PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, September 24, 2008, 9:00 a.m., at the Department of Public Health, 250 Washington St., Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Ms. Caulton-Harris (arrived at 9:50 a.m.), Mr. Harold Cox, Dr. John Cunningham, Dr. Muriel Gillick, Mr. Paul J. Lanzikos, Mr. Denis Leary (arrived at 9:40 a.m.), Dr. Meredith Rosenthal, Mr. Albert Sherman (arrived at 9:35 a.m.), Dr. Michael Wong, Dr. Alan C. Woodward and Dr. Barry S. Zuckerman. Dr. Michèle David, Ms. Lucilia Prates Ramos, and Mr. José Rafael Rivera were absent. 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 the Council will hear docket item No. 3 (Rescinding of the Massachusetts Ban in Children's Jewelry) would be heard first.

RECORDS OF THE PUBLIC HEALTH COUNCIL MEETINGS OF JUNE 11, 2008 and JULY 9, 2008:

A record of the Public Health Council Meeting of June 11, 2008 was presented to the Public Health Council for approval. Dr. Alan Woodward, Council Member, moved approval. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the June 11, 2008 record as presented. The record was distributed to the members prior to the meeting for review.

A record of the Public Health Council Meeting of July 9, 2008 was presented to the Public Health Council for approval. Dr. Michael Wong, Council Member, moved approval. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the July 9, 2008 record as presented. The record was distributed to the members prior to the meeting for review.

RESCIND REGULATION:

REQUEST TO RESCIND AMENDMENTS TO 105 CMR 650.000 – HAZARDOUS SUBSTANCE REGULATIONS TO BAN LEADED CHILDREN'S JEWELRY:

Ms. Suzanne K. Condon, Director, Bureau of Environmental Health, addressed the Council. She said in part, "We request the Council's approval to rescind the amendments to 105 CMR 650.000 – Hazardous Substance Regulations which

were approved for promulgation by the Council on March 12, 2008. As you recall, these amendments were proposed to protect children's health by instituting a ban on the manufacture, transport, or sale of children's jewelry containing a dangerous level of lead. However, since that time, federal legislation was signed into law that pre-empts the Massachusetts Department of Public Health's amendments."

Staff's memorandum to the Council dated September 24, 2008, noted, "The Department's regulations were scheduled to take effect on January 1, 2009, due to the need for private laboratory certifications and subsequent testing of jewelry items by the industry prior to the effective date. On August 14, 2008, President Bush signed into law the Consumer Product Safety Commission (CPSC) Improvement Act. The Department's Office of the General Counsel reviewed the new federal law and concluded that the law would pre-empt our lead in children's jewelry regulations. We were also advised that the federal statute was intended to pre-empt conflicting state regulations by a number of staff members in the Congressional offices directly involved in the passage of the law."

Ms. Condon, stated, the new law contrasts with the Department's standards approved by the Council. As you know, the Department's standards are 600 ppm total lead content and 15 ug/day accessible lead. The federal law is effective on February 10, 2009. The federal law only sets standards for total lead content. Unfortunately, the federal law does not require testing for accessible lead, which the Department feels is most important in terms of actual exposures to lead in children's jewelry. The federal law does however include all children's products containing lead, as well as some children's products containing certain phthalates."

Ms. Condon said further, "While the Consumer Product Safety Improvement Act pre-empts state and local standards for lead in children's products, it does not pre-empt state and local enforcement authority. The Department will conduct surveillance of jewelry marketed to children 12 years of age or under in Massachusetts and determine if it meets the federal lead standard. If children's jewelry is found that does not meet the federal standard, the Office of the Attorney General is authorized under the Consumer Product Safety Improvement Act to seek a court injunction halting its sale…In addition, DPH will conduct educational campaigns talking about these new requirements and how we intend to enforce them…What is on the shelves can stay and be sold until February 10th. That means, during this holiday season, it is up to us to really get out there in full force and remind consumers that there may still be lead that exceeds these limits; and so, buyer beware."

In conclusion staff asked, "The Bureau of Environmental Health requests that the Council rescind the amendments to 105 CMR 650.000 – Hazardous Substance

Regulations on the basis that these amendments have been pre-empted by the recent amendments to the U.S. Consumer Product Safety Act."

Council Member Dr. Alan Woodward made a motion for approval of rescinding the Regulations as requested by staff. Discussion followed by the Council (for full discussion see the verbatim transcript). Mr. Harold Cox asked about leaving the Massachusetts regulations in place so it would be on record and as a symbolic platform. Dr. John Cunningham said in part, "My thought is, can we amend the effective date of the regulations instead of rescinding the item itself and just push the effective date out until it is past the federal implementation?" "Legal staff advised against the suggestions: Attorney Donna Levin, DPH General Counsel, noted that to do that would just create legal confusion and that the Council's original intentions are already on record in the minutes of the Public Health Council. Attorney Susan Stein, First Deputy Counsel for DPH added, "…I don't think it is a good idea to adopt something that doesn't have a legal standard. I think it is confusing to the public and industry and they might question does it have legal standard or they may feel they have to challenge it legally – that would create unnecessary litigation. I don't think it is a good idea to just adopt something for symbolic reason when we know it isn't going to have any legal effect because it is inconsistent with the federal standard in the end. I don't think that is a good practice."

