

PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, December 10, 2008, 9:00 a.m., at the Department of Public Health, 250 Washington St., Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. All Members were present: Chair John Auerbach, Commissioner, Department of Public Health, Ms. Helen Caulton-Harris, Mr. Harold Cox, Dr. John Cunningham, Dr. Michèle David, Dr. Muriel Gillick, Mr. Paul J. Lanzikos, Mr. Denis Leary, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Dr. Meredith Rosenthal, Mr. Albert Sherman, Dr. Michael Wong, Dr. Alan C. Woodward, and Dr. Barry S. 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 that docket item 3b (Final Promulgation of 105 CMR 302.000, Congenital Anomalies Registry Regulations) had been pulled from the docket and will be rescheduled to be heard at a future meeting.

RECORD OF THE PUBLIC HEALTH COUNCIL MEETING OF OCTOBER 8, 2008:

A record of the Public Health Council Meeting of October 8, 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 October 8, 2008 record with corrections to three typos as pointed out by Dr. Alan Woodward. The record was distributed to the members prior to the meeting for review.

PROPOSED REGULATION: INFORMATIONAL BRIEFING ON PROPOSED REGULATIONS TO 105 CMR 970.000, PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURER CONDUCT:

Attorney Melissa J. Lopes, Deputy General Counsel, presented the proposed regulations to 105 CMR 970.000, Pharmaceutical and Medical Device Manufacturer Conduct to the Council, "I would like to start by giving a bit of background of why this is an issue, and what the issue is, and why it is a concern. According to the Prescription Project and Advocacy Group dedicated to advancing medical practice and policy, ninety-four percent of physicians nationwide have received food/drug samples, or other reimbursements and payments from industry. Pharmaceutical industry marketing expenditures directed at physicians doubled from 3.5 billion in 1996 to 7.2 billion in 2005, excluding pharmaceutical samples and medical device samples. Why are we

concerned about this issue? A number of studies have shown that there can be negative effects associated with industry to physician marketing, which include reduced generic prescribing, increased overall prescriptions rates, and the quick uptake of the newest, most expensive drugs, including those with only marginal benefit over existing options, with established safety records. Studies show that even small gifts can create an unconscious demand for reciprocity on the part of physicians."

Attorney Lopes, continued, "To address these issues, there has been sort of an evolution in terms of policy to address these. The first that you will see is non-binding guidelines. The American Medical Association, The Pharmaceutical Researchers and Manufacturers of America, The Advanced Medical Technology Association and The Office of the Inspector General have all developed voluntary guidelines but these lack measures to monitor and ensure compliance." She noted that there is pending federal legislation that would preempt state law with regards to financial disclosure if it passes [Physician Payment Sunshine Act of 2007]. It was noted that a lot of smaller medical device manufacturers wouldn't be captured under that law.

Atty. Lopes showed a chart with a comparison to other states. Massachusetts is the only state that is mandating its own restrictions to a state-authored manufacturing code of conduct and requiring disclosure of financial payments for medical device manufacturers. Atty. Lopes said further, "Massachusetts is proposing a robust approach to regulating both pharmaceutical and medical device manufacturing conduct with respect to industry payments to physicians. It is basically composed of three major components. There is the state-authorized Marketing Code of Conduct, (with) PhRMA (Pharmaceutical Research and Manufacturers of America) and AdvaMed (Advanced Medical Technology Association) voluntary codes as the floor. There is also a compliance program with detail of how the companies within the state have to comply with the state-authored marketing code of conduct. And the third part of the regulations is the disclosure requirement that mandates public disclosure of payments to physicians..."

She continued, "The first section is the Marketing Code of Conduct. It covers pharmaceutical and medical device manufacturing companies that employ a person to sell and market prescription drugs or medical devices in the Commonwealth. It also covers people who engage in the production, preparation, propagation, compounding, conversion or processing of prescription drugs or medical devices, or engages in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs or medical devices. Hospitals, wholesale drug distributors and retail pharmacists are not subject to the market restrictions within the Marketing Code of Conduct, even though they may engage in some of those activities that I have just listed. Who is affected by the

Marketing Code of Conduct? It's health care practitioners who prescribe prescription drugs for any person, and are licensed to provide health care in the Commonwealth, or partnerships or corporations comprised of such persons, or their agents. We have clarified in the regulations that this does not include bona fide employees of pharmaceutical or medical device manufacturing companies."

Atty. Lopes said further, "Prohibited activities under the Marketing Code of Conduct, First under the General Marketing Prohibitions and the regulations prohibit any grant, scholarship or subsidy that is provided in exchange for prescribing, dispersing or using prescription drugs, biologics or medical devices, the provision of payment of entertainment or recreational items of any value to a health care practitioner, who is not a salaried employee of the medical device or pharmaceutical manufacturer, and payments in cash or cash equivalents to health care practitioners, either directly or indirectly, except as compensation for bona fide services, and the provision of complimentary items, such as pens, coffee mugs, gift cards, flowers, etc."

