PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, December 12, 2007, 10:00 a.m., at the Department of Public Health, 250 Washington St., Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Mr. Harold Cox, Dr. John Cunningham, Dr. Michèle David, Dr. Muriel Gillick, Mr. Paul J. Lanzikos, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Mr. Albert Sherman (arrived at approximately 10:15 a.m.), Dr. Michael Wong, Dr. Alan C. Woodward and Dr. Barry S. Zuckerman arrived at approximately 10:20.a.m.. Absent Members were: Ms. Helen Caulton-Harris and Dr. Meredith Rosenthal. Also in attendance was Attorney Donna Levin, General Counsel, Department of Public Health.

Chairperson 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 the presentation announced on the revised docket would not be heard due to time constraints: "Betsy Lehman Center for Patient Safety Expert Panel 2007 Update - Weight Loss Surgery Best Practices to Protect Patient Safety". The Council Members introduced themselves to the audience.

RECORD OF THE PUBLIC HEALTH COUNCIL MEETING OF OCTOBER 10, 2007

A record of the Public Health Council Meeting of October 10, 2007 was presented to the Council for approval. A copy of the minutes was distributed to the Council Members prior to the meeting for review. Council Member Mr. Paul Lanzikos moved for approval. After consideration, upon motion made and duly seconded it was voted unanimously [Council Member Zuckerman not present to vote] to approve the Record of the Public Health Council Meeting of October 10, 2007 as presented.

REGULATION:

REQUEST FOR PROMULGATION OF AMENDMENTS TO 105 CMR 140.000 ET SEQ.: GOVERNING THE LICENSURE OF LIMITED SERVICES CLINICS:

Dr. Paul Dreyer, Director, Bureau of Health Care Safety and Quality, presented the Limited Services Clinics (LSCs) Regulations to the Council. He said in part, "…The proposed amendments set standards for LSCs, including the so-called "retail clinics" and make other procedural and technical changes and updates." Dr. Dreyer noted a change to page four (4) of the staff memorandum to the Council, dated December 12, 2007 as follows:

Several parties objected to the removal of the requirement for Public Health Council approval of licenses. Staff had proposed changing the section on license review to reflect current practice, as the Council had previously delegated approval of license applications to Department staff. "Because at the time the Council approved the delegation the Department did not make any changes to any of the relevant regulations staff proposes to maintain internal consistency by leaving section 140.120 of the regulation intact."

Staff's memorandum, dated December 12, 2007 gave background information as follows:

"In December 2006, representatives of MinuteClinic, a subsidiary of CVS/Caremark Corporation met with staff from the Department to discuss the MinuteClinic model for the operation of retail clinics – clinics situated on the premises of another retail business that provide a limited set of pre-identified services. As a result of the widespread interest and concern about the MinuteClinic model and retail clinics in general, the Department proposed amendments to the clinic regulation to govern the operations of such limited services clinics. Department staff briefed the Council about the proposed amendments on August 8, 2007." A copy of the originally proposed amendments is presented as Attachment 1 to the Council memorandum.

The Department held two public hearings on the proposed regulations, one in Boston on September 5, 2007 and one in Worcester on September 18, 2007. Staff indicated, "Written comments on the proposed LSCs regulations were accepted through September 28, 2007. Forty-seven individuals and groups submitted written comments; five individuals spoke at the hearings but did not submit written comments. In addition following the close of the comment period, the Department received letters of support from members of the General Court. On October 3, 2007 Senator Richard Moore and Representative Patricia Walrath, Senate and House Chairs of the Joint Committee on Health Care Financing sent letters to Commissioner Auerbach and the Council members stating their support for the Department's plan to promulgate regulations for the licensing of LSCs. On October 30, 2007, Senate President Therese Murray and Senators Robert A. O'Leary and Benjamin Downing sent a letter to Commissioner Auerbach and Council members expressing their support as well."

Staff further noted that the testimony covered a wide range of topics, and ranged from high level policy concerns to detailed comments about square footage of treatment rooms. Staff's memorandum further states, "Supporters of the amendments stressed the potential for LSCs to increase access to care for common, minor ailments in a cost effective manner. Opponents of the amendments stressed the potential of LSCs to further fragment an already fragmented system and expressed concerns about the ability of LSCs to provide high quality care. And further because LSCs are often staffed by Nurse Practitioners (NPs), concerns about quality in LSCs are often concerns about NP models of care…" Attachment 2 of the staff memorandum to the Council summarizes the testimony received through the comment period.

