long term there would be increased savings to the facilities due to decreased staff illness and decreased absenteeism.

A brief discussion followed between the Council and staff. Council Members Thayer and Pompeo inquired about current immunization requirements for health care workers. Ms. Donna Lazarik, Adult Immunization Coordinator for DPH's Immunization Program, responded, "In Massachusetts, health care workers in certain settings, maternal/child health care settings, are required to have immunity to measles, mumps, rubella and varicella, and OSHA requires that health care workers be offered Hepatitis B vaccine and health care workers that decline their vaccine need to sign a declination." She also noted that the vaccine costs about twelve dollars a dose. Dr. Carrow assured Ms. Pompeo that the LTC facilities cannot retaliate against any employee for refusing the vaccination. Chair Cote added, "Employers can impose expectations. These are expectations that we are putting forward as regulations. This does not prevent an employer from introducing a stricter guideline or requirement, but what this does is, it provides that each employer must offer the vaccines to their employees."

Council Member Sherman made the motion for approval. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the Request for Final Promulgation of Emergency Amendments to 105 CMR 150.000: Licensing of Long Term Care Facilities, Related to Employee Influenza Vaccinations; that a copy of the approved regulations 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, 875**.

**REQUEST FOR APPROVAL FOR FINAL PROMULGATION OF EMERGENCY AMENDMENTS TO 105 CMR 300.000: REPORTABLE DISEASES, SURVEILLANCE, AND ISOLATION AND QUARANTINE REQUIREMENTS, TO INSTITUTE THE REPORTING OF CASES OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION BY NAME:**

Mr. Kevin Cranston, Assistant Commissioner, Director, HIV/AIDS Bureau, presented the emergency amendments to 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements to the Council.

Mr. Cranston noted that emergency amendments were filed with the Secretary of the Commonwealth on November 14, 2006, which amended the regulations governing the reporting of cases of human immunodeficiency virus (HIV) infection by names. The prior regulations restricted HIV reporting to a code-based system. He said, "The changes made by the emergency amendments remain essential to bring the Commonwealth into

compliance with federal funding requirements and to avoid the loss of significant federal resources supporting HIV/AIDS prevention, care, and support services.”

Mr. Cranston further noted, “In December of 2006, the Ryan White HIV/AIDS Treatment Modernization Act of 2006 passed both houses of Congress and was signed into law by President Bush. The law mandates that states receiving Ryan White funding must implement an HIV reporting system acceptable to the federal Centers for Disease Control and Prevention (CDC) by April 1, 2008, to be eligible for future funding under this law. CDC has indicated that it would only find full name-based systems acceptable. In order for the data to be sufficiently mature to be counted for funding, Massachusetts must begin the reporting process as of January 1, 2007. Hence, the urgency to proceed immediately with implementation of names-based HIV reporting remains.”

Mr. Cranston stated that a public hearing was held on December 13, 2006, regarding these amendments. Approximately 40 people attended the hearing; five individuals provided oral testimony and presented written testimony. One additional written comment was received prior to the December 20, 2006 deadline. Staff’s memorandum to the Council (dated January 23, 2007) summarizes the comments in brief as follows:

- Acknowledged that the collection of names is mandated by the federal funding requirements and the amendments are necessary to protect essential resources supporting HIV/AIDS services in Massachusetts;
- The amendments are inconsistent with MGL Chapter 111 § 70F;
- The proposed regulations expose reporting physicians to civil liability for violation of MGL Chapter 111 § 70F;
- The regulations will reinforce existing stigma against persons with HIV/AIDS and will negatively affect the willingness of individuals at risk to be tested for HIV; there is a potential negative impact on the availability of anonymous testing;
- There is a need to expand and strengthen security and confidentiality protocols regarding the HIV/AIDS surveillance database and related records; these security protections need to be reviewed on a periodic basis;
- Individuals with HIV/AIDS have not been adequately involved in decision making about these regulations; and
- The amendments incorrectly signal laboratories that they no longer need to submit reports to the Department laboratory evidence of HIV infection.