The next section of prohibitions is prohibited meals and these are meals that are part of entertainment or recreational events, meals that are provided without an informational presentation made by a pharmaceutical or medical device marketing agent, or with such agent being present, meals for health care practitioners that are offered, consumed, or provided outside of the health care practitioner's office or hospital setting. The definition also includes academic medical centers and pharmaceutical or medical device specialized training facilities. The legislation's intent was to allow for informational presentations by such manufacturers on the latest prescription drugs or medical devices and so modest meals can be provided. This definition also recognizes the fact that some of these informational presentations cannot happen in a doctor's office because they involve large medical devices such as diagnostic equipment and laboratory equipment that cannot be moved easily from doctor's office to doctor's office and so those informational sessions usually happen in a specialized training facility. Meals that are provided to a health care practitioner's spouse or other guest are prohibited. The next category of prohibitions regards continuing medical education conferences or meetings, and the following prohibited payments, financial support for the cost of travel, lodging, attendance or other personal expenses of non-faculty health care practitioners...You cannot provide direct payment of meals at CMEs conferences or meetings and you cannot provide sponsorship of a continuing medical education that is not compliant with the appropriate standards set by ACCME or accrediting bodies."

Attorney Lopes continued with permissible activities: "Permissible meals are modest and occasional meals in conjunction with informational sessions in specified clinical training settings, and those are hospitals, academic medical

centers, or these specialized training centers that I discussed. You can sponsor meals at CMEs if it is ACCME compliant, third party scientific or educational conferences, charitable conferences or meeting, or professional meetings, and you can also provide meals pursuant to a written consulting agreement for bona fide services, a written sponsored research project for genuine research in clinical trials. Other permissible payments to health care practitioners include the reasonable compensation for the substantial and professional consulting services of a health care practitioner for genuine research in clinical trials; reimbursement of reasonable cost necessary for technical training on a medical device of the subject – if subject to a written agreement for purchase of the device; the provision of price concessions, such as rebates or discounts in the normal course of business; ad payment for bona fide services...Bona fide services include but not limited to research, participation on advisory boards, presentations at company-sponsored training, and royalties or licensing fees.”

Attorney Lopes continued, “Permissible payments with respect to CMEs, conferences and meetings include scholarships for residents and interns, as long as the recipients of the scholarships are not chosen by the pharmaceutical or medical device manufacturer and that it is a legitimate educational expense for these residents and interns, compensation and reasonable expenses for conference faculty that are involved in the content and in presenting at the conference and where the sponsorship is made directly to the conference or meeting organizers. A pharmaceutical or medical device manufacturer can provide money to sponsor a conference or CME event as long as it is the CME/Conference organizer who is deciding how the money will be spent and what the content of the conference will consist of.”

Attorney Lopes noted further, “Other permissible activities include the provision of peer review journals or other academic, scientific or clinical information, advertising in peer review journals, the provision of prescription drugs or medical device demonstration or evaluation units, the provision of free outpatient prescription drugs to establish patient assistance programs for the benefit of low income individuals, and technical assistance concerning the reimbursement information regarding products, including identifying appropriate coverage coding or billing of products.”

Attorney Lopes explained the compliance requirements of the regulations: “...Under the regulations, pharmaceutical and medical device manufacturers must adopt and comply with the Department’s State-Authored Marketing Code of Conduct, must adopt a training program in conjunction with the Department’s Marketing Code of Conduct, must adopt policies and procedures for investigating instances of non-compliance with the Marketing Code of Conduct, must identify a compliance officer charged with ensuring compliance with the Marketing Code of Conduct, and must file an annual report with the Department that includes a

description of its training program and investigative policies, identifies the name, title and address of its compliance officer, and certifies compliance with the Marketing Code of Conduct for that year." Ms. Lopes noted that a separate report is required in the Disclosure section on compliance activities through the year."

Atty. Lopes said, "...Under the Disclosure requirements of the proposed regulations, pharmaceutical and medical device manufacturing companies must report any fee payment, subsidy, or other economic benefit with a value of at least fifty dollars directly or through its agent to any covered recipient in connection with the company's sales and marketing activities. In the next slide, it provides a definition of covered recipient ... and it includes any person in the Commonwealth authorized to prescribe, dispense, or purchase prescription drugs and medical devices in the Commonwealth. It does not include bona fide employees of pharmaceutical or medical device manufacturers, or consumers who purchase prescription drugs or medical devices."

"...In terms of our definition of sales and marketing activities, it is the broadest state definition of sales and marketing activities. It includes activities beyond what most people would think of as purely sales and marketing. If you will note, the first section is advertising promotion or other activity that is intended to be used, or is used to influence sales or market share of a prescription drug, biologic or medical device; influence or evaluate the prescribing behavior of an individual health care practitioner to promote a drug, biologic or medical device; evaluate the effectiveness of a professional pharmaceutical or medical device detailing force. The second category of activities that it covers is product education and training, which usually has a marketing component to it and the third category is any economic benefit with a value of at least \$50.00 for any purpose other than the reasonable compensation, for the substantial professional consulting services of a health care practitioner in connection with genuine research project or clinical trial. It would include anything from reporting of the giving of product samples, free prescription drug samples, demonstration units, rebates, discounts, royalties, licensing fees, and other types of product developing consulting agreements that are not in conjunction with genuine research or clinical trials..."