Dr. Dreyer stated in part, "The written record, I believe, reflects the extraordinary interest that these regulations have generated. What I would like to do this morning is to focus on the changes we have made in response to testimony, as a way of highlighting the issues raised at the hearing, and the way staff has responded to those issues. Many of the comments concerning the regulations resulted from a failure to appreciate that the entire set of regulations at 105 CMR 140.000 applies to Limited Service Clinics unless otherwise stated. We realized that we were not as clear as we could have been on this point, and you will see this when we discuss specific sections."

Staff further noted that "Various commenters said that LSCs should be subject to the same standards that apply to other clinics. Staff notes that 105 CMR 140.000 in its entirety applies to all types of clinics, including LSCs, unless otherwise noted within the text of a particular section, so that LSCs are in fact subject to most of the regulatory requirements that apply to other clinic types. With respect to exceptions, the general principle is that the restrictiveness of the regulation should be determined by the intensity of the service being regulated. Thus ambulatory surgery centers must meet much more stringent physical plant requirements than mental health centers."

"…The first change that we have made is to the original definition [see Attachment 3 of the Council packet]. We have attempted to more clearly define the limitations of a Limited Service Clinic. We have changed the language to make it clear that Limited Services require only a focused history and physical examination that does not require patient disrobing and gowning, or venipuncture. We retained the restriction of CLIA-waived test only, and added other language that makes it clear that the Limited Services have to be preidentified in licensure applications submitted to the Department and we have included a list of exclusions. Limited Service Clinics shall not mean surgical services, dental services, physical rehabilitation services, mental health services, alcoholism or substance abuse services, or birth center services."

Dr. Dreyer said further, "Some of those testifying thought we should have a list in the regulations of what Limited Services were. We didn't think we could do this because we would constantly be updating the list and we would never be able to catch up as practice changes. We think that this change clarifies what we mean by LSC, what services will be included and what services will not be included. I should point out that much of the testimony asked us to put specificity into the regulations that we did not feel necessary because every application gets reviewed by my staff prior to approval. What will happen is, if an application comes in for a Limited Service Clinic and on the proposed list of services is a service that is questionable we won't approve it. We will have it removed from the list. For example, if someone came in and proposed to provide a pain service, we wouldn't approve that because a pain service would require access to Schedule 3 drugs, which we think wouldn't be appropriate in this sort of setting. We will exercise, as we do in all license applications, we will exercise appropriate judgment in determining what should be on the list and what shouldn't be on the list." Dr. Dreyer continued his review of Attachment 3 with the Council; please see that document for the changes made to the proposed regulations, after the public hearing and comment period. These changes

have been incorporated in the final proposed regulations dated December 12, 2007 (Attachment 4). Some changes are listed below:

- 140.205C makes it clear that LSCs shall provide a hand washing facility with hot and cold water and blade-type operating handles and knee or foot controls in each examination and treatment area. These requirements were in the original regulations but this change makes it explicit.

- 140.209: Clinic facilities used for patients should be accessible to handicapped individuals. The Department strengthened this by requiring that those clinics located on the premises of another entity shall be accessible through well-marked corridors or aisles that constitute an accessible route for handicapped individuals. A formal agreement must be in place insuring this accessible route be free of obstruction at all times. No license will be issued without an agreement in place.

- Amended the regulations to allow a taped message that directs patients to a toll-free number that will enable the patient to speak directly to a practitioner off hours.

- Changed the language in several places that required a roster of primary care physicians in the clinic's geographic area be maintained to "a roster of primary care practitioners, including community health centers in the clinic's geographic area, who are currently accepting new patients".

- 140.100F: requires LSCs to develop policies and procedures designed to identify and limit, if necessary, the number of repeat encounters with individual patients.

