

## **PUBLIC HEALTH COUNCIL**

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, January 14, 2009, 9:00 a.m., at the Department of Public Health, 250 Washington Street, Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Mr. Harold Cox, Dr. John Cunningham, Dr. Michèle David, Mr. Paul J. Lanzikos, Mr. Denis Leary, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Mr. Albert Sherman, Dr. Michael Wong, Dr. Alan C. Woodward. Absent Members were: Ms. Helen Caulton-Harris, Dr. Muriel Gillick, Dr. Meredith Rosenthal, and Dr. Barry Zuckerman. 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 further announced the order of docket items to be heard; and that the "Mass in Motion" Presentation will be heard after the congenital anomalies and DoN Regulations.

### **RECORD OF THE PUBLIC HEALTH COUNCIL MEETING OF NOVEMBER 12, 2008:**

A record of the Public Health Council Meeting of November 12, 2008 was presented to the Public Health Council for approval. Mr. Albert Sherman, Council Member, moved approval. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the November 12, 2008 record with corrections to three typos as pointed out by Dr. Alan Woodward and Mr. Paul Lanzikos. The record was distributed to the members prior to the meeting for review.

**REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO  
CONGENITAL ANOMALIES REGISTRY REGULATIONS 105  
CMR 302.000:**

Ms. Kristin Golden, Director, Policy and Planning for the Department of Public Health presented the Congenital Anomalies Registry Regulations to the Council on behalf of Dr. Lauren Smith, DPH Medical Director and Dr. Marlene Anderka, Director, Massachusetts Center for Birth Defects Research and Prevention, both were out of town. Dr. Anderka was present via speakerphone. Ms. Golden acknowledged Attorney Peggy Wiesenbergh, Deputy General Counsel and Attorney Donna Levin, General Counsel for their work on the regulations. Ms. Golden summarized the comments received from the public comment period and highlighted the changes made as a result of the comments.

Ms. Golden stated in part, "...These regulations are in compliance with the state law that was amended in 2002, that expanded the reporting time that used to be within ten days of the diagnosis, to within thirty days of the diagnosis. It also expanded reporting to include prenatal period, and up to three years of age. The statute specifically allows for information to be provided to researchers, as long as it is reviewed by a duly constituted IRB, and it requires DPH to promulgate regulations to implement this law."

Ms. Golden said, "Last May we brought you the proposed regulations and we commenced our public comment period. We had two public hearings in June, in North Hampton and Boston. We received public comments from 22 people within 20 letters...Overwhelmingly, comments received were in support of the regulation as written. Among those in strong support were Parents of Children with Special Needs and Birth Defects, the March of Dimes, the Federation for Children with Special Health Needs, and several physicians and researchers from many Boston area hospitals. Five letters were received that raised concerns about the regulations as written. Among those that recommended changes in opposition to the

regulations were the ACLU, the Mass Medical Society, the Jewish Alliance for Social Justice, the Abortion Access Project, and a Medical Ethicist from the BU School of Public Health.”

Ms. Golden continued, “Those who wrote in support of the regulation voiced strong support for the expanded collection of diagnosis in order to have a complete and accurate data source for research. They advocated for continued access for researchers, and they supported the use of this information to assess need for services and offer linkages to affected families...” Ms. Golden summarized the concerns into four categories: (1) inclusion of birth injury reporting, (2) collection of prenatal diagnosis and information relating to pregnancy loss (induced termination) (3) privacy and confidentiality (including how to release information to researchers) and (4) administrative.

The following information was provided during the PHC meeting and/or in the staff memorandum to the Council:

Key Elements of the Statute:

1. Require reporting and authorize collection of information about specific congenital anomalies from any physician making such a diagnosis. The report would include the following information: personal identifiers, demographics, diagnostic codes, physician identifiers, and hospital/provider identifiers.
2. Streamline reporting and minimize burden on physicians by authorizing medical records personnel in health care facilities (hospitals) and physician practice groups to act as agents for physicians for purposes of reporting.
3. Authorize release of data pursuant to M.G.L.c.111§24A to researchers for approved public health studies through a duly constituted review board, whose technical and ethical research review informs the process. Researchers must provide protocols and written assurances for maintaining confidentiality.

4. Authorize the Department to collect additional information (in addition to data items collected on the reporting form) subject to approval of a duly constituted institutional review board.
5. Establish an advisory committee to provide ongoing consultation to the Registry.

#### Summary of Changes to the Regulations:

Ms. Golden noted that several technical changes were made to the regulations for readability. For example, any instance of “mandated reporter” was changed to “physician or his or her agent” and some paragraphs were rearranged in ways that did not affect content.

The following changes were made in response to testimony received:

#### Definitions (105 CMR 302.005):

- All references from birth injury were deleted.
- Patient Identifiers: social security numbers have been deleted from the list of patient identifiers required.

#### Information Required To Be Reported Regarding Birth Injuries (105 CMR 302.015)

- This section was deleted.

#### Data Collection Manual (105 CMR 302.020):

- The data collection manual is required to include language stating that the collection of social security numbers is prohibited, that pregnancy loss that is not a fetal death be listed as pregnancy loss and whether it is case control surveillance eligible for the Centers for Disease Control and Prevention.

## Physician Reporting (105 CMR 302.040)

- The proposed regulations simplified the requirements for physicians by allowing for physicians to have “been informed” rather than “seen documentation” of a previous report.

## Confidentiality (105 CMR 302.070):

- Section (a): the following language was added “The department shall not require reporting of social security numbers. To the extent that patient identifiers are necessary to eliminate duplicate reporting, the department shall collect the minimum amount of data necessary to accomplish that task.”
- Section (d): in order to ensure that only the data subject requesting the information was included in the report, the following language was added: “..shall be disclosed after redacting information pertaining to any third person other than the physician who made or reported the diagnosis”
- Section (g): the following language was added “...the department shall not disclose any medical record or individually identifiable health information or patient identifiers relating to pregnancy loss that is not a fetal death without written, informed consent of the patient.”
- Section (i): a new section requiring the department to “institute security procedures to prevent unauthorized individuals from accessing information”
- Section (j): a new section requiring the department to “comply with applicable statewide records retention schedules” and setting out standards for destruction of data.