Discussion continued, Council Member Lanzikos asked that we include in the motion that: "(1) We commend staff for having taken leadership on this issue, a national issue; (2) We comment that the reason for rescinding this is to comply with federal laws; and (3) that we instruct staff to use the element of the values of the regulations as guidance in their field work, and in providing information to the Federal Government and anybody else." Dr. Woodward added a fourth amendment: (4) Report back to the Council with results of staff's monitoring the lead in children's products especially upon finding anything leeching more than 15 micrograms per day so the Council may push for more stringent standards at the federal and state level.

Dr. Woodward stated further, "…I want to commend Suzanne Condon and the Department for taking the leadership on this issue and clearly, Massachusetts has driven or at least helped drive this discussion and legislation at a federal level and I think that is tremendous success. Although our state rules are preempted, it is difficult to do this state-by state, and it is easier to control the inflow of these products at a federal level and my greatest pleasure is seeing that this addresses all products because I think jewelry is only a small part of what goes in children's mouths and I am actually more concerned about small toys, overall. I think we should say we had a great success here. I think this is, in part, the actions of the Council and this Department, I think we should

continue to take leadership and monitor this and suggest that yes, maybe a hundred parts per million is achievable and maybe even a lower level down the line, but we are clearly going in the right direction. We are doing it in a much broader fashion than in the initial legislation, so I think we should view this as a success…I think our focus should be moving forward now with this federal legislation and trying to push it as rapidly as we can and being all inclusive to a lower standard."

After consideration, upon motion made and duly seconded, it was voted unanimously [Council Members Ms. Caulton-Harris, Mr. Sherman and Mr. Leary not present to vote having arrived after this docket item; Dr. Michele David, Ms. Prates Ramos and Mr. Denis Leary absent] to **Rescind the Amendments to 105 CMR 650.000 (Hazardous Substances Regulations) to Ban Children's Leaded Jewelry with four amendments added by the Council as follows:**

1. Commend DPH staff for leadership;
2. Reason for this action is to comply with federal standards;
3. Staff shall use Massachusetts' stringent testing standards to test children's jewelry;
4. Report back to the Council with results of staff's monitoring the lead in children's products especially upon finding anything leeching more than 15 micrograms per day so the Council can push for more stringent standards at the federal and state level.

Ms. Suzanne Condon, Director, Bureau of Environmental Health, added as a final note, "I should mention that we are very actively involved at the federal level. In fact, Roy Petre, who is our Senior Policy and Regulatory Advisor in our Bureau, actually went down with one of our toxicologists and participated in the Consumer Product Safety hearing. People know that Massachusetts was right on top of this." Attorney Susan Stein noted, in response to questions by Mr. Lanzikos, "The Consumer Product Safety Commission would be the primary enforcing agency; and then the Act makes it clear that the state can use their existing enforcement tools to enforce the federal standards…"

Chair Auerbach added for the record, "…I would just want to add my commendation to Suzanne Condon. I think Suzanne has showed great leadership not just in terms of putting forward this original regulation, which I would say, Suzanne may have understated it, but I think are a number of indications that part of the reason that, after years of inactivity, there was movement in the federal level is that the industry that is concerned with these regulations , that has largely been the opposition to these regulations on the federal level, looked with alarm at the possibility of numerous state regulations that would be very strong and I think it is increasingly we are seeing industry has

this approach now, and following the smoking regulations experience that, if they see things on the horizon, there is an effort to sort of come in with something that maybe is at a lower level, that may be done in some of the more enlighten states, I would say. And so, this in all likelihood, contributed to the passage at the federal level. So, again, I want to commend you and Martha Steele, and Roy Petre, and your terrific staff that have worked on this."

Chair Auerbach said further, "I really want to say on the record, to thank the Governor because I think the Governor showed real courage and leadership in his willingness to veto the state language which would have rescinded this regulation, and he did that even at a point that it was clear that the federal regulations had been passed, but that he wanted to be on the record as affirming and supporting the leadership role of the Public Health Council in terms of taking on public health issues; and so, I would just like to, formally on the record, say thank you to the Governor for this support of the Council's work."

Note: For the record, Council Member Mr. Albert Sherman arrived at the meeting at 9:35 a.m., during Chair Auerbach closing remarks on the Rescinding of the 105 CMR 165.000 above and just before the Substance Abuse Regulations were heard. Council Member Albert Sherman joined the meeting, after the vote was taken. Council Member Mr. Denis Leary arrived at 9:40 a.m. during Mr. Michael Botticelli's presentation on the substance abuse regulations and Council Member Helen Caulton-Harris arrived at 9:50 a.m. during Attorney Tracy Miller's presentation on the substance abuse regulations. All three voted on the Substance abuse regulations below.

FINAL REGULATIONS: REQUEST FOR FINAL PROMULGATION OF 105 CMR 164.000: LICENSURE OF SUBSTANCE ABUSE TREATMENT PROGRAMS; REQUEST TO RESCIND 105 CMR 160.000; 105 CMR 161.000; 105 CMR 162.000; 105 CMR 165.000; 105 CMR166.000; 105 CMR 167.000; AND 105 CMR 750.000; AND REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 130.000: HOSPITAL LICENSURE AND 105 CMR 140.000: LICENSURE OF CLINICS:

Mr. Michael Botticelli, Director, Bureau of Substance Abuse Services, accompanied by Ms. Hillary Jacobs, Director of Licensure, and Deputy General Counsel Tracy Miller, presented the request for final promulgation of the substance abuse regulations. Mr. Botticelli said in part, "…In Massachusetts, the Bureau of Substance Abuse is the federally funded designated single state authority for substance abuse treatment and prevention services….We have overall responsibility for the quality of care in terms of substance abuse treatment that goes on in the Commonwealth. We contract a variety of intervention treatment and recovery support services and in addition inspect all treatment facilities. So, beyond the programs we contract with, we have

licensing authority for the provision of quality care, also, in those treatment programs. We license over three thousand addiction counselors in the Commonwealth, as well as, through Hillary's office, the response to complaints in relation to both counselor complaints and facility complaints."