Lengthy discussion followed by the Council Members. Please see the verbatim transcript of the meeting for the full text of the discussion. Council Members Drs. Woodward and Zuckerman noted their concern about patient care, specifically about adequate care for children by trained pediatric specialists at LSCs and appropriate referral of patients for further services. Mr. Cox asked for clarification on licensing requirements. Dr. Dreyer responded in part, "…All of the current requirements governing the clinical practice of clinics apply to Limited Services Clinics." Attorney Carol Balulescu, Deputy General Counsel for DPH added, "The Department doesn't have the authority to regulate private physician offices, or private nurse practitioner offices. The vast majority of settings, where folks receive individual medical care are not regulated by the Department. It is up to the Board of Medicine and the Board of Nursing to regulate those practices. We regulate the clinics and we regulate the hospitals."

Discussion followed about LSCs having convenient or adequate locations for their toilet facilities and janitor's closets. In addition, Dr. Muriel Gillick suggested that hand sanitizer dispensers be on site at LSCs, "…which would reflect cutting edge medical practice". The question of appropriate patient disrobing was discussed, Dr. Dreyer stated,

"…Certainly, disrobing, the prohibition means patients don't change into a Johnny. That is clearly prohibited. We are going to allow inoculations, flu shots, so if someone has to roll up a sleeve, then that is okay. A man removing an outer shirt when he is wearing a tee shirt might be appropriate." Discussion continued on the referral of patients, would the insurer pay twice? Dr. Dreyer stated that the insurers testified in favor of the regulations and that he would assume that like a physician referral, the follow-up care would be covered. Dr. Alan Woodward said in part, "…I think there needs to be a mechanism that is clearly defined, that there is a physician who is available to that nurse practitioner by phone within a matter of minutes, to provide advice on the unusual patient; and second, if that patient requires follow-up, it isn't just giving them a list. It is helping to expedite if they need acute back-up care that day…that some physician within the locale is available to see that patient that day, or within a reasonable period of time, depending on the acuity of it so that they have some coordination with local providers so that there is a mechanism other than, just send them to the Emergency Department if they are beyond the scope of the specific protocol."

Chair Auerbach summarized the requests by the Council Members and recommended that the Council table the LSCs Regulations until the next meeting so that staff can address the concerns brought up by the Council. Chair Auerbach asked that staff address the following issues at the next Public Health Council meeting (using the Attachment 3 format):

1. Conflict of Interest with regard to pharmacies – Is there any language that would limit that potential conflict;
2. Waiting room adequacy at LSC; does it need to be more distinct from the non-clinical section of the facility;
3. Tobacco sales prohibition or suitable warning signs about dangers of tobacco;
4. Clarify in the regulations what is meant by 'disrobing' of patients;
5. Adequacy of a single provider to provide both pediatric and adult care – adequate credentialing;
6. Location of toilet and janitor's closets – have more specific language in regulations;
7. Have in place cutting edge language about state-of-the-art use of hand sanitizers available in LSCs;
8. Language about the PHC having the Adjudicatory Tentative Hearing Decisions come before them in regards to the LSCs;
9. Adequacy of referrals made to physicians after a person sees LSCs including insurance payment issue and evaluation of quality of care.

For the record, Dr. Paul Dreyer added a final comment on the disrobing issue. He stated, "The regulation requires only a 'focused history and physical examination. It does not require patient disrobing and gowning.' The prohibition is only on patient disrobing and gowning." Chair Auerbach added, "…that is a significant clarification from what you said earlier – Here you are talking about the removal of all clothing except in order to put on a gown." Dr. Dreyer replied, "Yes, that's right."

During discussion, it was clarified that proposed regulations:

- Prohibit the provision of services in a LSC to patients younger than two years of age
- Prohibit childhood immunizations
- Allow Influenza shots for children over two if appropriate

Council Member Lanzikos brought up the issue of the regulations not referencing any federal or state statutes regarding handicapped accessibility. Chair Auerbach added, "I understand that to be a broader question of whether or not our current outpatient licensing regulations need to be revisited with regard to the issue of access to people with disabilities. The issue of hand sanitizer is also something that probably should be considered in that larger context. We will note those two that are broader suggestions for a future meeting where we revisit the clinic licensure issues."

Council Member Woodward raised the issue of requiring LSCs to except Medicaid patients or help the uninsured patients to sign up for insurance. Dr. Dreyer noted that none of the Department's licensing regulations address payment. "All of the entities that we license are free to contract with whatever payers they choose, and consistent with that general standard, we haven't addressed payment and I would argue appropriately so." It was noted during discussion that physician practices are exempt from clinic licensure regulations.