"Each annual Disclosure Report filed by a pharmaceutical or medical device manufacturing company will be made publicly available on an easily searchable web site established by the Department. The information provided will include fees, payments, subsidies, or other economic benefits related to the sales and marketing for the previous calendar year, including the provision of product samples and demonstration units", stated Atty. Lopes.

She further noted that Massachusetts regulations require strict compliance of Disclosure requirements and said, "There is a provision in the regulations that manufacturers don't knowingly structure fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the reporting requirements of Chapter 111-N and 105 CMR 970.000. A person who violates 105 CMR 970.000 shall be punished by a fine up to five thousand dollars per transaction occurrence or event and all persons subject to these regulations are under Duty of Good Faith compliance. There is a non-retaliation provision so that the Department can receive accurate reporting from all sources without people being retaliated against for providing us information on potential violations of these regulations."

In closing, Atty. Lopes noted the following implementation dates and information:

On July 1, 2009 require compliance with the new code of conduct; submission of information in Section 970.005 ...which is compliance with providing the name of their compliance officer and information on their training programs and how they are going to comply with these regulations and the first two thousand dollar fee so the Department can set-up the database and get it ready for the reports that will come in the next year. July 1, 2010 is the submission of the first disclosure report by pharmaceutical and medical device manufacturers, and this will cover the period of July 1, 2009 to December 31st, 2009. The Department will hold public hearings on January 9, 2009 (in Boston) and January 12, 2009 (in Worcester) and written comments will be accepted through 5:00 p.m. on January 19, 2009. After the hearings, staff will return with a summary of the public comments and their final recommendation on the regulations to the Council.

Chair Auerbach noted in part, "...We understand this to be an informational presentation and that the Council, as is its custom with informational presentations on new regulations that are being released for public comment, does not vote. Our role as a voting Council occurs after the public comment period, where we hear the response to the proposed regulations and we summarize that information and talk through the issues that are raised, that come forward through the public comment period. We look forward to having you come back at the end of that comment period and summarizing those comments, and we anticipate that, at that meeting, we will have a full and lively discussion because clearly there are many issues associated with these proposed regulations..."

Chair Auerbach noted further that any Council Member that may have a conflict of interest or even a perceived conflict of interest was asked not to participate in the discussion on these proposed regulations today since some of the Council Members are providers of health care or work for health care facilities.

Discussion followed and Council Member Mr. Paul Lanzikos asked some questions. One of the questions was "If the federal proposed Grassley bill legislation is passed how would these Massachusetts regulations be effected?" Attorney Lopes said the Massachusetts regulations would stay in effect except for the disclosure piece. In response to Mr. Lanzikos, it was clarified that even if an activity occurred in another state, these regulations apply to a physician practicing and licensed to prescribe in Massachusetts and that the "genuine research" definition is taken from the federal rules on genuine research and clinical trials and further that staff is still working on the definition of what \$50.00 per meal means per person or per group.

Council Member Ms. Lucilia Prates Ramos made comments. She said in part, "...I am hopeful that the public comment period is going to afford the Department opportunity to come up with a final regulation that will ensure the spirit of the regulation which is full transparency, cost containment and full disclosure. She asked for clarification in 105 CMR 970.008: "What does complimentary items really mean – does it include computers and costly test books? I think we need to be much more clear about the items being banned, disclosure is really important to protect the consumer...I want to know that my doctor is not working for the pharmaceutical company part time....I work with elders and limited English speaking and what are they being prescribed, I worry about them...Some of this research has contributed to the escalation of the cost of health care. Attorney Lopes replied in part that staff is trying to delicately balance the interests of consumers and legitimate research activities because research benefits consumers in the long run too. Council Member Prates Ramos noted that she didn't think the disclosure piece would infringe upon genuine research.

Chair Auerbach added, "I this will be an important regulation for us to have a very full and complete discussion about before we vote on its passage and we also believe very strongly for the reasons that Ms. Prates Ramos and Mr. Lanzikos commented on and soliciting many different public perspectives on this is going to be important for us to understand what can be done to ensure that the spirit of the regulation as required by legislation is actually carried out and we look forward hearing the public comments when you return..."

No Vote Information Only

FINAL REGULATION: REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 345 CMR 4.00 – LOW LEVEL RADIOACTIVE WASTE MANAGEMENT FUND REGULATIONS:

Ms. Suzanne Condon, Director, Bureau of Environmental Health, made introductory remarks and said in part, "...The purpose of us coming here today is to seek final approval on our regulations, to raise fees associated with our radioactive materials users and radioactive waste in the state. The primary reason we felt a need to raise the fees had to do with the fact that we had one of our largest radioactive materials users and waste generators in the State, the Yankee Row Nuclear Power Facility, out in the western part of the state, close. It was decommissioned and, therefore, no longer paying fees into the program." Ms. Condon noted that radioactive waste is now being stored primarily at the Pilgrim Nuclear Power Plant and other sites around the state since Barnwell facility in South Carolina has closed and Yuca is not available yet.