## Quality Assurance (105 CMR 302.080)

- Section (b): strengthened physician requirements for redaction of medical records so that “the physician, and/or agent, ~~may~~ shall employ reasonable measures to delete,

mask, cross out or otherwise render illegible other parts of the patient's record."

Ms. Golden noted that the Department was awarded a five million dollar grant from the CDC for the next five years. The funding began in December and the funding is contingent on the Department adopting these regulations. She further noted, "...There were comments received that asked whether or not DPH had the legislative authority to collect prenatal diagnosis, and there were also concerns raised about making sure that information around pregnancy loss was not collected in the registry, and that people specifically ask for the ICD-9 codes that correlate with induced terminations not be included in the registry...We have looked at this legally and conferred with people in Health and Human Services, and DPH feels comfortable in our interpretation of the statute, that reporting within thirty days of diagnosis allows for us to get diagnosis made prenatally. In addition, in order to receive the CDC funding, we do need to collect prenatal diagnosis. It also allows us to have a full, complete picture and fulfill our Public Health role, and we double checked the ICD-9 codes that are required, that are listed in the Definition section, or in the What's Required to be Reported, and the ICD-9 codes for Induced Terminations are not included in those codes."

Ms. Golden noted further that 21 other states and Puerto Rico collect prenatal data information with regards to birth defects similar to the regulations proposed. She noted that commenters opposed collection of any patient identifiers and had concerns about security of the data. In response she said "DPH has added language to the regulations to prohibit the capture of social security numbers, limited abstraction to the minimum necessary and now require written informed consent before the release of any personal medical information to researchers that has anything to do with women experiencing a pregnancy loss."

Ms. Golden noted a change in the Confidentiality section of the regulations for the record: "Under the Confidentiality section under Section G, page 9, it is changed to 'However, with respect to a

pregnancy that is not a fetal death, the Department shall not disclose medical record or individually identifiable health information, or patient identifiers, without written informed consent of the patient.' It is the same language. We just moved it around a bit to make sure that we knew what was modifying what." The Council was given a new page 9 with the updated language on it.

Please see the verbatim transcript of the proceedings for Ms. Golden's full presentation and discussion of the Public Health Council. During the discussion, Dr. Alan Woodward, PHC Member pointed out a correction to the definitions on pages one and two of the regulations that "Congenital Anomaly or Birth Defect" and the "Congenital Anomalies Registry" definitions are consistent and both contain "Birth Defect" in their content. Ms. Anderka agreed.

Dr. Michael Wong, PHC Member noted his concern about the need for the fines in the regulations to reflect the current Gold Standard and perhaps the Department or PHC should contact the Legislature about adjusting the fines. Ms. Golden said she would look into what other states are charging for fines. Chair Auerbach said they would decide on an action step later when they have the information from other states.

Mr. Paul Lanzikos, PHC Member asked how the "written informed consent piece would work"? Ms. Marlene Anderka replied via speakerphone, "The written informed consent would be obtained for any case of early loss, where an outside researcher asked for access. So, before that data could go to an outside researcher, the Department would obtain written informed consent from the mother. The contact of women to participate in research is the point at which informed consent would happen."

Ms. Suzanne Condon, Director, Bureau of Environmental Health, responded to Mr. Lanzikos' inquiry about cluster investigation and mapping capabilities. She informed the Council that her bureau had a very sophisticated Geographic Information System Center that merges health data with cluster analysis and that all identifiers are removed.

Council Member Albert Sherman moved approval on the Congenital Anomalies Registry Regulations. After consideration upon motion made and duly seconded, it was voted unanimously to approve **Final Promulgation of Amendments to Congenital Anomalies Registry Regulations 105 CMR 302.000** with Mr. Woodward's clarifications of the definitions as noted in the discussion above; and that a copy is attached and made a part of this record as **Exhibit No. 14, 918**.

**REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO DETERMINATION OF NEED REGULATIONS – 105 CMR 100.000:**

Ms. Joan Gorga, Director, Determination of Need Program, accompanied by Dr. Paul Dreyer, Director, Bureau of Health Care Safety and Quality, and Attorney Carol Balulescu, Deputy General Counsel presented the proposed amendments to the Determination of Need Regulations. She said in part, "...I am here today to request that the Council approve amendments to 105 CMR 100.000, Determination of Need, which were approved as Emergency Amendments by the Council in November and promulgated on an emergency basis in December. I am also here to summarize and respond to public comments about the Emergency Amendments."

Ms. Gorga noted that the proposed amendments allow for DoN filings to be submitted in electronic format. Chapter 305 extends Determination of Need jurisdiction to two previously exempt types of health care projects, outpatient projects with a capital expenditure in excess of twenty-five million dollars and physician-owned ambulatory surgery centers that are Medicare certified. Before the enactment of Chapter 305, the law provided that outpatient expenses were excluded from the calculation of a capital expenditure for DoN purposes. With the passage of 305, the legislature removed this exemption for any outpatient project in excess of twenty-five million dollars. In addition, before the changes, any ASC that was physician-owned and controlled was not required to obtain a license from the Department to operate the ASC. With the change, any ASC that

seeks Medicare certification, including those that are wholly physician-owned, must now obtain a license from the Department and, before applying for a license, must receive approval from the DoN program.”