Staff’s memorandum to the Council also provided a summary of staff’s response to the above comments (in brief):

- The Department concludes that the amendments are not in conflict with M.G.L. Chapter 111, §70F;
- The Department developed instructions to reporting providers and educational materials for consumers that encourage discussions between clinicians and patients about the new surveillance system; reporting providers are permitted a year to re-report previously reported patients in care to enable full disclosures of the revised regulations and possible re-consenting for care by existing patients if appropriate;
- The Department anticipates no reduction in the volume of testing following the implementation of names-based HIV reporting, based on the experience of other states; the Department will continue to fund and support anonymous HIV testing, which is unaffected by these amendments;
- The Department commits to reviewing existing security and confidentiality protocols and to reporting out on possible enhancements within six months;
- The Department will continue to promote the importance of early identification of HIV infection, the benefits of treatment, the availability of confidential and anonymous testing in the Commonwealth, and the extraordinary security protections surrounding the HIV/AIDS surveillance database;
- Since the beginning of the regulatory change process HIV positive consumers have been involved in decision-making via the HIV Surveillance Implementation Team and consultation with the Statewide Consumer Advisory Board, as well as public discussions with the Massachusetts HIV Prevention Planning Group, Massachusetts Title I and Title II HIV Care Coordinators, and the Title I Planning Council, each of which include the significant participation of publicly identified persons with HIV/AIDS;
- The Department, in consultation with the HIV Surveillance Implementation Team, recommends the addition of clarifying language to ensure that laboratories continue to provide laboratory evidence of HIV infection to support complete reporting of HIV by providers. Initially the Department believed that laboratories were adequately covered under 105 CMR 300.170 as well as 105 CMR 180.00 (The Operation, Approval and Licensing of Clinical Laboratories). Based on inquiries received by the Department's Clinical Laboratory Program, the Department realized there was confusion. As a result, the Department decided to add clarifying language in 105 CMR 300.180 (C) in an attempt to rectify the confusion;
- For clarification purposes the Department also decided to return to the original language of "physicians and other health care providers," rather than "any health care providers," because members of the HIV implementation team felt there might be confusion among the public and providers as to whether there was a

change in individuals required to report under the regulations. Since there was no change, the Department determined it would be better to retain the original language and avoid confusion.

Mr. Cranston further noted, “Based on the comments received, the Department is requesting that two amendments to the regulations be approved. As stated, above, both changes are for clarification purposes and do not substantively change anything that was previously approved by the Public Health Council.” The two amendments are:

1. An amendment that would add laboratories back as a reporter of communicable diseases, and some additional language that makes it explicit how laboratories are to report HIV and AIDS cases. Laboratories have always reported communicable diseases to the Department.
2. An amendment that adds physician back as a reporter of communicable diseases. Although physician is covered by health care provider and therefore was redundant, the change created more questions, and it was determined that the Department should revert to the original language.

A brief discussed followed. Council Member Thayer requested clarification on the anonymous testing sites (which are not required to do any reporting to the Department) versus a diagnosing physician and his facility that are responsible for reporting the diagnosis of HIV infection to the Department. Dr. Cranston and Ms. Fogerty explained, noting that HIV Counseling and Testing sites only perform a preliminary HIV antibody test and are not qualified to make a medical diagnosis. Therefore, the HIV Counseling and Testing Sites following their preliminary test refer individuals to their physicians for a definitive HIV diagnosis. Dr. Cranston said in part, “For example, if at the anonymous testing site, a diagnosis of HIV infection comes back, a further diagnosis about whether the infection is AIDS or HIV is only something a physician can do with additional analysis. A physician would be able to determine whether an HIV or AIDS case report is to be submitted.”

Council Member Sherman made the motion for approval. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the **Request for Final Promulgation of Emergency Amendments to 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements, to institute the reporting of cases of Human Immunodeficiency Virus (HIV) infection by name** with the two amendments as noted above; that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as **Exhibit No. 14,876**.

**REQUEST FOR FINAL PROMULGATION OF PROPOSED AMENDMENTS TO 105 CMR 305.000 (CONFIDENTIAL BIRTH INFORMATION):**

Attorney James Ballin, Deputy General Counsel, presented the request for final promulgation of proposed amendments to 105 CMR 305.000 to the Council. Atty. Ballin

noted in part, "...These regulations were initially promulgated in 2001. The proposed amendments to the Confidential Birth Information regulations are primarily intended to clarify and expand the permitted use and disclosure of confidential birth information and to make the regulations consistent with the Department's Confidentiality Policy and Procedures regarding access to confidential Department data. The amendments specifically do the following:

1. Clarify existing regulatory requirements;
2. Revise the definitions for "de-identified data" and "limited data sets" to make the regulations consistent with the Department's Confidentiality Policy and Procedures;
3. Allow the sharing of confidential birth information that is not otherwise restricted by law or court order with other government officials in other vital records jurisdictions pursuant to a data exchange agreement. The data exchange agreement explicitly restricts the use to only the authorized purposes and prohibits further disclosure of any confidential birth information provided to another state; and
4. Permit the sharing of confidential birth information with the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention, which funds the Registry of Vital Records and Statistics through a cooperative grant. NCHS would be permitted to use and disclose confidential birth data with appropriate restrictions specified in 105 CMR 305.040 (H) on page 7 of the final version of the regulations."

Staff noted that a public hearing was held on December 15, 2006. No oral or written testimony was received during the public hearing and no comments were submitted during the comment period. Attorney Ballin noted: "that one minor wording change was made to the pre-hearing draft for clarification. Specifically, the word 'release' was deleted from the definition of 'disclose' in 105 CMR 305.004 to avoid confusion with the use of the word 'release' in 105 CMR 305.060. This one word deletion is shown on page 3 in the final version of these regulations."

Council Member Thayer asked Attorney Ballin, "What specific birth information are you referring to, parents, where you were born and when you were born?" Attorney Ballin said, no, that information would be considered the legal portion of the birth certificate. This covers only the medical portion of the birth certificate, information about prenatal care and information about birth delivery outcomes. It does not include the name of the child and the legal portion of the birth information."

Mr. Sherman moved approval. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the **Request for Final Promulgation of Proposed Amendments to 105 CMR 305.000 (Confidential Birth Information)**; that a

copy of the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as **Exhibit No. 14,877**.

**COMPLIANCE MEMORANDUM: PREVIOUSLY APPROVED DoN PROJECT NO. 6-1396 OF BROOKSBY VILLAGE, INC.: REQUEST FOR A SIGNIFICANT CHANGE TO DECREASE THE NUMBER OF BEDS AND GROSS SQUARE FEET OF NEW CONSTRUCTION, AND DECREASE THE PROJECT'S MAXIMUM CAPITAL EXPENDITURE:**

Ms. Joan Gorga, Director, Determination of Need Program, presented the Brooksby Village, Inc.'s request for a significant change to the Council. Ms. Gorga said in part, "...Brooksby Village has requested a decrease in the total number of approved beds from 320 Level II beds to a total of 104 level II beds, 11 of which are DoN exempt beds. Related to the decrease in beds is a request to decrease the Gross Square Feet (GSF) of new construction from 183,153 GSF to 71,752 GSF and a decrease in the inflation-adjusted maximum capital expenditure (MCE) for the project from the inflation adjusted \$55,911,525 (October 2006 dollars) to \$17,095,628 (October 2006 dollars) resulting in cost savings of \$38,815,897 (October 2006 dollars)."

Staff's memorandum to the Council (dated January 23, 2007, issued January 16, 2007) further explained, "CCRCs are permitted to construct a maximum of one Level II bed for every five residential units. Therefore, the original DoN for Brooksby, which proposed 1,542 residential units, allowed the construction of not more than 308 beds. Since Brooksby intended to utilize the 12 bed exception, the original bed complement approved in the DoN was 320 Level II beds. Brooksby through the significant change intends to reduce the original 320 to 104 (93 DoN approved and 11 DoN exempt) and use only 88 at this time leaving 16 out of service. Brooksby intends to use 16 of the 80 acquired Hamilton House beds leaving 64 out of service. The beds affiliated with the CCRC must retain all of the original conditions of the DoN, including the prohibition against seeking certification for reimbursement by Medicaid. However, the Hamilton House beds are not subject to such restrictions and in fact are eligible for Medicaid certification. Thus, although the licensing of the facility is a separate function of the Department apart from the DoN program, the Department notes that there will have to be two separate licenses to appropriately account for the two types of beds. The total Level II bed complement of the Renaissance Garden facility related to the CCRC will therefore be 88 beds. The 16 ex-Hamilton House beds will be licensed separately and remain outside of the DoN. Brooksby as a corporate entity will thus have a total of 104 Level II beds. The Department has indicated that future movement of the Brooksby and Hamilton house beds in and out of service within the approved 104 bed complement will not be subject to additional DoN requirements although plan review and licensure requirements will apply to any such movement. If, in the future, Brooksby intends to add beds beyond the 104 approved beds, it must meet all licensing and DoN requirements in effect at that time. Conditions have been added to the DoN to reflect that policy."