Mr. Botticelli said further, "Why did we embark on this multi-year complex project? Well, first of all, our regulations had not been revised since the mid 1990s, and these regulations really incorporated changes in the standards of care, that our understanding of effective practice of substance abuse treatment has changed dramatically over the past ten years, and these regulations needed to reflect that, as well as changes in federal regulations. We wanted to make sure that our regulations were consistent. To address areas that were not currently part of our regulatory structure, particularly those that governed the provision of treatment services for special populations, chiefly adolescent treatment, treatment services for pregnant women, treatment services for co-occurring populations, those with both mental health and substance abuse issues, elders and people with disabilities, and programs and services in certain clinical settings, which we will talk a little bit more about. Improved access, we wanted to make sure that our regulations really improved quality of care and improved access to services, and also, one of the big goals was to recognize and simplify, and make sure that our regulations were consistent. Our current regulations have seven chapters and two guidance documents, and in our review we found that there were actually redundancies in many of those and actually inconsistencies between our regulations as they governed certain treatment modalities. This was no small undertaking. Our regulations intersect with other regulations in the Department, other state agencies, as well as federal regulations. So we needed to make sure that our current regulations reflected and supported other regulatory structures, on the federal level, the Drug Enforcement Administration and SAMHSA (Substance Abuse Mental Health Services Administration) as well as our Department's own regulations in other divisions such as the Drug Control Program, Division of Health Care Quality and our sister state agency, The Department of Mental Health..."

Mr. Botticelli noted that they held nine meetings with multiple stakeholders as it related to the development of the regulations: advisory groups meetings with multiple providers in different treatment modalities, and with payers such as MassHealth, Behavioral Health and Managed Care organization directors, and their consumer advisory board.

Attorney Tracy Miller explained, "We have combined all of the regulations into one chapter, and it is divided into two sections. The first part is the general section that applies to all the general requirements, and the second part is related to difficulty of care and we think by doing this it is clearer and easier for providers and consumers to understand which part is relevant to them. Part 2 is

divided into Acute Services, Resident and Rehabilitation, Outpatient Services, and Opioid treatment. The other thing that we have put into the regulations now, if you do approve them today, our intention is that they would become effective December 26, 2008. After we were here in February, we went to public hearing. A public hearing was held on March 27, 2008, and the record for comments was open from February 23rd through April 3rd. We received 20 comments. Thirteen people testified at the public hearing. There were 18 written submissions and all the written submissions were posted on their web site. The comments are detailed in Attachment A of the Council packet, which has been attached and made a part of this record, see Exhibit No. 14, 910. Some of the commenters were: Mental Health and Substance Abuse Corporations of Massachusetts (MHSACM); Massachusetts Association of Behavioral Health Systems, the Massachusetts Hospital Association (MHA) the Recovery Homes Collaborative, The Institute for Health and Recovery and from a number of consumers.

Ms. Hillary Jacobs highlighted the substantive changes in the proposed regulations. She stated in part:

- Changed the nomenclature "substance abuse" to "substance use disorders" the appropriate way to refer to people with the different disorders;
- Clarified that the regulations are aimed at substance abuse treatment programs not recovery treatment services;
- Eliminated any reference to DSM-4, the diagnostic manual for people with mental health and substance abuse disorders which is out of date and instead referred to APA and diagnostic criteria;
- Revised the severe weather policy for Opioid Treatment programs in accordance with SAMHSA and C-SET director's letter;
- Changed the TB requirements to match current DPH TB policy;
- Revised First Offender Drug or Alcohol Education in accordance with C-Set's protocol;
- Streamlined the regulations related to hospitals, clinics, and DMH facilities by narrowing the scope of the regulations to focus only on substance abuse treatment requirements;
- Streamlined supervisory requirements for the staff members and training requirements for medical directors at the request of the providers;
- Revised drug screening requirements for the Opioid Treatment Program;
- Modified the Take Home Dosing Schedule in the Opioid Treatment Programs.

Ms. Jacobs said further, "That an agency cannot deny admission to anyone solely based on the fact that they are on a prescription medication. We feel that helps improve access to treatment for people across the continuum. There have been a number of medications that people sort of consistently say, you can't be in our

program if you are on this prescribed medication, and that prescribed medication effectively diminishes access to the continuum of care for people on prescribed medications....We also retained the requirement that efforts be made to prevent discharging a person from an agency to a homeless shelter or the street. This being a part of the Governor's Task Force initiative to end homelessness...We request final promulgation of these regulations 105 CMR 164.000 and amendment of 105 CMR 130.000 (Hospital Licensure) 105 CMR 140.000 (Licensure of Clinics) and rescinding of the seven chapters of regulations listed in your packets."