Chair Auerbach stated, "I have been conferring with Ms. Levin, it seems unlikely, that given the list of suggested amendments for consideration, that we will have the opportunity to draft that language adequately for your consideration and then actually do a vote today. What I think, therefore, I would suggest, is that we table the discussion that we are having on this particular regulation at this meeting, at this time, and begin the discussion in the January meeting where we have, between now and then, shared suggested language for consideration, for possible amendments, and that will be drafted by a combination of General Counsel and Health Care Quality staff…"

Council Member Sherman moved for tabling of the regulations until the next meeting in January. After consideration, upon motion made and duly seconded, it was voted unanimously to table the discussion and vote on the **Promulgation of Amendments to 105 CMR 140.000 et seq.: Governing the Licensure of Limited Service Clinics** until the January 9, 2008 meeting of the Council. The material presented to the Council members on the Limited Service Regulations (staff memorandum and four attachments) are attached and made a part of this record as **Exhibit No. 14, 894.**

DETERMINATION OF NEED PROGRAM:

INFORMATIONAL BRIEFING ON PROPOSED DETERMINATION OF NEED GUIDELINES FOR ENVIRONMENTAL IMPACT:

Due to time constraints these proposed regulations were not heard or discussed at all.

COMPLIANCE MEMORANDUM:

PREVIOUSLY APPROVED PROJECT OF NEW ENGLAND SINAI HOSPITAL – REQUEST FOR A TRANSFER OF SITE OF 19 HOSPITAL BEDS LICENSED TO PROVIDE CHRONIC DISEASE SERVICES FROM NEW ENGLAND SINAI HOSPITAL STOUGHTON TO A SATELLITE FACILITY AT NEW ENGLAND REHABILITATION HOSPITAL, WOBURN:

Ms. Joan Gorga, Director, Determination of Need Program, presented the request by New England Sinai Hospital to the Council for the transfer of the 19 hospital beds to a satellite facility in Woburn, MA. Staff recommended denial of New England Sinai's request.

Ms. Gorga said in part, "…The Department, within the twenty day period of filing the Transfer of Site, received comments objecting to the proposed transfer from three Interested Parties. Consistent with DoN Regulations, Public Health Council action is necessary. Staff is recommending denial of the proposed Transfer of Site. The regulations governing Transfers of Site under the Determination of Need Program are very specific. The Transfer must not substantially change the population served, defined as the population residing in the cities and towns who patients ranked numerically from highest to lowest, contribute a cumulative seventy-five percent of the facility's total discharges. New England Sinai seeks to transfer beds from Stoughton to Woburn. The Hospital, however, does not presently include Woburn in its list of the first seventy-five percent of patients, ranked numerically or orderly, and added to seventy-five percent. Therefore, serving Woburn would change the population served, and New England Sinai does not meet the test for substantial change of the population served."

Ms. Gorga stated and staff's memorandum to the Council also states, "Staff has analyzed the data included in the NESH application. Staff notes that the town of Woburn, location of the planned satellite, does not appear on the submitted list of the first 75% of towns ranked ordinally and aggregated cumulatively to 75%. The proposed transfer does not meet the test for substantial change of the population served as defined in 105 CMR 100.720 (I)(1): "The proposed transfer will not substantially change the population served by the facility, defined as the population residing in the cities and towns whose patients when ranked ordinally contribute cumulatively 75% of the facility's total discharges." The applicant has included a list of the towns proposed to be served in the future by the project. The regulations do not discuss the future substantial changes in the population proposed to be served and therefore this information is not of valid use in the analysis."

Staff's analysis further states, "105 CMR 100.720 (I)(1) has a second part, which reads, 'provided that the transfer of site request shall not be approved if the proposed site of the transfer is a city or town that ranks higher on the 75% discharge list of another facility that provides the same services than it does on the 75% list of the facility proposing the transfer, unless there has been demonstration that the proposed transfer will not result in

duplication of services'. Staff further noted, "The Department has historically determined that the two parts of the 105 CMR 100.720 (I)(1) are to be analyzed in order. Therefore if an applicant doe not meet the first test for substantial change of the population served, the second part of the section does not pertain. However, data submitted either in response to staff's request from the Interested Parties or as part of the Parties comments indicate that Woburn is one of the towns identified by Youville Hospital as part of its cumulative 75% of discharges for FY2007, and by Kindred Peabody and Kindred Waltham for FY 2006 and Year to Date 2007. Thus, even if the second part of the analysis applied, the Applicant would not satisfy the requirement…"