Ms. Condon said further that after releasing the proposed fee increases to the Council in October, they sent notices out to more than 500 licensees, telling them of the proposal. The Department received only three comments, "One from a licensee that said, seems reasonable to me; two that raised questions about the appropriateness of our raising fees when we didn't have a radioactive waste site in this state. Our response to those comments is there are requirements in terms of reporting and gathering information by staff, a lot of work that has nothing to do with the state having a designated radioactive waste site. The third comment was from a licensee who uses devices that contain radioactive materials but does not generate waste so they questioned whether or not it was appropriate for the Department to charge them a fee. Ms. Condon noted that the state statute designates who is charged a fee so it is beyond the Department's control to change that.

A brief discussion followed by the Council whereby it was noted that the fee increase was modest and less than the inflation rate. The fee hasn't been increased since 1993 and the proposed increase is enough to fund the program right now and is consistent with other state's fees. Mr. Bob Walker, Director of the Radiation Control Program at DPH noted that the funds go into a trust fund that roll over from year to year and the money can only be spend on low level waste. Mr. Walker further noted that 99% of the Low Radioactive Waste can be sent to Utah for many years to come and that only 1% of the radioactive waste is problematic. Council Member Paul Lanzikos suggested to staff that licensing fees should be reviewed often to maximize revenue and also so increases are modest for the fee-payers. Ms. Condon said they reviewed their fees often about every couple of years.

Dr. Alan Woodward made the motion to approve the Amendments to 345 CMR 4.00. After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Final Promulgation of Amendments to 345 4.00 – Low Level Radioactive Waste Management Fund Regulations** and that a copy of the approved amendments be attached and made a part of this record as **Exhibit Number 14,917**.

DETERMINATION OF NEED PROGRAM:

PREVIOUSLY APPROVED PROJECT NO. 2-4931 OF PLANNED PARENTHOOD LEAGUE OF MASSACHUSETTS:

Ms. Joan Gorga, Director, Determination of Need Program, presented the Planned Parenthood League of Massachusetts request to the Council. Ms. Gorga noted, "Planned Parenthood League of Massachusetts is before you this morning for a significant change to its project for new construction to replace and relocate the existing Ambulatory Surgery Center in Worcester, which was approved in July of 2008. The approved maximum capital expenditure (MCE) was \$6,196,653. The hospital is requesting an increase in the MCE to \$7,596,653 as a result of increased construction costs. Architects for the Holder originally submitted the plans to a cost estimator, to develop a cost for the original DoN application. When the Holder put the project out to bid to contractors, the estimates returned were far higher than the original estimates. Bids received from four contractors ranged from 4.7 million to 7 million, compared to the 3.5 million for the same costs in the original estimates. That is just for the construction part of it. A value engineering process with the contractor submitting the lowest estimate further reduced the cost by a hundred thousand dollars. The Holder has concluded that the variance was a combination of market volatility and an inaccuracy in the original estimate. The additional costs of the project will be funded through an increase in bond financing."

Ms. Gorga continued, "Staff has analyzed the request of Planned Parenthood for an inflation adjusted increase of eight hundred and ninety-one thousand and thirty-seven dollars in the approved MCE from an inflation adjusted MCE of six million seven hundred and five thousand, six hundred and sixteen dollars in October 2008 dollars to seven million five hundred ninety-six thousand, six hundred and fifty-three dollars, also in October 2008 dollars, and Staff has determined it was reasonable. Staff notes that increases in the line items of the adjusted MCE are only in the areas directly affected by construction, or as corrections due to the omission of interest costs staff found that the requested changes in the MCE were reasonable. The amended DoN also requires Planned Parenthood to contribute additional community initiatives, an approximate \$44,552 dollars based on the increase in the maximum capital expenditure. Planned Parenthood has been in communication with the Office of Healthy

Communities to develop the expanded initiatives and it has been mutually decided to expand the original initiatives proportionately, using the additional funds.”

Ms. Gorga noted for the record, “Staff summarized the comments of the Interested Parties and included copies of their letters in the mailing. Both Interested Parties commented on the Holder’s selection of Cutler Associates, a non-Union construction company. Both Interested Parties alleged that Cutler Associates uses subcontractors that violate the rights of the workers. However, the issues raised in the Interested Party letters are beyond the purview of the Determination of Need Program and, therefore, Staff have not commented on these issues. Staff recommends approval of the request of Planned Parenthood for an increase in the approved MCE. Both the Applicant and the two Interested Parties are here today...”

Discussion followed by the Council. Dr Alan Woodward, Council Member clarified with staff, “This is a modification based on the realities of the construction costs, versus their initial estimate and that is the extent of it. There is no change of scope.” Ms. Gorga agreed.