Council Member Albert Sherman moved for approval. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the Request for **Final Promulgation of 105 CMR 164.000: Licensure of Substance Abuse Treatment Programs; Request to Rescind 105 CMR 160.000; 105 CMR 161.000; 105 CMR 162.000; 105 CMR 165.000; 105 CMR 166.000; 105 CMR 167.000; and 105 CMR 750.000; and Request for Final Promulgation of Amendments to 105 CMR 130.000: Hospital Licensure and 105 CMR 140.000: Licensure of Clinics** and that a copy of the approved regulations be attached and made a part of this record as **Exhibit No. 14, 910.**

Dr. Michael Wong, Council Member added for the record, "...I would like to thank the three of you and all the organizations that helped update these regulations. The old system we were working with was archaic and antiquated and I think any of us in the room who are physician providers or providers of mental health services or substance abuse services are just applauding these changes...I think this is going to really make things much easier to get folks into treatment, maintain in treatment, and actually encourage after care..."

Dr. John Cunningham, Council Member wanted it noted on the record to Staff that he really appreciated Appendix A in the substance abuse packet of materials to the Council, that it summarized everything and made it clear to him how he should vote on the regulations. Council Member Denis Leary noted his Thank you to the substance abuse staff and said, "I worked in substance abuse for 15 years under the previous regulations, and I really appreciate the effort you put into these regulations – it looks fantastic."

Mr. Paul Lanzikos, Council Member had a question about the governing bodies: "There's two parts to the question...I am concerned that you may be keeping people from participating because they don't want to be publicly identified. How does that process work? The second part is if the corporation is domiciled outside of Massachusetts, you are requiring an advisory council and it is questionable to me whether, on the advisory council, you require someone also to be in recovery?"

Ms. Hilary Jacobs replied, "The first part of the question is that we would never expect that the person who is in recovery on the governing board to be publicly identified. When consumers addressed that, because that was one of the comments, this was one of the opposing comments, what about anonymity, and consumers' point of view on this was that there are many consumers who are willing to break their own anonymity, and that they didn't feel that that was a barrier, but we, in the regulations, do not require that anyone break their anonymity, rather that we get an affirmation from the agency that, yes, they have in fact sought out someone in recovery and that they do or do not have that person, and what the efforts were that they made to have that person...Relative to the advisory council, I would have to say that there is a glitch – there is nothing that would require it. We would suggest it and hope that they would respect the spirit of this, which is to have some figure local to your community to give input in that way."

Council Member Lanzikos moved to amend 105 CMR 164.030, Section (A) (3), page 18 of the regulations to include "at least a member of the advisory council be in recovery." Mr. Sherman who moved the approval of the regulations agreed to the amendment and Dr. Woodward who seconded the motion agreed to the amendment. After consideration upon motion made and duly seconded, it was voted unanimously <u>to approve</u> the regulations with Mr. Lanzikos' amendment.

Council Member Harold Cox added for the record, "...I just want to note and look for an opportunity for us to have a further conversation about the issue of capacity because I am still aware that, even with these improvements, and even this may assist some individuals in getting this better access, we still have an issue of capacity for individuals who need to get services, as well as there is still always the important question about effectiveness of service, and I am hoping that, at some point, Commissioner, that we can actually have a fuller conversation about what the state is actually doing and what kinds of additional things we need to actually be thinking about, and how effective our treatment processes actually are."

Chair Auerbach replied, "I can see from Mr. Botticelli's enthusiasm that he would be happy to come back and join us for that discussion; and so, we will work with the schedule of the Council to make sure that we do have that important discussion..."

Council Member Albert Sherman asked, "What do we do on a Friday night at eleven o'clock when they want to find a bed for a twelve year old kid?" Mr. Botticelli replied, "...with the leadership of the Governor and the Legislature we have actually received additional funds over the past few years. Part of our

strategic priority has been to increase the continuum of care largely for adolescents. There are regulations that reflect our current knowledge about what is effective practice for adolescents, but one of the things that I think has been happening, about six months ago, we actually opened our first Youth Detox Stabilization program for twelve to seventeen years old in Worcester, and just a number of weeks ago, we actually opened a second program in Brockton. It was part of the Continuum of Care in terms of both servicing youth with substance abuse disorders and their families who are in crisis. We actually do have two programs now. We were one of the first states in the country that actually has Youth Detox and Stabilization programs."

Dr. Michael Wong added, "This is sort of the flip side of Dean Cox's observations and queries. Can we actually open up the discussion on what the prevention programs are, to actually start decreasing the utilization and the need for the programs? How effective are these? What is going on on those Friday nights with the 12, or in our case over at the Beth Israel Deaconess Hospital, the 17,18, 19 year old college kid who is acting up for the first time, and is suddenly in the emergency room and can't get any place and ends up in our ICUs for periods of time?

Chair Auerbach stated, "Just to clarify, I hear a call by the Council to have a longer presentation and discussion on issues of prevention and treatment of substance abuse services, a focus on existing services, the evidence of the efficacy of those services, and the gaps that exist in terms of services for particular populations, as well as particular modalities." Ms. Caulton-Harris, Council Member added, "I would like to look at services across the Commonwealth, and where access really could be a challenge."

Council Member Dr. Barry Zuckerman said, "Important clarification on the way we organize services in terms of mental health, given the overlap, co-morbidity, substance abuse and mental health particularly, but children who, while there may be some substance abuse, their major presenting issue is probably the behavior of what's going on. How do we, because these are vulnerable kids, whether you call it substance abuse or mental health. Is there a collaborative effort with mental health with these kinds of efforts?"