Ms. Gorga spoke about the access issue. Staff memorandum states that "the proposed transfer of site will significantly increase access to chronic disease hospital beds for the population residing in Woburn and the surrounding communities. NESH studied the patient discharges from five local area acute care hospitals, the Medicare discharges from these hospitals and the DRG classifications of the patients and has estimated a need for beds for approximately 340 additional patients per year. NESH states that there are at present no chronic disease hospital beds in Woburn. In addition, the applicant has stated that the mileages and drive times to the four other long term care hospitals or LTCH hospitals in the area are prohibitive. The applicant submitted letters of support from four of the five local acute care hospitals in the area (Lahey Clinic Medical Center, Winchester Hospital and HallmarkHealth which includes Lawrence Memorial and Melrose-Wakefield Hospitals). The letters are very supportive of the services provided by NESH proposes to provide to the area and are complimentary of the high quality of service provided by the applicant. The letters further note the proximity of the proposed project to their facilities and some of the letters note difficulties in placing patients with complex DRGs in a chronic hospital setting."

Staff noted that in order to determine the capacity of LTCH beds in the area, staff requested data from the four existing providers, Youville, Kindred Peabody, Kindred Waltham and Shaughnessy-Kaplan Hospitals. Staff also calculated the distance and the driving time from Woburn to each facility using mapquest.com…Staff said, there are 409 LTCH beds within 34 minutes of the proposed site in Woburn and that the four area LTCH facilities are operating at an average of 74.5% occupancy. The four facilities have a combined total of 104 empty beds and could easily assimilate the additional 340 patients per year and the 19 beds proposed for the satellite. Even assuming that the four facilities set a maximum occupancy of 85% there would be 61 available beds in the area."

Staff continued, "It is true that there are no LTCH beds in Woburn. Most of the cities and towns and most of the acute hospitals in the Commonwealth do not have LTCH hospitals in their communities as there are 16 LTCH hospitals and 351 towns and cities in the Commonwealth. True, it would be convenient if facilities were available closer to home, but the Determination of Need program assesses unmet need. The consideration of access in the regulation means unmet need, not convenience. Staff has determined that there are at least 61 available empty beds within 34 minutes driving time of the Woburn area. Based on this availability of beds, staff does not find that there is an access problem in the area."

Ms. Gorga discussed post Determination of Need procedure for Transfer of Site applications and recent Court Findings:

"Interested Parties submit comments within the first twenty days following application for a post DoN Action, such as a Transfer of Site; and, as you know, there were comments from three Interested Parties. Staff often requests additional data from the Interested Parties, especially in a Transfer of Site because it is important to assess the service areas and the seventy-five percent lists, which define compliance. Data including numbers of licensed and operating beds, and occupancy statistics, and data on the service areas, including the seventy-five percent list, were requested by the Staff from the other long term care hospitals in the area. Because of the high degree of interest in this proposal, Staff accepted additional sets of comments from the applicant and the Interested Parties on this application. The Applicant submitted a response to the Interested Party comments, and the Interested Parties commented on that response of the Applicant. As a result, each group submitted two sets of documents. Although beyond the level of public comment required, or even officially sanctioned by the regulation, Staff benefited from a thorough discussion of the issues. The discussion is summarized in the Staff Summary, where staff has also responded in detail to the comments of the Applicant. Staff would like to mention several issues which were raised in the comments."

Ms. Gorga continued, "The DoN regulations govern Transfer of Site of approved DoNs as well as site location of new DoNs. The Transfer of Site regulations have been in force for over twenty years, and have been upheld by the courts as recently as last month, in the case of MRI Associates versus the Massachusetts Department of Public Health, which noted that, if the Department cannot stop an applicant from moving to a different location, the DPH will have lost all geographical control over the distribution of resources within this State, and then could not possibly assure the appropriate allocation of resources, or prevent their unnecessary expansion. The Court went on to say that, if that occurred, resources could be concentrated in a few places, or moved to the same city…There are sixteen of these facilities in the Commonwealth and 351 cities and towns in Massachusetts. Staff notes that it would be convenient if facilities were available closer to home, but it is the responsibility of the Determination of Need Program to assess unmet need, not convenience. The court case previously noted, which has been decided by the Suffolk Superior Court, and upheld by the Appellate Court, called attention to the fact that the word convenience does not appear in the DoN statutes, or the regulations. Need not convenience is the basic criterion of the DoN Rules and Regulations."