Ms. Elizabeth Skidmore, Representative for Carpenters Local 107 of Worcester and Central Massachusetts, testified before the Council on behalf of the Simon James Interested Party. Ms. Skidmore praised Planned Parenthood for the work they do for women. She also said she was a supporter of two other things (1) creating more jobs for women in construction and (2) creating construction jobs with contractors who follow the law in regards to Workers Compensation Coverage, wage an hour, and paying their taxes. This job came down to a choice between Elaine Construction and Cutler Associates. She said that Cutler Associates uses subcontractors that don’t hire women and also have a long and troubling history with not following the construction labor laws. She read a list of violations by sub-contractors used by Cutler Associates. In closing, Ms. Skidmore said, “I am asking you, to not approve the project, but to instead require Planned Parenthood not to use a particular contractor, but use a contractor that does not have a documented history of breaking laws in relation to the construction laws.”

Attorney Christopher Souris, New England Regional Council for Carpenters, addressed the Council, on behalf of the Rocky Thompson Interested Party. He said in part, “...I am going to get right to the point. Why is this a problem for you? You are a Council in state agency, whose Chief Executive Officer, the Governor, has declared it as a major policy priority, to attack the problem of tax and insurance fraud through illegal misclassification on a multi-agency level. It includes, as a policy matter, there is a task force, but the executive order recognizes that this problem manifests itself in the context of the jurisdiction of

multiple agencies. You are confronted with a project that is being built by a contractor that the Union has submitted evidence has a history of using subcontractors that illegally misclassify their employees and commit tax fraud. Chapter 111, Section 25C, in the third to the last paragraph, specifically gives the Department the authority to give and withhold, and withdraw, and terminate Determinations of Need, in the event that the Applicant fails to comply with all of the provisions of law relating to the construction, licensure and operation of health care facilities, and complying with such further terms and conditions, as the Department reasonably shall require. I think that provision clearly gives this Department the power and the authority to impose reasonable terms and conditions on this project, as a condition of granting it permission to go forward, to prevent fraud from taking place...The Staff recommendation was that this issue was not within the purview of the Council and I think that it actually is squarely within the purview of the Council and I would request that the Council revisit the issue, look at the issue, consider the issue because it actually wasn't considered..."

Attorney Carol Balulescu, Deputy General Counsel, Department of Public Health explained staff's recommendation to the Council: "I did advise Ms. Gorga when she brought the information to me, that this was not within the purview of the Department, in terms of the Determination of Need. As Dr. Woodward pointed out, this is really an amendment to a previously granted Determination of Need, and it is an amendment to cost only. The gentlemen who just spoke referred to a section of the General Laws that talks about compliance with state laws, regarding the construction and operation of health care facilities. That is really referenced to our own licensing requirements, and requirements around not the entities that provide the construction, but the actual physical plan of the facilities within the Commonwealth. My analysis of this was that this is not relevant, that the only question before the Council is the significant change to the maximum capital expenditure that came before you. As Dr. Woodward pointed out, had there not been this change, Planned Parenthood would have been free to go ahead with the construction as planned. Had the estimates come in at the level that they have now seen, they would have been able to go ahead and proceed and it never would have come back before the Council."

Discussion continued by the Council. In response to further clarification requested by Council Member Dr. Barry Zuckerman, Atty. Balulescu said, "It is not the role of the Council to get involved in disgruntled bidders in projects that have been approved through the DoN process." Attorney Donna Levin, General Counsel for the Department of Public Health added, "There is a further concern here. We are being asked to condition this application or table this application based on what I heard was evidence that one contractor has against other; that there is an investigation going on by the Attorney General's Office and I don't think it is the purview of this Council to get involved at that level when there is

an investigation...I think what Carol is saying is the Determination of Need was approved, and what is coming up now is a technical financial correction here which comes nowhere near to being involved in these issues, but I would have a concern for the whole DoN, if we are talking about a situation that is under investigation."

Attorney Carol Balulescu added, "DoN applies to the applicant. The Applicant is Planned Parenthood. To attach conditions to a DoN, to an applicant, that may or may not be within an applicant's control, extends the process, I think, beyond what the statute contemplates. Any condition would apply only to the applicant. Again, it would not apply to anybody who is a contractor or a subcontractor, or an employee of a subcontractor. That type of condition could lead to a Determination of Need process that probably would not withstand a legal challenge."

Discussion continued by the Council. Mr. Paul Lanzikos noted, "...The issues that are being raised are a genuine and serious concern...The material impact would be much more effective if we were getting this opinion or information from a state agency that has proper regulatory oversight to say whether it is our Wage Division or the Attorney General, to say that, for some reason, this is not a bona fide or qualified bidder and then that provision that was referenced may come into play, but to have charges presented in a less formal way, I don't think is within the structure of the decision making that is available to us." Dean Harold Cox, Council Member asked for more guidance in voting on this item "since serious allegations have been made, and staff states that this information is outside the purview of the Council." Chair Auerbach added in part, "I am hearing the frustration that these are issues that we care about but that we are being advised that it is not within our authority, or the DoN process, to allow us to do that." Dr. John Cunningham, Council Member asked, "...Is it within the purview of that process to require applicants to accept responsibility for the classification of the employees of the contractors or subcontractors that they choose in their building projects?" Dr. Paul Dreyer, Director, Bureau of Health Care Safety and Quality noted that he thought it would be difficult to require that of the applicants and that applicants have to assume that if the contractors are doing business in the Commonwealth they are bona fide and legal otherwise they wouldn't be doing business and bidding on projects.