Mr. Michael Botticelli answered, "Absolutely, I probably misrepresented when I talked about adolescents with substance abuse disorders. It is the norm that adolescents present with a wide variety of both substance abuse and mental health services, and even beyond that, we actually have an interagency council, focusing on youth services. Many of our kids and their families are involved with DYS and DSS services. We actually look at kinds of comprehensive treatment for adolescents and, again, it points to Dean Cox's point about what we have in effect for adolescents."

Dr. Zuckerman noted further, "...These kids show up in our emergency rooms and there are no beds. They just stay in our emergency room 12 to 40 hours and/or they get admitted to the hospital. It is not a great place for these kids. There are other implications of this. The hospital doesn't even get paid because it is not a mental health facility. The state has always gotten free beds because the kids are placed, but nobody is paying for it...The kids suffer. We have an adolescent now who has assaulted two nurses in the last week because this isn't a mental health facility. There is no place to put this child...This remains a big problem if not bigger than it has always been and I fully support what you are doing but I want to put that kind of emphasis on what we are doing..."

Dr. Alan Woodward, Council Member noted in part, "that Massachusetts is going to become the first state to abolish ambulance diversion come January 1, 2009 and one of the major impediments causing boarding in our emergency departments and backing up hospitals is placement of patients with substance abuse and mental health issues and in particular adolescents." He said the diversion issue will hopefully put more emphasis on this problem and it is something that is critical that we deal with.

DETERMINATION OF NEED PROGRAM:

REQUEST FOR APPROVAL OF PROPOSED DETERMINATION OF NEED GUIDELINES FOR ENVIRONMENTAL IMPACT:

Dr. Paul Dreyer, Director, Bureau of Health Care Safety and Quality, made introductory remarks, noting the people responsible for putting together the "green guidelines": Mr. Jere Page, Senior Analyst, Determination of Need Program, who will speak on behalf of Ms. Joan Gorga, Director, Determination of Need Program, who could not be present, Attorney Carol Balulescu, Deputy General Counsel, Mr. Paul Lipke, Senior Advisor for Energy in Buildings and Health Care Without Harm who was present to answer technical questions; Mr. Bill Ravenski, Director of the Boston Regional Campaign of Health Care Without Harm who was not present but worked on the guidelines; and lastly, Mr. Michael Feeney, Director of Indoor Air Quality, Bureau of Environmental Health, who helped strengthen the guidelines and was present for questions.

Mr. Jere Page, Senior Analyst, Determination of Need Program, presented the green guidelines to the Council. He stated in part, "...The purpose of this memorandum is to request the Public Health Council's approval of staff recommendations for revisions to the Proposed Guidelines for Environmental Impact. The guidelines, which were first presented to the Council at the June 11th meeting, incorporate new developments in environmentally sound practices in the construction, renovation and operation of health care facilities, many of

which have already been adopted by health care providers. Staff presented the Green Guidelines to the Council with a recommendation for adoption of the standards and a requirement that applicants achieve a minimum of 38% of the available credits, the minimum credits for a designation of certifiable. The Council enthusiastically embraced the Guidelines and moved that the minimum designation should be not certifiable but silver, which is the equivalent of 50% to 56% of the minimum credits."

Mr. Page continued, "After the June meeting, the Department accepted public comments for four weeks, which ended on July 15th. Children's Hospital, the Massachusetts Hospital Association, the Massachusetts Extended Care Federation, Beth Israel Deaconess Medical Center, and Senator Richard T. Moore of the Massachusetts Senate all sent in comments. The comments received covered topics ranging from concerns about the applicability of the Guidelines, to renovation projects, to request for delay in the implementation date…We had general comments on renovation, the review process, the implementation dates, voluntary environmentally friendly operational practices, ancillary buildings, and the effect on capital cost. The comments involved in each of these categories to the proposed guidelines, but I would like to focus on the comments on renovation and implementation dates since we are proposing revisions on these comments based on the comments in these two areas. Regarding renovation, all the commenters noted the difference between renovation and new construction and indicated that the two should be treated differently in the Guidelines. All noted that not all of the points applicable in construction are applicable in renovation. Several comments suggested that in a renovation, only thirty-eight percent of the points should be required rather than the fifty percent required for silver level certification. The Department has considered all arguments, and has revised the Guidelines for renovation to include only gut level renovation. Renovation for expansion of an MRI service will not be subject to the Green Guidelines. The definition of gut renovation is defined as construction within the existing building that requires complete demolition of all non-structural building components. After demolition, only the floor, the deck above, the outside walls and structural columns would remain."

He said further, "Regarding implementation dates, the Massachusetts Hospital Association stated that the October 1, 2008 date for implementation is unrealistic and suggested that the Guidelines should instead be effective January 1, 2009. The Massachusetts Extended Care Federation requested that the effective date for implementation in nursing homes, proposed to be April 1, 2009 be delayed."

Based on these comments, staff is proposing the following revisions to the Guidelines:

- Implementation dates for acute care hospitals, chronic disease hospitals, and ambulatory surgery centers be January 1, 2009 and that July 1, 2009 would be the implementation date for nursing homes;

- Clarification in the Guidelines that they apply only to gut renovations;

- Addition of Appendix 3 in the Guidelines to address the prevention of mold/water damage in five areas.

Discussion followed by the Council. Council Member Meredith Rosenthal inquired about the alteration of the language around renovations. Would providers try to get around the guidelines and are a lot of renovations coming forward that would be affected by these guidelines? Dr. Paul Dreyer responded by noting that many of the renovation projects are so minor that there would be no points and that the Department's intent was to focus on major renovations with large capital expenditures and he didn't see providers trying to game the system because the incremental expense in complying with the guidelines is not large.