Staff noted further that the proposed annual operating costs and capital expenditures associated with the proposed NESH transfer of site are below the DoN expenditure minimums of $698,947 (October 2007 dollars) and $1,520,886 (October 2007 dollars), respectively. The proposed transfer of site will not result in a substantial change in service or a substantial capital expenditure."

In conclusion staff noted, "Staff finds that the proposed transfer of site does not satisfy the Transfer of Site Procedures at 105 CMR 100.720 (I(1)(2), which require that it will not change the population served, and will substantially increase access to the service at the new site. Staff finds that the transfer of site will change the population served, because the population served by NESH does not include the proposed site of the satellite, the town of Woburn, within the list of the first 75% of the communities in the service area. Staff also finds that the transfer of site will not significantly increase access at the new site since there are 61 empty LTCH beds within 34 minutes of the proposed site. The existing LTCH hospitals have an average occupancy of 75%. While it may be convenient for the acute care hospitals in the Woburn area to support a LTCH program to be implemented in Woburn, Staff finds no access issue."

Mr. Lester Schindel, CEO/President of New England Sinai Hospital addressed the Council and said in part, "The primary focus of our presentation today will be that NESH has identified an unmet demand for services of 340 discharges in the area contiguous to where we want to place this satellite, that is, the Woburn/Burlington/Winchester area, that we also believe that this demand takes into account the current supply of services. The capacity issue, as identified by Staff, we believe does not exist. Their calculation of capacity was based on operating beds. In many cases, that is not the same as Staffed beds. You will see on page 4 of their application, there is a big discrepancy in that. Kindred Hospital has listed it appropriately. There staff beds and their occupancy are very consistent. It is very difficult to perceive, being a hospital administrator as I have been for 29 years, that I could really staff up thirty to forty beds at a time. In long term care hospitals, there are many patients suffering from various infectious diseases which require private rooms. This accounts for 20 to 25% of Sinai's cases." Mr. Schindel also noted that convenience is important to patient families; that local physicians have barriers in placing chronic care patients in the area; and that they are experts in long term care.

Dr. Lawrence Hotes, Chief Medical Officer, New England Sinai Hospital testified before the Council, noting the specialized care that rehabilitation patients need. Dr. Andrew Villanuera, Chairman of Pulmonary Care of Lahey Clinic Medical Center said that with the resistant organisms appearing the beds are needed; patients are often elderly with elderly family members who find it very difficult to travel 30 minutes each day to see a sick spouse; that the ICU gets backed up and ER is put on diversion because they don't have the critical care beds needed; and further that the current system is not meeting the needs of patients around the Lahey Clinic area."

Chair Auerbach, noted the time constraint issue and that they may lose the quorum due to members having to leave. He told the applicant that the Council read the documents and that they took this application very seriously and would they mind, the applicant not having anymore speakers but allow other interested parties to address the Council and further that during the question and answer period, they would have another opportunity to raise another issue.

Note: Council Member Albert Sherman left the meeting during Atty. Kalman's presentation below.

Atty. Edward Kalman, Legal Counsel on behalf of Sinai Hospital addressed the Council briefly, "There are issues here of correcting of the analysis and important public policy issues. I will point out to you that Chart 4, this is the seminal chart. There are a number of beds assigned to the Shaughnessy Hospital. However, the data submitted and in the record shows Shaughnessy Hospital discharged 0 patients to the cities of Burlington, Winchester and Woburn. Therefore, they are effectively not available. Also, the difference between operating beds and staff beds, the 73% occupancy, if you apply the 25% rule that you heard here, there is full occupancy. I must go to Kindred Peabody. The difference in beds between those that are occupied and staffed is one bed at Kindred Peabody. Kindred Peabody presents special challenges because it doesn't have a Medicaid contract, and what they suggest is that, when they get a case that crosses over, that exhausts Part A days, and crosses over the Medicaid, that they will treat that case as either bad debts or send them to another Kindred Hospital. I know what bad debt means. That means collection activities, and I know that sending patients during a single episode of illness to another facility is wrong. The Public Health Council has situated chronic care hospitals very close to tertiary care facilities in the State. The Boston hospitals have Youville in Cambridge, the Shaughnessy in Boston. North Shore Medical Center has the Shaughnessy Kaplan Hospital, a fine institution, which is connected by a tube. Boston Medical Center has Radius a few blocks away. Baystate Medical Center has a Kindred facility less than a quarter of a mile away. The Lahey Clinic is the only tertiary care facility in the State that does not have immediate access to a long term care hospital and what we have is three hundred and forty cases that, undeniably, are not able to access this care. That is a matter of need, not convenience."