Ms. Gorga noted the grandfather provisions included in the amendments: “For outpatient projects in excess of twenty-five million dollars, statute provides that any project that seeks approval of final architectural plans by February 10, 2009 is exempt from DoN review. For ASCs, the law provides that any ASC that was in operation or under construction as of August 10, 2008 is exempt from DoN Review.” She said further, “Staff is proposing amendments to define the terms relative to the grandfathering provisions. The definitions for the outpatient projects incorporate the Department’s current two-step process for plan review and set not only the statutory date for final plan submission, but also the date by which applicants must submit the initial plan materials. For ASCs, the definition of under construction requires that persons planning to operate an ASC must have progressed at least to the point that either the present location is under construction or renovation or funds have been committed for the acquisition of a majority of the equipment.”

Ms. Gorga noted that a public hearing was held on December 5, 2008, six parties testified at the hearing and eight parties submitted written comments. She said, “Proposed changes to the Emergency Amendments are suggested in response to public comments about the definition of Health Care Facility and the treatment of Community Health Centers under the proposed changes...Staff is recommending that the definition of Health Care Facility include Clinics (105 CMR 100.020) and exclude Federally Qualified Community Health Centers (105 CMR 100.014 (B)).

“In conclusion, Staff requests approval for promulgation of the amendments as noted. Further Department action resulting from the approval of Chapter 305 is necessary. Licensure requirements for currently operating physician-owned ASCs will be presented by Staff at the February Council meeting. In addition, a work group with the

task of updating the DoN Guidelines for review of ASCs will begin meeting early next month. Draft guidelines from that process will be presented to the Public Health Council. Public comments will be solicited at that time, and the final guidelines will be brought back to the Council.”

Discussion followed by the Council (see verbatim transcript for full discussion). Questions by the Council to staff were (1) Will the volume of work increase for the DoN staff as a result of these regulations. Staff replied that because of the economy, some of the applications they usually have been working on routinely each year may not be in the pipeline – so it will be an offset (2) How would the Department monitor and enforce compliance with this provision? Staff noted that often attorneys for proponents of disaggregation write to the Department for an opinion informing them of the projects and a facility must apply for a license and the Department’s Plan Review Team will find out that the project has no DoN and note the capital expenditure. The project would not be licensed and would be sent to DoN to apply for one and there would be fines and sanctions and competitors are quick to report a project that has not complied with the DoN Regulations. It was further clarified that Ambulatory Surgical Centers (ASCs) are required to file a DoN regardless of the capital expenditure amount.

Dr. Michèle David made the motion to approve the regulatory amendments. After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Final Promulgation of Amendments to Determination of Need Regulations – 105 CMR 100.000 et seq.**; and that a copy be attached and made a part of this record as **Exhibit No. 14, 919.**

Chair Auerbach commented in part, “...I do think that this regulation coming on the heels of regulations passed in the last couple of months, that included such things as requirement of any beds being added for the first time require a DoN, the elimination of grandfathering exemption letters really do represent something to note, which is the most significant Determination of Need changes in more than 25 years, and really represent a new era of scrutiny in

terms of a range of different activities that haven't had to go through the regulatory and DoN process before. I want to note that and commend the Council for updating the regulations – these very important regulations. I want to thank the staff. I know enormous amounts of work went into this and paying attention to how to do this, do this thoughtfully and in a way that was transparent and included adequate time for public comment. It took a lot of thought and a lot of attention; and Ms. Gorga, in particular I want to say that I appreciate your and your staff's willingness to assume additional responsibilities and while Dr. Wong was appropriately sensitive in being concerned about this not becoming a burden, and we are hopeful that it doesn't become that way, I would just say that I commit, on the part of the Department's leadership, to working with you that, if this does create an additional burden on the DoN office, we will make sure that the office has the appropriate resources so that it can handle that additional area of responsibility, but thank you and thank you to the Council."

**PRESENTATION: "MASS IN MOTION – A NEW INITIATIVE TO ADDRESS OBESITY IN MASSACHUSETTS":**

Mr. Stewart Landers, Senior Program Director, Commissioner's Office, presented the "Mass in Motion" presentation to the Council. Excerpts from his presentation follow:

- Over the past twenty years, the United States has experienced a significant rise in obesity and overweight. In 1990, the prevalence of obesity in every state in the nation was under 15% and, in ten states, that rate was less than 10%. By 2007, 49 states, including Massachusetts, had a prevalence of obesity of greater than 20%.
- In 2007, thus more than one in every five Massachusetts adults, or approximately one million people, was obese. This number represents a doubling of the rate of obesity.
- The consequences of obesity and overweight are serious: Health Disease, High Blood Pressure, Stroke, Type 2

Diabetes, Abnormal Blood Fats, Metabolic Syndrome, Cancer, Osteoarthritis, Sleep Apnea, and Reproductive Problems.

- Prevalence of Type 2 diabetes in Massachusetts has nearly doubled in the past decade, from about 3.8% to almost 7.4% in 2007. The prevalence of diabetes is higher for low income residents. People with incomes below \$25,000 have the highest rates of prevalence of diabetes.
- This epidemic is even more acute in both low income communities and in communities of Color. Low income residents are more likely to be overweight and obese for a variety of reasons, including greater use of fast foods and other inexpensive foods that are high in caloric value and are less healthy nutritionally.
- DPH Goals: (1) Decrease the number and percentage of both adults and children who are overweight and obese. (2) Decrease the prevalence of chronic disease associated with unhealthy eating and lack of physical activity.
- DPH Objectives: (1) Make the promotion of wellness and the prevention of overweight and obesity a top public health priority (2) Create conditions that encourage, nurture and promote wellness with particular focus on the importance of a healthy eating, vitamin supplements and physical activity.
- DPH Action Steps: (1) Document the extent of the obesity epidemic in Massachusetts, including the disproportionate effect on certain populations (2) Highlight innovative and successful programs across the Bay State and present new action steps (3) Pass A Menu Labeling Regulation via the Public Health Council (4) Pass a regulation requiring student Body Mass Index collection via Public Health Council (5) Support Legislation to Ban Trans Fats in Foods in Massachusetts and Promote health foods in schools, and ban junk food (6) Statewide Public Information Campaign (7)

Interactive Wellness Website (8) Executive Order requiring the purchase of healthful foods with state contracts (9) Workplace Wellness Initiative including a toolkit for all employers and (10) Public-Private Partnership Grants to cities and towns.