Council Member Paul Lanzikos asked what projects would be affected by the change in the implementation dates and what was the value in changing the dates. Staff noted that they are not aware of any projects in the pipeline rather that the change was an accommodation to the nursing home industry and more a symbolic change. Council Member Dr. Alan Woodward clarified with staff that all major construction projects would require the silver standard including the gut level renovations and that anything short of a gut level renovation would not be held to these guidelines.

Council Member Dr. Alan Woodward moved for approval of the guidelines as presented by staff. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve **the Determination of Need Guidelines for Environmental Impact**; and that a copy of the approved guidelines be attached and made a part of this record as **Exhibit Number 14,911.**

Council Member Lanzikos asked how the Department planned on informing the general public about these new guidelines. Staff noted that a press release would be issued. Mr. Paul Lipke added that the Department would be presented at the Massachusetts Hospital Association Conference on October 3rd and again on October 29th together with the City of Boston, the National Organization LEED Health Care, the U.S. Rebuilding Council and others to outreach to the entire engineering and architectural community as well as facility directors. Dr. Woodward added in part, "....We have taken sort of a lead on this in health care is there any leverage that can be accomplished or utilized as a result of taking this action that could extend it to a more broad sphere and can we include that in the press release...I would suggest that that in our press release the Public

Health Council might have an interest in suggesting that, from a public health perspective, we would encourage the dissemination of this kind of focused guidelines and intent across all buildings." He noted that Seattle has green guideline requirements for all its buildings not just health care institutions. Mr. Lipke also noted that the Governor has a Zero Energy Buildings Task Force that is currently working on the retrofit of all existing buildings and new construction in the state and that the Division of Energy Resources would be likely allies in such an effort.

Chair Auerbach asked if there was any opposition to the Department including that sentiment in the press release. No objections.

PROJECT APPLICATION NO. 4-3B23 OF MASS BAY RADIATION SERVICES:

It was noted for the record that Council Member Dr. Muriel R. Gillick is recusing herself from discussion and voting on this application.

Mr. Bernard Plovnick, Consulting Analyst, Determination of Need Program, presented the Mass Bay Radiation Project to the Council. He said in part, "...Mass Bay Radiation Services, the applicant, is a Limited Liability Company to be formed through a joint venture with Caritas Carney and Milton Hospitals. Mass Bay today seeks DoN approval of a substantial change in service that would permit the acquisition of a linear accelerator for the establishment of a licensed clinic to provide radiation therapy services on the campus of Caritas Carney Hospital in the Dorchester section of Boston. In our analysis of this project, we applied the DoN Guidelines for megavoltage radiation therapy services, which measures unmet need from the standpoint of the State as a whole. As of today, the guidelines permit the establishment of up to six new radiation therapy services statewide by the year 2010."

Mr. Plovnick also noted, "Under Health Care Requirements, the DoN Guidelines require an applicant for a new medical radiation therapy service to demonstrate a minimum of 250 new radiation therapy patients per year in the area to be served. For the 2007, the Applicant documented 304 potential new patients from the cancer registries of the two hospitals and from private physician office records. Approximately one third of the total potential cases was drawn from each of these three sources. According to the applicant, the case data collected from the private physician's offices were patients whose cancer was diagnosed at those physician offices, and were thus not captured by the hospitals' cancer registries. Secondly, the applicant documented, based on a study of a patient records from a large oncology practice in its service area, that average patient waiting time to begin radiation treatment was higher than the Guideline's standard of seven days. This suggests that the proposed radiation therapy

service will not unnecessarily duplicate existing capacity in the area. And one final item that I bring up merely for the record, the staff summary inadvertently omitted any specific mention of the reasonableness of the cost of construction proposed by this project. In our analysis, we compared the space allocated to the service and the associated construction fit up cost with more recent radiation therapy project approvals and found that the proposed project was on he low end of the range for both space and cost per gross square feet....We recommend approval of this project with eight conditions and with a recommended capital expenditure of $9,475,564 (October 2006 dollars)...Included among the conditions is a provision that Mass Bay contribute a total of $473,778 dollars to fund the community health initiatives in the Community Health Network areas 19 and 20; and for improvement in medical interpreter outreach services to patients with limited English proficiency and a requirement that, within two years, the service will be accredited in radiation oncology by the American College of Radiology." The Mark Taylor Ten Taxpayer Group registered on this application but did not submit comments.

Dr. Daniel O'Leary of Caritas Carney Hospital and Joseph Morrisey of Milton Hospital and Dr. Theresa Favaldi were present to answer questions but did not address the Council.

Council Member Sherman moved for approval of the application. After consideration, upon motion made and duly seconded, it was voted (unanimously) [Dr. Muriel Gillick recused] to approve **Project Application No. 4-3B23 of Mass Bay Radiation Services**, based on staff findings, with a maximum capital expenditure of $9,475,564 (October 2006 dollars) and first year incremental operating costs of $2,208,389 (October 2006 dollars). The staff summary is attached and made a part of this record as **Exhibit No. 14, 912**. As approved, the application provides for a joint venture of Caritas Carney and Milton Hospital, to acquire a linear accelerator and establish a radiation therapy service. The service will be located in leased space on the campus of Caritas Carney Hospital at 2100 Dorchester Avenue, Boston, MA 02124. The new service is intended to address the problems of patients having long waiting times to begin treatment and long travel times to receive treatment at the nearest existing radiation therapy services. This Determination is subject to the following conditions:

1. Mass Bay shall accept the maximum capital expenditure of $9,475,564 (October 2006 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. Mass Bay shall make an equity contribution of $2,210,347, or 23% of the total approved maximum capital expenditure of $9,475,564 (October

2006 dollars).