Ms. Gorga noted, "The reason given for the decreased number of beds, and the related decreases in GSF and MCE, is the more specific knowledge of the needs of the residents

that has been gained since the approval of the DoN. Experience has demonstrated that the Brooksby residents are aging in place in their residential units and will not require as many long term care beds as were originally projected. In reviewing this request, staff examined whether the changes were reasonable in the light of past decisions, were not foreseeable in light of past decisions, not foreseeable at the time the application was filed and were beyond the control of Brooksby Village. Consistent with Council's past decisions, staff finds that the changes are reasonable, could not have been reasonably foreseen and were not reasonably within the control of Brooksby Village."

Mr. Sherman moved approval. After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Previously Approved DoN Project No. 6-1396 of Brooksby Village, Inc.'s** Request for a Significant Change. Based on Staff's findings the Department found the changes were reasonable, could not have been reasonably foreseen and were not reasonably within the control of Brooksby Village. This amendment decreases the number of beds and GSF of new construction and decreases the project's maximum capital expenditure to \$17,095,628 (October 2006 dollars). Under this significant change, the total approved beds will be reduced to 104 (93 DoN approved beds and 11 DoN exempt beds) and use only 88 at this time leaving 16 out of service. With these 88 beds, Brooksby will use 16 of the 80 beds acquired in 2002 from Hamilton House Convalescent Center in Needham and moved to Brooksby Village via an approved transfer of site. The total Level II bed complement of the Renaissance Garden facility related to the CCRC will therefore be 88 beds. The 16 ex-Hamilton House beds will be licensed separately and remain outside of this DoN. Brooksby as a corporate entity will thus have a total of 104 Level II beds. This amendment is subject to the following conditions:

1. The holder shall be permitted to move the Brooksby and Hamilton House beds in and out of service within the approved 104-bed complement and will not be subject to additional DoN Requirements although plan review and licensure requirements will apply to any such movement.
2. If in the future, the holder intends to add beds beyond the 104 approved beds for Brooksby Village, it must meet all licensing and DoN Requirements in effect at that time.

**CATEGORY 2 APPLICATION: PROJECT APPLICATION NO. 4-3B18 OF BOSTON MEDICAL CENTER FOR EXPANSION OF THE EXISTING RADIATION THERAPY SERVICE THROUGH ACQUISITION OF A CYBERKNIFE STEREOTACTIC RADIOSURGERY SYSTEM AND RELATED RENOVATION:**

Mr. Jere Page, Senior Analyst, Determination of Need Program, presented the Boston Medical Center application to the Council. Mr. Page said in part, "...Boston Medical Center Corporation (BMC) has filed a Determination of Need application to expand its existing radiation therapy service through acquisition of a CyberKnife stereotactic radiosurgery unit (CyberKnife) and related renovation to accommodate the unit in its

Consolidated Cancer Care Building (the Moakley Building) on BMC's campus. The Moakley Building, which opened in November 2006, is a state-of-the-art medical services building designed to consolidate BMC's ambulatory cancer care services and provide the most advanced cancer-fighting technology, as well as offer BMC patients the chance to participate in leading cancer research trials."

Staff's written summary to the Council, dated January 23, 2007 explains, "The Advisory Board Company ( a membership of 2,500 of the country's largest health systems and medical centers and provides best practices research and analysis to the health care industry) reports that the CyberKnife unit is a miniature LINAC (linear accelerator) attached to a robotic arm that uses image-guided robotics to target one or more locations during a single treatment session, is used mainly on more difficult to treat, surgically complex tumors, has the ability to eliminate these tumors with fewer treatment sessions, is non-invasive, and requires no inpatient stay for most patients. The Board further reports that CyberKnife SRS also creates treatment options for a broader patient population because it can be used on tumors that are small or irregularly shaped and previously considered inoperable, and also notes that CyberKnife allows surgeons and radiation oncologists to destroy lesions with a precise dosage of radiation, sparing the healthy tissue surrounding the tumor. As a result of being non-invasive, CyberKnife is not considered surgery, but its effect is being considered 'surgical' because it is able to destroy the lesion."