Discussion followed by the Council (please see verbatim transcript for full discussion). It was noting during discussion the importance of being culturally sensitive when working with ethnic communities. For instance, offer healthier alternatives for present foods eaten rather than offer a whole new set of foods. The Council also discussed the addiction and comfort issues of food; having a food makeover section (substituting healthier versions of food) on the Mass In Motion Website; questioned the necessity of vitamins in a healthy diet; suggested DPH work with providers that deliver food to people in programs such as "Meals on Wheels" to ensure healthy food is delivered; being sensitive to obese children regarding BMI measuring in schools and advertisements on the "T".

### **No Vote/Information Only**

#### **PROPOSED REGULATION:**

#### **INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 200.000 – REGULATIONS GOVERNING PHYSICAL EXAMINATION OF SCHOOL CHILDREN:**

Dr. Jewel Mullen, Director, Bureau of Community Health Access and Promotion, briefed the Council on the Body Mass Index (BMI) regulations. She said in part, "Our goal is to improve screening and the monitoring of children's weight status across the State; and, by doing so, improve the kind of information that we get and how we actually use it, in order to give parents a more accurate idea of what their children's weight status is, to promote healthful lifestyles, and to encourage communication between families and their primary care providers. Currently, 29% of middle school students in

Massachusetts are overweight or obese, and 26% of high school students are overweight or obese. Accordingly to a recent report, Massachusetts ranks 27<sup>th</sup> among U.S. states in childhood overweight status.”

She said further, “Massachusetts students are a little bit less overweight than students in the country, 14% compared to 11% overweight and 15% compared to 13% obese. The highest proportions of overweight children are Black and Hispanic...Early detection of children at risk for subsequent overweight is important because, if we can detect that risk, we can also help to circumvent development of obesity and all the disease states that we know are associated with it. The BMI regulations are just one part of the Wellness campaign that is being proposed.”

Dr. Mullen continued, “Currently in schools, children are weighed and their heights are measured annually, but there is no requirement for BMI calculation and there is no putting that information into a context to help people know whether or not those numbers put a child in a category of underweight, normal weight or overweight. The height and weight data that are collected also are not required to be reported to parents or to the Department of Public Health.... What we are proposing with this new BMI regulation is to discontinue the annual height and weight screening that I mentioned earlier, that is done now Kindergarten through Grade 12 and instead require that schools collect, in Grades 1, 4, 7 and 10, heights and weights of the students, and then calculate their BMI. There are CDC guidelines that we follow. The BMIs that are calculated are then used to put the students in percentile ranking for under, normal or overweight. The proposed amendments require that the schools communicate this information to parents or caretakers of the children in writing along with information on what can be done to follow-up....Additionally, the school districts will provide back to DPH aggregate information on students’ body mass index. Parents are given the option to decline having their children participate, and it will be the option of local school boards to say whether or not they want additional examinations to continue.”

Dr. Mullen noted that they are recommending discontinuing the annual vision and hearing screenings and instead doing them less frequently to ease the burden on school nurses. The timetable for vision would be entry through grade 5, once in middle school and once in high school; and for hearing it would be entry to third grade, once in middle school and once in high school.

Staff noted further that implementation of these regulations will be phased in over time. School districts that have a contract through ESHS will be required to comply with these regulations in the first full school year following promulgation (2009-2010). Other school districts must begin meeting this mandate beginning the second full school year following promulgation of these regulations.

In closing, Dr. Mullen stated in part, "...We believe there are multiple benefits to these amendments, first is that we will be providing families with more accurate information about their children's weight status...We are also enabling the School Health Services Division in DPH to make better use of the information because it will actually be reported back to us in aggregate. We will be collecting more information on BMIs in elementary school age children than we have through any current surveillance system, and as we go forward with all of our other initiatives to improve health, lessen the prevalence of overweight and obesity, we actually will have a way to measure what some of the impact of these other programs has been because we will have a measure that we will be able to follow over time."

Discussion followed by the Council (see verbatim transcript for full discussion). Discussion involved parents receiving additional information about their Child's BMI measurement (Dr. Mullen said the additional information would be provided); adequacy of proposed vision, hearing and BMI screenings (Dr. Mullen said the proposals had been reviewed by medical experts and are not meant to take the place of yearly physician visits); and that the outcome data collected should be meaningful to understanding what changes have occurred as a result of these proposals.

**NO VOTE/INFORMATION ONLY**

**INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 590.000, STATE SANITARY CODE CHAPTER X: MINIMUM SANITATION STANDARDS FOR FOOD ESTABLISHMENTS, REQUIRING THE POSTING OF CALORIE INFORMATION:**

Ms. Suzanne Condon, Director, Bureau of Environmental Health, accompanied by Priscilla Neves, Medical Director, Food Protection Program, Bureau of Environmental Health and Attorney Priscilla Fox, Deputy General Counsel, Legal Office, addressed the Council.

Ms. Condon stated in part, "...In order to help empower consumers to make healthier food choices and help reduce overweight and obesity prevalence, we are proposing to require designated food establishments to post calorie information. The mechanism for requiring these postings is under the State Sanitary Code under Food Establishments (105 CMR 590.000). Our Food Protection Program in concert with the Local Boards of Health carry-out and enforces the Food Establishment Regulations.

Ms. Condon said further, "The proposed amendments would add requirements for defined food establishments to show calorie information for all listed or pictorially displayed food items shown on menus or menu boards; and, just for comparison purposes, in large part, our regulations mirror those of New York City and the State of California, which became effective in April of last year."

Ms. Condon displayed slides with pictures of menus from New York and California restaurants with the calorie information on them. She noted an interesting occurrence in New York, food establishments reduced the calorie content of some of their food items.