3. For Massachusetts residents, Mass Bay shall not consider ability to pay or insurance status in selecting or scheduling patients for radiation therapy services.

4. Mass Bay shall operate only radiation therapy equipment that has received pre-market approval from the United States Food and Drug Administration.

5. At the time of licensure of the service, Mass Bay shall submit a copy of a certificate of organization signed by the Secretary of State of the Commonwealth of Massachusetts.

6. Within two years following licensure of the service, Mass Bay shall submit to the DoN Program Director evidence of accreditation in radiation oncology by the American College of Radiology.

7. With respect to its professional medical interpreter service, Mass Bay shall:

   a) Identify the specific roles and responsibilities of a coordinator to ensure the optimal and timely provision of competent medical interpreter services;
   b) Prohibit the use of minors;
   c) Affirm the use of trained interpreters only, including center staff, to provide medical interpretation and/or logistical support;
   d) Direct staff to identify , upon referral of a patient for health services, the patient's preferred language for discussion of health related concerns;
   e) Provide interpreter services at no cost;
   f) Ensure the coordination and quality of interpreter services during all encounters and procedures;
   g) Assure posting of signage at all points of contact and public points of entry informing patients of the availability of interpreter services at no charge;
   h) Develop a detailed plan for training clinical, support and administrative staff on the appropriate use of interpreters;
   i) Formulate a comprehensive strategy to inform referral sources and community members about the services available at the Mass Bay Radiation Services clinic, particularly the availability of interpreter services;

j) Conduct periodic coordination with community groups to gather information about new and emerging LEP populations in the clinic service areas;
k) Implement a reliable and valid system for scheduling and tracking requests for interpreter services and for review of the quality of interpreting sessions, inclusive of the use of employees;
l) Initiate a formal plan to identify the systemic support necessary and to conduct outreach to non-English speaking communities throughout the satellite clinic service areas;
m) Ensure the inclusion of LEP patients in patient satisfaction surveys; and
n) Assess the quality of Interpreter Services and to monitor the competence of interpreters, inclusive of employees.

In addition Mass Bay shall:
o) Notify the Office of Health Equity of any substantial changes to its Interpreter Services Program, follow recommended National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health Care (materials available online at http://www.omhrc.gov/templates/browse.aspx?1v1=2&1v1ID=15)
p) Provide an Annual Progress Report to the Office of Health Equity within 45 days following the end of the Federal Fiscal Year.
q) Submit a plan for improvement addressing the above items to the Office of Health Equity within 60 days of DoN approval.

8. Mass Bay shall contribute $473,778 (October 2006 dollars) over five years to support initiatives sponsored by the Alliance for Community Health (Community Health Network Area #19), Blue Hills Community Health Alliance Community Health Network Area #20), and the Statewide Mass Partnership. On an annual basis, Mass Bay will provide $94,756 as follows:

    a) The Alliance for Community Health ("CHNA #19") will receive $35,000 of the annual distribution of funds to be used in support of its activities as follows:

        i. Mini-grants awarded through an open, competitive request for responses (RFR) with preference given to projects and/or activities that are science-based, directed by healthy communities principles, and with priority given to those targeting the elimination of health disparities. Each program that receives funding will be required to conduct an annual evaluation and report on its progress in achieving the identified priorities. CHNA #19 will submit a detailed

budget to the Office of Healthy Communities (OHC) upon receiving the funds, and yearly thereafter. The CHNA will annually submit to OHC a summary report of programs funded, outcome, and budgets. The CHNA and the OHC may re-assess need and funding priorities periodically; and

ii. General community capacity building and program support including, but not limited to, coalition coordination, training programs and networking opportunities that promote and build on a healthy communities/health disparities framework.

b) Blue Hills Community Health Alliance (CHNA #20) will receive $35,000 of the annual distribution of funds to be used in support of its activities as follows:

i. 30% for contribution to member training and development to provide professional development concentrating on the issues of health disparities. The trainings will focus on coordination of services to vulnerable populations;

ii. 30-50% for five years will be used for mini-grants awarded through an open, competitive RFR process with preference given to projects and/or activities that are science-based, directed by healthy communities priorities, and targeted toward eliminating racial and ethnic health disparities. Each program that receives funding will be required to conduct and report an annual evaluation. CHNA #20 will submit a detailed budget to OHC upon receiving the funds, and yearly thereafter. On an annual basis, CHNA #20 will submit to OHC a summary report of programs funded, outcome and budgets. CHNA #20 and OHC may re-assess need and funding priorities periodically;

iii. 20% for ongoing CHNA #20 programmatic support including administration; and

iv. UP to 10% for developing and implementing a strategy for evaluating CHNA #20.

c) The Statewide Mass. Partnership will receive $24,756 per year for five years, which will be used for healthy community planning and grants. Annual reports to the OHC are required. The information

from these annual reports may be used to re-assess need and funding priorities periodically.