Discussion continued and Council Member Helen Caulton-Harris said, "We are really talking about two things here. We are talking about Planned Parenthood before us to get an increase in terms of what the market will bear in the construction project. This is the vote we are here to take. The second one has to do with equity and fairness in contracting, and we have heard, again, that this is not within the purview of the Public Health Council, no matter how all of us feel viscerally about that as a very, very important issue. If we are going to be

having this discussion, then we would be having it with all DoN's it would appear, and that really would set a very bad precedent as far as the Department of Public Health is concerned. I think we need to figure out how we wrestle with this as individuals, perhaps as people in our own work places. I am not quite sure. I think we all heard a compelling case, but I do think we are here for one specific reason, and that is to vote around the increase and the project's maximum capital expenditure. That's the vote we are here to take. I would recommend that we figure out how to do that in a way that gets us to the next step and moves us along." Council Member Mr. Dennis Leary, added for the record, "...I want to make it clear that I feel it is not within our responsibility and probably more appropriate to stay within the guidelines that our Counsel has advised us on, to address the issue at hand and not be evaluating the conduct of contractors, which to me is totally beyond the realm of what we are supposed to be doing."

Discussion continued; please see the verbatim transcript for full discussion. Dr. Alan Woodward, Council Member said in part, "We should approve this request for an increased expenditure and if there are legitimate concerns, which it sounds as though there may be, then there must be other avenues through state structure to ensure that contractors are abiding by all appropriate and applicable laws and regulations." Mr. Lanzikos noted that he agreed with what the last few Members said and that he would like to hear from the applicant.

Note: As parliamentary procedure requires, a motion was on the table and seconded so the Members would have to vote on it before hearing from the applicant.

Council Member Albert Sherman moved approval of the application. After consideration, upon motion made and duly seconded, it was voted: (Chair Auerbach, Ms. Caulton-Harris, Dr. John Cunningham, Dr. Michèle David, Dr. Muriel Gillick, Mr. Paul J. Lanzikos, Mr. Denis Leary, Dr. Meredith Rosenthal, Mr. Albert Sherman, Dr. Michael Wong, Dr. Alan Woodward, and Dr. Barry Zuckerman in favor; Dean Harold Cox opposed; Ms. Lucilia Prates Ramos abstained; and Mr. José Rafael Rivera recused) to approve the significant change amendment to **Previously Approved Project Application No. 2-4931 of Planned Parenthood League of Massachusetts** based on staff findings. As approved this amendment provides for an increase in the project's maximum capital expenditure from \$6,196,653 (February 2008 dollars) to \$7,596,653 (October 2008 dollars). This amendment is subject to the following conditions:

1. Planned Parenthood League of Massachusetts shall provide an additional \$44,552 in community initiatives based on an increase of \$891,037 (October 2008 dollars) in the Maximum Capital Expenditure as described in the request for significant change. The community initiatives will fund programs that

address local and regional health priorities in areas of need as assessed by the Office of Healthy Communities. Specific initiatives must be developed collaboratively by the Office of Healthy Communities and Planned Parenthood League of Massachusetts (within a reasonable time frame not to exceed three months) and may include mini grants, community capacity building, training and evaluation.

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

The break down of costs follows:

Land Costs:

Land Acquisition	\$	833,695
Site Survey and Soil Investigation		33,000
Non-Depreciable Land development		<u>41,720</u>
Total Land Cost	\$	908,415

Construction Costs:

Building Acquisition Cost	\$	766,305
Depreciable Land Development Costs		326,519
Construction Contract (including bonding contract)		4,247,524
Fixed Equipment not in Contract		80,000
Architectural & Engineering Costs		739,000
Pre-Filing Planning & Development		139,481
Post-Filing Planning & Development		65,000
Other: Regulatory and Permitting		27,000
Net Interest Expense During Construction		111,890
Major Moveable Equipment		<u>250,000</u>
Total Construction Costs	\$	6,613,238

Financing Costs

Costs of Securing Financing		75,000
Total Financing Costs		<u>75,000</u>
<u>Maximum Capital Expenditure</u>	\$	7,596,653

Ms. Diane Luby, President, Planned Parenthood League of Massachusetts addressed the Council. She said, "Part of the reason that we are back here is because, although Planned Parenthood sent out numerous requests for Proposals, we are not a client that every contractor wants to work for. There have been many articles in national papers about Planned Parenthood building

projects in Aurora, Illinois and in Denver, Colorado, where those contractors were personally picketed and harassed at their house throughout the entire project. As you know, Planned Parenthood has protestors at our facility every single day. We certainly wanted to go, and did our initial contract as Ms. Skidmore said, with Elaine Construction. We did have an outside cost estimator give us a cost of 3.35 million, and because we did not have a huge amount of people respond to this, I don't think we had the competitive bid process that we needed. You understand that we are a non-profit and to get a bid that was over twice what we had gone for was not realistic for us. We attempted to get the contractor who built the facility, who has a signatory agreement with the carpenters in our last facility in Springfield. Their biggest client in Worcester objected strenuously to them working with us; so they did not bid on the project. We reached out to many people to do this. What Ms. Skidmore did not say is that, during the course of this that I personally have met with her. I asked her for language that could be included in the contract with the contractor, that would assure that we had women working on this, and they would not provide this to me with Cutler as the contractor."