Ms. Condon explained the proposed regulations, "...These proposed regulations will apply to any food establishment within Massachusetts that is one of a group of food establishments, of which there are at least 15 doing business in the United States, offering for sale substantially the same menu items, in servings that are standardized

for portion size and content, that operate under common ownership or control, or as franchised outlets of a parent business, or do business under the same name...The calorie information must be verified by licensed nutritionists or dieticians, documentation of which must be available upon inspection."

Ms. Condon continued, "These regulations will NOT apply to public and private school cafeterias (already supplying menus provided by nutritionists) or to meals prepared for patients in licensed health care facilities. Under existing regulations, these entities already require the involvement of nutritionists, and these criteria are evaluated as part of the inspectional process. In addition, the regulations do not apply to grocery stores or supermarkets except for those that operate a food establishment that is located in the facility (e.g., a coffee shop or deli that makes sandwiches on site as a ready to eat food). Food items to be exempt from these regulations include self-service items that already have calorie information on their labels in accordance with existing federal labeling laws. Further, for alcoholic beverages sold in covered establishments, a display of average calorie values will be accepted."

Ms. Condon further noted that the impact on Local Boards of Health is expected to be minimal because they already inspect food establishments (if the calorie information is posted the food establishment is in compliance). It is also thought to be a minimal cost to the chains that are already in compliance with menu labeling standards due to the New York and California laws. It was noted that approximately 2800 food establishments in Massachusetts would have to comply with these regulations. The penalties for non-compliance are outlined in the regulations at 105 CMR 590.019 and state in brief "not more than one hundred dollars for the first offense and not more than five hundred for a subsequent offense..." The Board of Health can suspend or revoke a license or close an establishment if they believe the establishment is not complying with the regulations.

Staff noted that they will return to the Council seeking final approval after the public hearings are held, probably on February 24 in Boston

and February 25<sup>th</sup> in Worcester. Discussion followed by the Council. Council members raised the following points: caloric labeling should be put into a context (for instance, how many calories an average person should consume in a day); the fact that the price of the food item often determines if a person will buy it because it is what they can afford; and about the possibility of the Public Health Council advocating to the USDA about healthier food choices.

## **NO VOTE/INFORMATION ONLY**

### **PROJECT APPLICATION NO. 4-3B64 OF LAHEY CLINIC HOSPITAL, INC.:**

It was noted for the record that Council Members Dr. Michael Wong, Dr. Michèle David and Ms. Lucilia Prates Ramos recused themselves from discussion and voting on Lahey Clinic Hospital.

Ms. Joan Gorga, Director of the Determination of Need Program, provided a brief history on the transplantation program in the Department (see verbatim transcript). She noted that Lahey Clinic performed 31 kidney transplants in the last year and 52 liver transplants. "It is the most active liver transplant program within the region", she said.

Mr. Jere Page, Senior Analyst, Determination of Need Program, presented the Lahey Clinic Hospital application to the Council. He said, "...Lahey Hospital is proposing to provide pancreas transplantation services, and the hospital is part of the New England Pancreas Consortium. To determine the need and availability of pancreas transplants in Massachusetts hospitals, Staff has reviewed organ recovery activity in Region 1 as designated by the United Network for Organ Sharing, otherwise known as UNOS. Region 1, which includes most of New England, is part of the current UNOS Organ Allocation System, which plays a major role in the supply of donor pancreases for transplant and also maintains the patient waiting list for the service in the region. Staff review pancreas transplant activity in all transplant centers in Region 1 to determine

how this activity, might further impact the availability of pancreas transplants in Massachusetts hospitals.”

Mr. Page continued, “Lahey anticipates creating three pancreas/kidney transplants, combination transplants in 2009, the first year of operation and five pancreas/kidney transplants in 2010, the second year of operation. With regard to need, based on current data provided by the New England Organ Bank, which is the procurement agent for New England, there will be an estimated sixty to eighty pancreases that will be available in Region 1 for transplant in 2009, and there are currently about two hundred and four patients involved in the region on the pancreas waiting list. There is quite a discrepancy in those numbers, and based on the application of the revised conservative transplant rates of the projected 2010 Massachusetts population, we estimate about 44% pancreas transplants may be performed annually in Massachusetts by 2010. Given this data, this is the estimated number of pancreases available for transplant in Region 1 in 2009, the magnitude of the current patient waiting list, and the 2010 population-based estimates for pancreas transplant, staff has determined that the Lahey’s project volume is based on reasonable assumptions. There is no maximum capital expenditure associated with this project. The recommended incremental operating cost is one hundred twenty-eight thousand five hundred and sixty-two dollars for the program’s first year of operation, which was 2009, and that represents three transplants at a projected cost of forty-two thousand eight hundred and fifty-four dollars per transplant. We are recommending approval with conditions.”

Mr. Page noted a correction to the staff summary, Table 3, under the Year 2007. “We list 34 total transplants in the first six months. That is the total for the entire year, not just six months. So the total for all of 2007, in Region 1, which is essentially most of New England, there were thirty-four total pancreas transplants.”