Chair Auerbach noted that there were three registered Interested Parties who wished to address the Council. Atty. M. Daria Niewenhous of Mintz, Levin, Cohn, Ferris, Glousky and Popeo P.C., noted that she was there representing Kindred Healthcare and that the speakers would introduce themselves. Mr. Robert C. Gladney, Executive Director of Kindred Healthcare and their eight hospitals in Massachusetts, introduced himself and said a few words: "I agree completely with staff conclusions. This is an urgent matter for us. Opening up this facility would hurt our operations. We build our budgets according to the needs we have currently met in the community. We do have excess capacity and I will say that on staff beds versus operational beds, we have seasonality in this business where, in the winter time, we have a lot more patients because of the flu season. In the summertime, we have a lot less. We staff up and down all the time. We are very comfortable with managing staffing based on need in the community, and we do have the excess capacity." Next, Thomas Dowley, Administrator of Kindred Hospital - Boston North Shore - Peabody addressed the Council, "As we noted in the staff summary, we have the capacity, the expertise and the continued interest to provide clinical care to all of our hospitals and with inpatients, especially Lahey Clinic. The Lahey Clinic is our number one admitter, and it is our number two admitter at the Waltham Hospital. Ms. Katrina Melton, Administrator of Kindred Hospital –Northeast – Waltham followed, she said in part, "…We do provide the same services as any of the other LTCFs that are represented in the room today. There are beds available in both facilities, both Kindred North Shore and Kindred Waltham today, and ongoing. Our

clinical liaisons are available and they are eager to assist Lahey Clinic or any other referral service in providing their patient needs, as well as any discharge difficulties that they are having at that time. We do believe that staffing to census is prudent in hospitals, utilization across the board. It is standard practice to staff to what your consistent census is, and as Bob reiterated earlier, that we do staff according to seasons, according to census, according to acuity. It is standard practice to staff up and down, depending on what is going on, and if this request is approved, then it definitely will hinder and hurt both of our facilities. Part of what the transfer of site regulations are intended to prevent hurting other facilities and it will hurt both facilities."

Atty. Niewenhous closed with stating, "…We listened carefully to the comments that Sinai provided, and nothing said here today alters the data that has been provided, that you have carefully reviewed, that staff has carefully reviewed, or provides additional relevant information. It is not your role here to address any internal system problems at Lahey that may affect discharge planning and placement of patients. Basically, Lahey desires to have an additional LTC facility close to its Burlington campus, and we note, to have a contractual relationship to provide physician services at the proposed satellite. These desires go to issues of convenience and perhaps advantageous business interests and are not relevant in analyzing this Transfer of Site request. The staff summary sets forth the very valid reasons why this request cannot be approved under the regulations and Ms. Gorga has presented the analysis to Council and we won't reiterate her points here. The staff summary correctly applies the Transfer of Site regulations in a manner consistent with how DPH has historically interpreted them. This interpretation has been upheld by the Superior and Appeals Court. Consistent, clear and concise application of these regulations is essential to ensure that all providers have a level playing field and a proper degree of certainty in their health planning process. A change in interpretation and a different application of these regulations would contravene the purpose of the DoN Program and, in this particular case, would allow a provider to leap frog out of its own service area to provide services where there is significant excess capacity. Affirming Staff's recommendation to deny the application is the only appropriate, legally correct and, frankly, judicially sustainable outcome."

Notes: Drs. Wong and Zuckerman left the meeting, prior to Ms. Banks presentation. Nine members still present: Chair Commissioner Auerbach, Mr. Cox, Dr. Gillick, Mr. Cunningham, Dr. Woodward, Ms. Prates-Ramos, Mr. Rafael Rivera, Dr. David, and Mr. Lanzikos.