Ms. Luby continued, "I also met with Mark Erlich, who is the Secretary/Treasurer of the New England Regional of Carpenters, to see if we could come up with some accommodation, and what we have done with the contractor is met consistently with him. We have been assured that we will have the ability to audit the wage sheets of all the subcontractors. It is hugely important to Planned Parenthood League of Massachusetts that these wage and labor laws are complied with. These are people that we see in our health centers. These are people that we want to have these benefits."

In closing she said, "The last thing I will say is that we chose Cutler with huge amount of representation from the Worcester community, on a building committee that we had. This is a contractor that I think has been there sixty or seventy years. They have a good reputation in the community and I have personally have assurances from the President, Fred Mulligan that they will adhere to all labor laws..."

PRESENTATION: A PROFILE OF HEALTH AMONG MASSACHUSETTS ADULTS, 2007", By Helen Hawk, PhD, Acting Director, Health Survey Program, and Bonnie Andrews, MPH, Epidemiologist, Health Survey Program, Bureau of Health Information, Statistics, Research and Evaluation; Georgia Simpson May, Director, Office of Health Equity:

Dr. Helen Hawk, Acting Director, Health Survey Program made introductory remarks, "We will start off with Massachusetts Behavioral Risk Factor Surveillance System (BRFSS) highlights from our 2007 data. The focus of our presentation will be on race/ethnicity disparities in health. Long term trends and

some selected indicators comparing Massachusetts and national figures of the United States. In 2007, 21,500 respondents completed the survey. More than 50% of the survey was state-added questions reflecting the current needs of public health in Massachusetts. We are a fully integrated partner in the Department of Public Health and most of the programs are a close collaborative, and our data is the basis for many presentations and reports.”

Ms. Bonnie Andrews, MPH, Epidemiologist, Health Survey Program, Bureau of Health Information, Statistics, Research and Evaluation, presented highlights from the “A Profile of Health Among Massachusetts Adults, 2007” report:

- Older adults have higher percentages of fair or poor health than younger adults. Low education (less than a high school education) has a higher percentage than high education (four years of college or more), and Black and Hispanic respondents had higher percentages than White respondents
- In the 18-64 age group, females are less likely to be uninsured than males, and Black and Hispanic respondents are more likely to be uninsured than White respondents
- Older adults have less current tobacco smoking than younger adults. Low education has more current tobacco smoking than high education
- Older adults are more likely to be obese than younger adults. Black and Hispanic respondents are more likely than White respondents to be obese and females are less likely than males to be overweight or obese
- Older adults are more likely to be diagnosed with diabetes – 65 plus are more likely than 35 to 64 year olds to be diagnosed with diabetes

Dr. Hawk noted some time trends in race and ethnicity (age-adjusted):

- Hispanics have the highest level of fair and poor health and the gap between Non-White and White populations persist over this time period....
- Current tobacco smoking is decreasing and despite fluctuations. The trend is significantly lower for the White population, however, the prevalence of smoking for all three of those groups is about equal
- Overweight and obesity is on the rise for all these sub-population groups, Blacks have the highest percentage of obesity and the gap between them and Whites tend to increase and maybe Hispanics soon will reach the same level.

- The prevalence of diabetes is rising significantly, with Hispanics out-pacing Blacks, which is 17% now. The gap is widening.
- Hispanics have the lowest levels of people involved in physical activity. The trend is positive for groups, White and Blacks, and the percentage is okay, compared to national.
- No disparities by race/ethnicity in mammography screening. The trend is positive, and it is positive for Hispanic and White, but Blacks maybe did not reach significance, but are about the same, and mammography rates are 90% in Massachusetts for 2007, one of the highest numbers nationally

In summary, Dr. Hawk said, "...We saw that health insurance coverage is lower for some population groups; young non-Whites and Low Educated. We saw the positive impact of Health Care Reform, which decreased significantly the percent of uninsured among all these groups. Some indicators, as overweight is on the rise for everybody. However, current tobacco smoking is encouraging. Regarding the trend, recognizing the importance of analyzing race/ethnicity disparities, and we, of course, will continue collecting the data, monitor that, as well as Health Care Reform impact. We have a mixed picture about health indicators trends by race/ethnicity and health care access and utilization disparities. While preventive measures show improvement and no significance between sub-populations, obesity, diabetes is a matter of concern..."

Ms. Georgia Simpson May, Director, Office of Health Equity, gave her thoughts on the data to the Council. She said in part, "Due to the achievement of the Health Care Reform, we have newly insured individuals however, and according to the Boston Globe these individuals are still utilizing the Emergency Rooms for care." She indicated, this may be due to two reasons (1) limited access to primary care physicians and (2) the Emergency Room Interpreter Law which requires that interpreters are present for patients in acute care hospitals, noting that people will return to a facility where their language is spoken. She said further, "How do we broaden the interpreter services that we offer at our facilities so we see a change in this ER trend?"