Council Member Dr. Alan Woodward moved approval. After consideration, upon motion made and duly seconded, it was voted unanimously (Dr. Michael Wong, Dr. Michèle David and Ms. Lucilia

Prates Ramos recused) to approve **Project Application No. 4-3B64 of Lahey Clinic Hospital, Inc.**, based on staff findings, with a maximum capital expenditure of \$0 and first year incremental operating costs of \$128,562 (August 2008) dollars. The staff summary is attached and made a part of this record as **Exhibit No. 14,920**. As approved, this Determination of Need provides for pancreas transplantation services at Lahey Clinic Hospital's main campus in Burlington as part of the New England Pancreas Consortium or any successor implemented under the sponsorship of UNOS and/or the New England Organ Bank, as applicable, such as the UNOS Region 1 Regional Pancreas Oversight Committee. This Determination is subject to the following conditions:

1. This approval for pancreas transplantation services is contingent upon Lahey Clinic Hospital complying with the terms set forth in the Memorandum of Understanding of the NEPC approved in April 1991 as part of DoN Project No. 3622.
2. Lahey shall participate in the NEPC Central Selection Committee or any NEPC/UNOS successor committee to evaluate and select final candidates for pancreas transplantation. The Committee shall hear appeals of any patients who believe they have been improperly eliminated in the pre-screening process by Lahey.
3. Lahey shall use, and each patient shall meet, the selection criteria as described in the NEPC application Section IV: Recipient Selection Criteria, which was approved in June 1997. Any changes in these criteria must be submitted to the Commissioner, Department of Public Health, for approval. Any patient who is proposed for pancreas transplantation who does not meet each of the patient selection criteria shall be reviewed by the NEPC Administrative Committee or any NEPC/UNOS successor committee.
4. Lahey shall publish in the patient informational material provided to each patient on the Kidney-pancreas and pancreas transplant procedure, the kidney-pancreas and pancreas

transplant survival rates of the applicable facility as well as the average transplant survival rate of the NEPC, or similar body fulfilling the same functions and responsibilities as NEPC.

5. Lahey shall collect the clinical and cost data involved with the Hospital's pancreas transplant program in such format as requested by the Department of Public Health on an annual basis.
6. Lahey shall enter into referral arrangements for provision of pancreas transplantation with any acute care hospital in New England which desires such an arrangement.
7. For Massachusetts residents, Lahey shall not consider ability to pay or insurance status in the evaluation or recipient selection process. Massachusetts residents who are uninsured or are insured through government programs shall have equal access to transplants. Free care will be provided to non-Massachusetts residents by the Hospital in accordance with existing hospital free-care policies.
8. Lahey shall not reduce Medicaid intensive services or procedures, or primary care services or procedures as a trade-off for pancreas transplants.
9. Lahey shall not, as a consequence of its undertaking a pancreas transplant program, reduce the amount of free care provided to patients who have not received pancreas transplant services below the amount of free care provided during the Hospital's 2008 fiscal year, as adjusted for inflation.
10. Lahey shall have its pancreas transplant protocols, including consent or withdrawal of consent policies, organ procurement policies and confidentiality policies, reviewed and approved by the NEPC Ethics Committee or any NEPC/UNOS successor committee.

11. In regards to payment rates set by the Division of Health Care Finance and Policy (DHCFP), Lahey shall be reimbursed no more than \$42,854 (August 2008 dollars) for each pancreas transplant. Future increases in organ acquisition fees will routinely be added to the per transplant reimbursement. Inflation factors calculated by DHCFP will be used to reassess the reimbursement for transplants and retransplants annually.
12. Lahey shall provide a total of \$50,000 (August 2008 dollars) not to exceed five years to support the community health service initiatives described in the staff summary in Section H: Community Health Initiatives which states: "Lahey has agreed to provide a total of \$50,000 (August 2008 dollars) for a period not to exceed five years to support community-based programs and projects that are designed to serve populations in need. The funding of these initiatives shall begin upon licensure approval of the pancreas transplantation services. Lahey will work with the Department's Office of Healthy Communities (OHC) and the local Community Health Network Area (CHNA #15) to develop programs and projects in compliance with the Department's Community Health Initiatives Guidance Document. Furthermore, Lahey agrees that it will work with the OHC and the CHNA to formalize the plan within 90 days of the Public Health council approval of this project. Finally, Lahey will file annual written reports to the OHC for the duration of the approved initiatives and agrees to work with the OHC in developing methods to evaluate the effectiveness of the initiatives."
13. With regard to its interpreter service, Lahey shall meet the program requirements detailed in the staff summary, Section C: Operational Objectives which states in part: "The Office of Health Equity (OHE) has recently conducted a review of the policies and procedures in place related to language access for non-English or Limited English Proficient (LEP) speaking patients who use Lahey's services. Based on this review, OHE recommends, and Staff agrees, that as a condition of approval, Lahey enhance its existing Interpreter

Services program by providing the following elements of interpreter services policies and procedures in order to improve access to the Hospital's services for non-English or LEP-speaking residents in the service area. To satisfy this condition, Lahey must:

- Update program policies and procedures to include specific language that clearly states that interpreter services are available at no cost, that only trained interpreters should be used to provide medical interpretation and/or logistical support, that the use of minors as interpreters is prohibited, and that discourage the use of family members or ad hoc interpreters.
- Identify how Lahey patient data on race and ethnicity will be used to improve patient care and eliminate health disparities.
- Include the coordinator of Interpreter Services in all decision-making processes that have an impact on communities that are racially, ethnically, and linguistically different.
- Include LEP patients in satisfaction survey.
- Provide a supplemental progress report on the most current DoN conditions as part of the annual Interpreter Progress report.
- Develop a plan to track all interpreting sessions, inclusive of the employee bank.
- Develop procedures detailing when to use volunteer staff interpreters, how to access them and how their responsibilities will be met when working as volunteer trained interpreters.
- Develop a detailed plan for training clinical, support and administrative staff on the appropriate use of interpreters.
- Establish a plan to ensure the availability of and assuring the quality of interpreter services at its affiliated practices and centers.

In addition, Lahey shall submit a language needs assessment and a plan to address the above requirements to OMH within 45 days of the DoN approval, and the Hospital shall notify OMH of any substantial changes to its Interpreter Services Program. Also, the Hospital shall follow recommended National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health Care. Lahey will also provide an annual progress report to OMH within 45 days of the end of the federal fiscal year.