Ms. Maureen Banks, R.N., President of Shaughnessy Kaplan Rehabilitation. Hospital addressed the Council, "I will only address things not in the written documents, most specifically to respond to the Lahey comments. In the past 12 months, Shaughnessy has received 188 referrals from Lahey, of which we accepted 96%, and in fact, accepted them within four hours of receiving the referral. Our proximity to the North Shore Center, as was referenced, allows us also to take patients quicker into the facility than a stand alone hospital can. We have received and continue to actively work with all of the acute care hospitals, placing our liaisons in all of the acute care hospitals to be able to expedite transfer of patients. In reference to the infection control issues, it certainly is an

incredible burden and problem with pulmonary patients. We run at a 73% capacity currently, and we could go up to and 85% capacity before there was any issue in terms of a problem with cohorting patients. Of our 120 beds, all of the beds are staffed and open, and we provide all of the services that Sinai offers within those hundred and twenty LTC beds."

Attorney Carl Rosenfield of Foley and Lardner, representing Shaughnessy Kaplan made a couple of brief points. "I think consideration of this application requires, as part of the consideration, a recognition of the purposes of the DoN program, which is stated in the regulations, which is to really ensure the allocation of health care resources and the reasonable availability of those resources, and that was taken into account by the courts in the Western Mass. MRI case, in deciding the validity of the regulation, and its application in those particular circumstances, which are very similar to these. You have the providers who were attempting to move outside their existing service area in a heavily regulated area in a heavily regulated field, and they were attempting to move into an area where existing providers had excess capacity. And so, the Department decided to deny that application, and that was upheld by the courts."

Attorney Rosenfield said further, "I would also state that this is a fully regulated service. It is not like an acute hospital service, and that means that not only are the numbers of beds regulated and limited, but their distribution is limited, and this regulation is specifically adopted to really control and limit the movement of beds to areas that at least were confined to your existing service area, and that any movement outside the service area had to be based on a convincing demonstration that there were a significant increase in access, and that has been interpreted to mean that the move would satisfy an unmet need, and I don't think those factors are here, and I don't think any evidence has been presented by the applicant to bolster its claim that it would meet an unmet need and access would be improved."

Mr. Daniel Leahey, Interested Party and President/CEO of Youville Hospital, Cambridge testified before the Council and said: "…The Centers for Medicare and Medicaid has really attempted to more narrowly define the types of patients that could come to long term care hospitals for admission, and at Youville we have had a particular response around that. People that may be familiar with our facility a decade ago, it's a very different type of facility today. We have shifted to a clinical focus involving patients with complex medical needs, including ventilator dependent, cardiac and respiratory failure, severe wounds, oncology and post organ transplant patients…In addition, to possessing both the clinical capabilities to manage these patients, we feel that we have sufficient bed capacity, as well, to meet any future demand; and regarding Lahey Clinic, I would just note that, in the last year, our admissions from Lahey Clinic went up 250% from the year before. I think it is reflective of the types of services that we provide in support of the Tertiary Care Centers. Youville believes that the Woburn satellite proposed by the New England Sinai would duplicate services in our geographic area, and there has been no demonstration of unmet need. Specifically with regards to the cities and towns that the satellite proposes to serve, I would note that this represents, 10% of the discharges from Youville Hospital last year came from those cities and towns…"

Chair Auerbach recommended that they adjourn the meeting and table the New England Sinai Hospital Transfer of Site request. Council Member Paul J. Lanzikos made the motion for adjournment and tabling of NESH until the next meeting of the Council. After consideration, upon motion made and duly seconded, it was voted unanimously to adjourn the meeting and table **Previously Approved Project of New England Sinai Hospital** until the next meeting of the Council, which is scheduled for January 9, 2008. A copy of staff's memorandum to the Council, dated December 12, 2007 is attached and made a part of this record as **Exhibit No. 14, 895**.

Note: The Determination of Need Guidelines entitled, "Informational Briefing on Proposed Determination of Need Guidelines for Environmental Impact" had not been discussed or heard at this meeting due to lack of time.

The meeting adjourned at 12:35 p.m.

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John Auerbach, Chair

LMH