Discussion followed by the Council. Council Member Dr. Michèle David stated, "I serve primarily the Limited English Proficiency population at a safety net hospital and in my work I have done significant patient advocacy because, even when a patient comes to us, they don't know that they can call after hours. You have to continually educate the patient to understand that. They don't understand the concept of 24/7 access. So it is not just saying to them, this is what you have. It is also that consumer education is really of primary importance in the kind of population we take care of in terms of looking at health disparities, in addition to

all the access and issues related to health care disparities from the recipient's point of view."

Council Member Mr. Jose Rafael Rivera inquired about smokeless tobacco use, wondering if its use has increased because of the no smoking bans. Staff indicated that the question has been dropped from the BRFSS survey due to a very low response rate. Dr. Bruce Cohen, Bureau of Health Information, Statistics, Research and Evaluation noted that they welcomed the Council's ideas about additional topics that they could cover in the BRFSS survey.

Council Member Mr. Paul Lanzikos noted that they are mandated by the state Executive Office of Elder Affairs to conduct an annually survey and said, "There must be some logistic way that we can incorporate some of the questions that would be useful to you into a survey that we are already doing." Council Member Helen Caulton-Harris inquired about information specific to the Western region of the state. Dr. Hawk clarified that the report they were discussing is by EOHHS Regions but that they had geographical data by CHNA available that they will get to her. Council Member Dr. Muriel Gillick asked for clarification on how staff adjusted the data in the report. Dr. Hawk replied, "The report has certain limitations because it is designed for a broad audience, so the tables in the report use univariate analysis. We did not provide cross-tabulation, for example, how the age and socioeconomic status and race were correlated. We analyzed the data by age separately, by race/ethnicity separately, by EOHHS region separately. This is a report that is focused on the certain variable not on correlation."

Chair Auerbach asked a question, "Are we seeing significant changes in terms of health equity? Are we seeing significant changes in terms of access to health care and health outcomes as a result of health care reform? Is it possible to do a sub-analysis of this - to take a look and see if in the period since Health Care Reform, whether or not the gap is closing at all or even getting larger? Dr. Hawk replied, "We have some long term trends in the amount of non-insured by race/ethnicity, where you are absolutely right, Whites are going down considerably, while Hispanics and Black have no significant trend on percentage of not insured. So, when you look at the picture you cannot say the gap is closing. However, the percentage of people that could not see a doctor, due to cost, in the past year is decreasing significantly for Hispanics...Regarding percentage of people that have personal care provider, overall, it is high, but in 2007, Hispanics, during the whole year, even after Health Care Reform implementation, have the significantly lower percentage of people that did not have personal care provider, the reason, I don't know, many reasons may be involved in that..."

Dr. Bruce Cohen offered to come back to the Council during the summer with the 2008 preliminary Health Equity data. Chair Auerbach replied, "That would be wonderful."

Dr. Michèle David inquired whether the BRFSS report is linked to hospital data on for instance, heart failure rate and cardiovascular diseases. Dr. Bruce Cohen explained that the hospital discharge data is collected by the Division of Health Care Finance and Policy and is analyzed separately. He said further, "We have some questions of self-report around diabetes, heart disease and other kinds of diseases but we don't link it to medical records or follow-up directly with the sources...This is still an anonymous survey." Council Member Lucilia Prates Ramos asked if the BRFSS sampling targets the very different Portuguese speaking communities because there are geographical differences in access to information and that plays out differently in a Portuguese speaking community in Ludlow versus a Portuguese speaking community in Southwestern Massachusetts. She said further, "In the future, I would strongly recommend that you think about including those particular groups and including elders and breaking out those particular groups. That would give us a much clearer, concise picture and there are plenty of community partners who would be willing to work with you in doing that..."

Dr. Hawk replied that the BRFSS is available in English, Spanish and different versions of Portuguese and she said further that they planned to subtract and subset the more defined communities in order to analyze their health and their health utilization because it may be a huge factor..." Council Member José Rafael Rivera suggested that a question on alternative forms of health care be included on the BRFSS.

FOLLOW-UP ACTION LIST:

- Licensing fees should be reviewed often to maximize revenue and keep increases modest for rate payers (Lanzikos to Sue Condon)
- Touch base with Secretary of Elder Affairs about possibly linking their survey with the Department's BRFSS Survey (Lanzikos to Bruce Cohen, Helen Hawk, Auerbach)
- Dr. Bruce Cohen offered to come back to the Council during the summer with the 2008 preliminary Health Equity data.
- José Rafael Rivera suggested that a question on alternative forms of health care be included on the BRFSS.

- Lucilia Prates Ramos requested that BRFSS staff break down the data further to sub-groups in the Portuguese communities and also include the Elderly population.

The meeting adjourned at 12:00 p.m.

John Auerbach, Chair

LMH