Staff's recommendation was based on the following findings:

1. Based on staff's analysis and findings found in the staff summary dated January 14, 2009 for Project Application No. 4-3B64 on Lahey Clinic Hospital for the Public Health Council. This application was filed by Lahey Clinic Hospital, Inc. to provide pancreas transplantation services at the Hospital as part of the New England Pancreas Consortium.
2. The health planning process for the project was satisfactory.
3. Need exists for a program in pancreas transplantation at Lahey Clinic Hospital based on projected utilization, as discussed under the health care requirements section of the staff summary.
4. Lahey is certified by the Medicare Program to perform kidney transplantation and therefore meets the eligibility standards of the Department.
5. The project, with adherence to certain conditions, meets the operational objectives of the DoN Regulations.
6. The project satisfies the compliance standards for the service, and Lahey will comply with the Department's Hospital Licensure Regulations.

7. No capital expenditure is associated with the project.
8. The incremental operating costs of \$128,562 (August 2008 dollars) are reasonable based on an estimated cost of \$42,854 each for the three pancreas transplants anticipated in FY 2009, the first year of operation. All operating costs are subject to review by the Division of Health Care Finance and Policy ("DHCFP") according to its policies and procedures. The per-transplant cost should be reassessed annually by the DHCFP according to its policies on inflation.
9. The project is financially feasible and within the financial capability of the Hospital.
10. The project satisfies the requirements for relative merit.
11. The proposed community health initiatives, with adherence to a certain condition, are consistent with the DoN regulations.

**PROJECT APPLICATION NO. 5-4932 OF THE WEST BRIDGEWATER MA ENDOSCOPY ASC, LLC D/B/A COMMONWEALTH ENDOSCOPY CENTER:**

Mr. Bernard Plovnick, Consulting Analyst, DoN Program, presented the West Bridgewater application to the Council. Mr. Plovnick in his address and his staff summary to the Council noted the following information:

"The West Bridgewater MA Endoscopy ASC, LLC d/b/a as Commonwealth Endoscopy Center, a Massachusetts limited liability company, is seeking a Determination of Need (DON) for transfer of ownership of Commonwealth Endoscopy Center, Inc. ("Commonwealth"). Commonwealth, a single specialty ambulatory surgery center, is located at 120 West Center Street, West Bridgewater, MA 02379. West Bridgewater Endoscopy is a new entity that has been formed by Commonwealth and AmSurg

Holdings, Inc. a Tennessee-based company which has purchased a 51% share of Commonwealth's assets. AmSurg is a wholly owned subsidiary of AmSurg Corporation, a publicly held corporation which specializes in the development, acquisition, and operation of ambulatory surgery centers in partnership with physician practices throughout the United States. Currently, all 176 ambulatory surgery centers owned and operated by AmSurg Corporation are located outside of Massachusetts. The proposed transfer of ownership is set forth in an extensive asset purchase agreement. West Bridgewater Endoscopy will assume responsibility for operation of the existing facility, consisting of two operating suites and three prep/recovery beds, at the existing location. The parties to the agreement state a belief that the new operating company, combining Commonwealth's clinical and operational expertise with AmSurg's resources, management experience, and operational experience will result in a stronger, higher quality provider of gastroenterological services of the surrounding communities."

Mr. Plovnick said, "Based upon a review of the application as submitted, staff finds that the application satisfies the requirements for the Alternate Process for Change of Ownership found in 105 CMR 100.600 et seq. Specially, staff finds that the applicant satisfies the applicable standards applied under 100.602 as follows:

- A. Individuals residing in the Hospital's health systems area comprise a majority of the individuals responsible for decisions concerning:
  - 1. approval of borrowings in excess of \$500,000;
  - 2. additions or conversions which constitute substantial change in services;
  - 3. approval of capital and operating budgets; and
  - 4. approval of the filing of an application for determination of need.

Under the terms of Section 7.10 of the proposed operating agreement, the Applicant shall establish a Special Approvals Committee (SAC) empowered with the above responsibilities. The

SAC shall be composed of three persons appointed by AmSurg and two persons appointed by Commonwealth and a majority of the SAC shall be residents of the Center's primary service area and/or health systems area.

- B. The Applicant consulted with EOHHS concerning the access of medical services to Medicaid recipients at the Center. According to EOHHS, a freestanding ambulatory surgery center must provide a minimum of three clinical specialties to be eligible to become a Mass Health provider. As a result, Medicaid access is not a relevant issue to the Applicant, a single specialty provider.
- C. The Division of Health Care Quality has determined that the Applicant has not been found to have engaged in a pattern or practice in violation of the provisions of M.G.L.c.111, §51(D)."

In closing, Mr. Plovnick said, "Staff has found satisfactory compliance with each of the above requirements, and recommends approval of this project with one condition...There is no capital expenditure associated with this project and no Ten Taxpayer Groups have filed petitions."

Council Member Dr. Michael Wong moved approval of the application. After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Project Application No. 5-4932 of The West Bridgewater MA Endoscopy ASC, LLC d/b/a Commonwealth Endoscopy Center's** transfer of ownership of a single specialty (endoscopy) ambulatory surgery center. This Determination is subject to the following condition:

1. The applicant shall meet the Medicare conditions of participation for Ambulatory Surgical Services and shall maintain Medicare certification.

For the record, the applicant and his attorney were present but did not testify.

## **PRESENTATION: “INTERPRETER SERVICES IN MASSACHUSETTS ACUTE CARE HOSPITALS”:**

Chair Auerbach made introductory remarks and said in part, “...The provision of interpreter services in Massachusetts Acute Care Facilities is important to the Department, as a mechanism for ensuring that patients receive equitable, culturally and linguistically appropriate care...”

Ms. Georgia Simpson May, MMHS, Director, Office of Health Equity presented an overview of the Office of Health Equity to the Council and made introductory remarks about the interpreter report. She was accompanied by Mr. James Destine, MA, M.Div, Coordinator, Hospital Based Interpreter Services and author of the report and Mr. Jordan Coriza, Office of Public Health Communication and Strategy and Independent Interpreter.