Staff's summary further indicates, "The Advisory Board Company further notes that clinical indications for CyberKnife treatment are covered by Medicare reimbursement. BMC notes that, from a cost perspective, CyberKnife technology is more cost-effective than surgical resection of a tumor and involves no anticipated inpatient stay or surgical intervention. BMC also reports that a comparison of operating costs for Gamma Knife, another stereotactic radiosurgery technology currently offered at New England Medical Center, indicates that the operating cost per patient for the proposed CyberKnife is less than the operating cost per patient for Gamma Knife, which requires surgical intervention to place the head frame into the patient prior to treatment."

Discussion followed. Dr. Lawrence Chin, Professor and Chief of Neurosurgery, Boston Medical Center, replied to questions by Council Members Thayer and Askinazi on what cancer tumors may be treated with a CyberKnife. The following tumor types were mentioned: primary tumors of the lung, solitary metastasis to the brain, solitary tumors in the kidney (may in selected cases be used instead of the Whipple procedure), tumors in the extremities, spine, or primary pancreatic tumor. The CyberKnife has also been used for non-cancerous benign tumors such as meningiomas, and for arterial venous malformation.

In conclusion, staff noted, "Staff finds need for the proposed BMC CyberKnife stereotactic radiosurgery system. Staff notes the limited availability of CyberKnife services in Massachusetts, as well as the significant clinical benefits of CyberKnife treatment, and believes that a number of existing and future BMC cancer patients would benefit from this therapy. Staff also believes that the impact of the proposed BMC

CyberKnife service on traditional radiation therapy (megavoltage radiation therapy) will be proportionately small due to the selective application of CyberKnife. Staff further believes that the proposed BMC CyberKnife will not have a negative impact on the existing Beth Israel Deaconess Medical Center's CyberKnife service, since demand for both is institution-specific with little or no reliance on outside referrals.”

Mr. Sherman moved approval. After consideration, upon motion made and duly seconded, it was voted unanimously to approve Project Application No. 4-3B18 of Boston Medical Center, based on staff findings, with a maximum capital expenditure of \$4,600,000 (September 2006 dollars) and first year incremental operating costs of \$1,930,000 (September 2006 dollars). A staff summary is attached and made a part of this record as **Exhibit No. 14, 878**. As approved, this application provides for expansion of the existing radiation therapy service through acquisition of a CyberKnife stereotactic radiosurgery system and related renovation to accommodate the system in the Medical Center's existing Moakley Building, located at 830 Harrison Avenue. This Determination is subject to the following conditions:

1. BMC shall accept the maximum capital expenditure of \$4,600,000 (September 2006 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 752.
2. BMC shall contribute 100% in equity (\$4,600,000 in September 2006 dollars) to the final approved maximum capital expenditure.
3. For Massachusetts residents, BMC shall not consider ability to pay or insurance status in selecting or scheduling patients for the CyberKnife service.
4. BMC has agreed to provide a total of \$230,000 (September 2006 dollars) over five years to fund the development or expansion of the programs detailed below to address specific healthcare needs and issues identified by Boston HealthNet community health centers in Mattapan and South Boston.

**a) Community Health Network Area (CHNA #19) – Alliance for Community Health**

BMC will provide CHNA #19 (Alliance) with \$18,400 per year over five years for a total of \$92,000 to support mini-grants that address health disparities in cancer care within Boston area communities identified by the Alliance. BMC also will participate in the review and screening of mini-grant applicants. In addition, BMC will provide the Alliance with \$4,600 per year over five years, for a total of \$23,000 for CHNA administrative support. Total funds provide to the Alliance over five years will be \$115,000.

**b) Mattapan Community Health Center – “Health Care Revival Initiative”**

BMC will provide \$11,500 per year over five years for a total of \$57,500 to build upon the success of the existing Health Care Revival Initiative which is

a faith-based community-focused, outreach program established in 1997, and designed to address public health issues that affect the health and spirit of community residents. The program addresses these community health needs through distribution of health information, screenings, and other activities. The program has also developed a “Community Health Report Card for Mattapan and Hyde Park” to track its progress. Total funds provided to the Mattapan Community Health Center to support the Health Care Revival program over five years will be \$57,500.

c) South Boston Community Health Center – Cancer Education Programs

BMC will provide \$11,500 per year over five years for a total of \$57,500 to develop new comprehensive, ethnically/racially sensitive, cancer education programs that focus on elimination of preventable risk factors (e.g., through health and wellness-diet, exercise), cancer screenings (breast, cervical, skin cancers) and data collection (monitoring impact of intervention). BMC notes that cancer mortality data reported in the “Health of Boston 2004 Chartbook” indicates that South Boston experienced cancer mortality rates that are higher than the City of Boston as a whole. Total funds provided to the South Boston Community Health Center to support the Health Care Revival program over five years will be \$57,500.