Ms. Simpson May said in part, “... The Office of Health Equity is designed to promote the health and well being of racial, ethnic and linguistic minority populations throughout the Commonwealth. Some of the current initiatives that come out of the Office include a CLAS Initiative and the disparities grants which Commissioner Auerbach is committed to, in support of reduction in health disparities across the Commonwealth. There are actually 27 grantees, totally one million dollars in awards. We have been supporting the local screenings of the now award-winning “Unnatural Causes” documentary and we will be doing language access and interpreter services, and the outcomes of the current effort underway.”

Ms. Simpson continued, “Massachusetts is linguistically diverse. There are over a hundred different languages spoken in the Commonwealth, and more than 20% of the Commonwealth’s residents, age five years of age and older, speak a language other than English at home and of that population, 44% spoke English less than very well. The foreign born population accounts for 14% of the State’s population, which is an increase of 18% from the 2000 census. Why is this important? It is important because we can anticipate that language access needs will continue to increase as the

population continues to increase and becomes increasingly diverse. It is critically important that there is a seamless exchange of information between provider and patient. If not, these are some of the repercussions. We can anticipate impairments in discussion of symptoms, which may result in misdiagnosis, misinformation around treatments and decisions, delay in care and treatment, poor clinical outcomes and possibly malpractice and could possibly increase health care costs..."

Ms. Simpson May said further, "In this first annual report, we will highlight some of these areas. Seventy-two acute care hospitals in Massachusetts were surveyed and all 72 completed and responded to the survey. The report covers Federal Fiscal Year October 2006 to September 2007."

Mr. James Destine provided a Powerpoint Presentation of the report to the Council. Some statistical highlights follow:

- Massachusetts mandates that hospitals provide Interpreter Services 24 hours a day, seven days a week at no cost to the LEP patients. Hospitals use four models in their language service delivery: staff interpreters, employee bank/volunteer, on-call per diem, and contracted staff.
- Massachusetts acute care hospitals reported a total of one million two hundred two thousand and thirty-one (1,202,031) completed interpretation sessions during the Federal FY 2007.
- Face to face and telephonic interpretation were identified as the two primary methods used to provide this type of services. Eighty percent were conducted face to face and twenty percent telephonically. The frequency of the usage of one method over another does not necessarily translate into superior quality.
- Top ten languages most frequently encountered by acute care hospitals: Spanish, 512,221, Portuguese 260,510,

Russian 82,663, Chinese 69,761, Haitian Creole 56,770, Cape Verdean 50,652, Vietnamese 45,069, Arabic 16,224, American Sign Language 11,403, and Albanian 9,593.

- Massachusetts hospitals are committed to ensuring access to meaningful communication for all individuals seeking medical treatment.
- Massachusetts hospitals are providing a substantial number of interpretation sessions.
- Massachusetts hospitals face challenges meeting the needs of an increasingly linguistically diverse population.
- MDPH must develop a multi-faceted strategy to measure the quantitative outcomes and work to improve the quality of language services at all Massachusetts hospitals. The following recommendations will further advance industry standards:
  - Develop a monitoring system to ascertain the qualification, capacity, and competence of companies and hospitals that train medical interpreters.
  - Standardize testing at hospitals for language proficiency prior to hiring an interpreter.

Standardize the definition of interpretation sessions. Currently, each hospital defines the interpretation session per encounter or patient.

Hospitals:

- Establish data tracking mechanisms to capture requests for interpretation services as well as cancelled or completed sessions.

- Establish quality improvement measures to capture wait time between a request and the provision of service.
- Adoption of the Recommendations above will improve quality of care for LEP patients; ensure competency of all interpreters across the state; provide consistency with data reporting for future assessment; increase service utilization, reduce delays in care, reduce costs, and increase provider and patient satisfaction.

Mr. Jordan Coriza, Office of Public Health Communication addressed the Council. He noted that he feels the FLNE report (a bi-annual publication of MDPH with language data collected by the Mass. Department of Education for students whose primary language is not English) data is more accurate than old census data for the department to use and having been a hospital interpreter himself he wanted to say that interpreters are organizing and there is a group called National Coalition of Interpreter Certification that is looking into certifying interpreters and looking at training standards.

Discussion followed by the Council (please see verbatim transcript for full discussion). Dr. Michèle David noted that as a physician she uses interpreters and sometimes due to her schedule running late, she loses the interpreter. She believes there needs to be certification of interpreters because sometimes the interpreters she has experienced have been inaccurate in their translation. Dr. Michael Wong agreed with Dr. David, also as a physician, he has witnessed inaccurate interpretation of what was said. A conversation was had around the problems immigrants may have at the point of prescription pick-up. Are the directions on the bottles in the correct languages? And further, Is how to take the medication explained to the patient correctly? In part, Ms. Lucilia Prates Ramos said that “interpreters are necessary but are only a Band-aid approach to quality of care.” Chair Auerbach said, “There is a need for a system-wide approach – the responsibility doesn’t lie in a single location.” Mr. Jordan Coriza noted that Interpreter Services are not a reimbursable service for hospitals. Chair Auerbach noted that cost involved need to be acknowledged as part of the solution in figuring out how to provide

interpreter services in the correct language in a culturally sensitive way to people.

In conclusion of the discussion Chair Auerbach stated, "It is clear that the Council has a great deal of interest in this issue and we really value your work and understand the importance of it...We hope we can work collectively to give you both the support and the resources needed so that we are able to strengthen our work here and also the work at the facility level...Thank you for the work you do."

### **No Vote/Information Only**

#### **Follow-up Action Steps:**

- Woodward suggested that vitamins are not necessary in a healthy diet as advocated in Mass Motion Campaign
- Wong suggested that caloric labeling should be put into a context (for instance, how many calories an average person should consume in a day) on menus (Menu Labeling Regulation)
- David suggested the possibility of the Public Health Council advocating to the USDA about healthier food choices

The meeting adjourned at 12:20 p.m.

John Auerbach, Chair

LMH