Funding for each of these initiatives will begin upon project implementation and notification to the Office of Health Communities (OHC) and CHNA 19 at least two weeks prior to implementation of the BMC CyberKnife service. In addition, the CHNA will determine the fiscal agent for the funds provided to the CHNA for its mini grants programs and CHNA administrative support. In addition, BMC, in conjunction with the Alliance and the OHC, shall meet annually to review the outcomes of the above programs receiving both direct funding (community health centers) and indirect funding (mini-grant recipients). BMC shall also file all reports required by the OHC detailing compliance and outcomes of these initiatives.

5. With regards to its interpreter service, BMC shall:

- Update its policies and procedures to prohibit the use of minors and to use only trained interpreters, including hospital staff who provide medical interpretation and/or logistical support.
- Ensure ongoing training for all hospital clinical staff on the appropriate use of interpreter services and diversity/cultural competency training.
- Ensure that established translation guidelines and procedures for developing timely, accurate, competent, and culturally appropriate patient educational materials are followed.

- Include the Interpreter Services Director in decision-making processes that affect people with LEP, including appropriate methodologies for collecting race and ethnicity data.
- Ensure that the Interpreter Services Coordinator serves as a support to registration and admission departments for the collection of case mix data involving race, ethnicity and language.
- Ensure that the hospital's data collection system includes self-reported race, ethnicity and language information from patients, and submit a plan to OMH on how these data will be used to improve interpreter services for BMC patients.
- Continue to post signage in the Emergency Department and at all key points of entry into the hospital. Signage must be posted in conspicuous areas and be made available in the primary languages identified by the language needs assessment that informs patients of the availability of interpreter services at no charge.
- Conduct an annual Language Needs Assessment utilizing external sources as well as internal sources of data, and involve community-based organizations in the process.
- Use telephonic interpreter services only as a last resort, and tape interpreting sessions conducted telephonically and in all languages.
- Continue outreach to the LEP communities in the hospital's service area to ensure that patients are aware of BMC's interpreter services, and that these services are available at no cost.
- Ensure the availability and quality of interpreter services at its hospital-licensed satellite facilities.

A plan to address these interpreter service elements shall be submitted to OMH within 120 days of the DoN approval, and BMC shall notify OMH of any substantial changes to its Interpreter Services Program. Also, BMC shall follow recommended National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health Care, as well as submit an annual progress report to OMH on the anniversary date of the DoN approval.

Staff's recommendation was based on the following findings:

1. BMC proposes to expand its existing radiation therapy service through acquisition of a CyberKnife stereotactic radiosurgery system and related renovation to accommodate the new system in the Moakley Building on the BMC campus in

Boston.

2. The project meets the requirements of the health planning process consistent with the Guidelines for Megavoltage Radiation Therapy Services (Guidelines).
3. BMC has demonstrated demand for the proposed CyberKnife service, as discussed under the Health Care Requirements factor of the Staff Summary.
4. The project, with adherence to certain conditions, meets the operational objectives of the Guidelines.
5. The project meets the compliance standards of the Guidelines.
6. The recommended maximum capital expenditure of \$4,600,000 (September 2006 dollars) is reasonable, based on a similar, previously approved project.
7. The recommended incremental operating costs of \$1,930,000 (September 2006 dollars) are reasonable for the operation of a CyberKnife unit and related renovation to accommodate the unit.
8. The project is financially feasible and within the financial capability of BMC.
9. The project meets the relative merit provisions of the Guidelines.
10. The project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.
11. The Mark R. Taylor Ten Taxpayer Group (TTG) registered in connection with the proposed project, but did not submit written comments or request a public hearing.

The meeting adjourned at 11:15 a.m.

LMH/lmh

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Paul J. Cote, Chair