The reasons for this approval with conditions are as follows:

1. Mass. Bay Radiation Services, a limited liability company to be formed as a joint venture of Caritas Carney Hospital and Milton Hospital, proposes to establish a megavoltage radiation therapy service with the acquisition of a linear accelerator to be located on the campus of Caritas Carney Hospital in Dorchester, MA.

2. The Department found the health planning process for the project to be satisfactory.

3. The Department found, consistent with the Guidelines, that Mass Bay has demonstrated demand for the proposed radiation therapy service, as discussed under the Health Care Requirements factor of the Staff Summary.

4. The Department found that the project, with adherence to a certain condition, meets the operational objectives of the Guidelines.

5. The Department found that the project meets the compliance standards of the Guidelines.

6. The Department found that the recommended maximum capital expenditure of $9,475,564 (October 2006 dollars) is reasonable, based upon on similar, previously approved projects.

7. The Department found the recommended incremental operating costs of $2,208,389 (October 2006 dollars) to be reasonable compared to similar, previously approved projects for radiation therapy services.

8. The Department found that the project is financially feasible and within the financial capability of the Applicant.

9. The Department found that the project meets the relative merit provisions of the Guidelines.

10. The Department found that the project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.

STAFF PRESENTATION: "PREPARATION FOR BOTH SEASONAL AND PANDEMIC FLU":

Dr. Alfred DeMaria, Director, Bureau of Communicable Disease Control, began the presentation: "As the mosquito season winds down, the influenza season is gearing up. I will give you briefly where we stand in terms of new things that are happening, new initiatives, and new ways of distributing vaccine. First of all, last year, we estimated about 2.7 million doses of vaccine administered in Massachusetts and that was probably the highest amount we have ever had, and when we look at that, about three-quarters of that was actually privately purchased, not state purchased…We buy a substantial amount of vaccine currently. We used to buy half of what we have distributed now…It's about 25% of the vaccine and because of the competition in the market now, we are actually able to buy more vaccine for the same amount of money this year, so we are getting 808 thousand doses. About two hundred thousand of those are actually Thimerosal free. The vaccine supply has become available earlier in the season….I think we will get the vaccine out there about two weeks earlier than last year. Last year was typical in that the peak of influenza activity occurred in February. So, we are making the point to push for continued vaccination after Thanksgiving, after the Christmas and New Year Holidays…"

Some highlights from Dr. DeMaria's presentation included the following information (please see verbatim transcript for full text): Last season was worse then previous years in terms of flu activity, part of that was due to the genetic drift of the virus. A genetic drift to A/H3N2 virus and also a shift in the B virus to the Demagatta line; DPH now recommends that all children from six months to 18 years of age get vaccinated against influenza, however it is not required this year. Staff is watching closely viral resistance, 11% of the H1N1 strain in the United States and 25% in other countries became resistant to oseltamivir so we have to be careful about using antiviral medications. This year's vaccine has two new strains in it so it should be a highly effective vaccine. We have two different choices of vaccine and two different distribution systems. Pediatric vaccines are now shipped directly to point of use (the provider) instead of coming to the state Department of Public Health as required by federal law. The state purchased vaccine is still distributed through the local health departments. The vaccine began arriving in August and all the vaccine should be distributed by the end of October. The Department is discussing the best way to distribute flu vaccine effectively to school age children, keeping in mind, the potential burden on primary physicians if every patient must come in at the same time for a flu shot; the potential burden on school nurses if it is distributed at the school themselves and on the local health departments. Dr. DeMaria said, "We are looking at a variety of ways to accomplish that because we think it is beneficial for the children in terms of morbidity and mortality, and it is beneficial for the rest of us because more and more we recognize that children are the vectors of influenza."

Discussion followed and during that Council Member Ms. Helen Caulton-Harris raised the point about using their state local supply to vaccinate teachers. Dr. DeMaria said it is expected that private and public employers would include the vaccine in their budgets. Ms. Caulton-Harris replied, "We have to say to them, we are not able to use state supplied vaccine to vaccinate you, even though we recognize that this is a public health threat for you, in terms of school aged children in your classrooms…we need to have those kinds of discussions."

Dr. DeMaria further noted that there will be a series of facilitated discussions across the state, which will be highlighted on the web site, for people to attend in parts of Massachusetts to discuss adult vaccinations. Discussion continued. Chair Auerbach summarized, "…I would add that I think it is hard. We may, as public health officials, need to have a somewhat different strategy with regard to how we discuss flu vaccination and its efficacy. I would say that my own experience, as the Public Health Commissioner, is that we supported the importance of flu vaccine by saying to people; this will prevent you from getting the flu. I think it is more accurate to say, this reduces the likelihood that you will develop flu and if you develop it, you may develop a milder case…The studies on the older population, in particular, those with compromised immune systems, it may not be 100% effective. As Dr. DeMaria said, the vaccination gives you more protection than you otherwise would have is an important message to say but different than saying it will absolutely guarantee you and then when somebody gets the flu, they may say, well, see, it didn't work, and then be less likely to have the flu vaccination in the future." He asked Dr. Muriel Gillick what she thought about it. She replied, "I think you are right. To echo Dr. DeMaria, which was no vaccine is a hundred percent ineffective, and that might be kind of a slogan."

Discussion continued some of the comments by the Members are: Dr. Alan Woodward noted in part that direct distribution of the vaccine rather than a two stage distribution is the direction we should go and also said "…It is important that we get out the message to the public that no vaccine is a hundred percent effective but even if you get it, it will attenuate it, and it has other ramifications; if a higher percentage of the population is immunized, that has significant impact as far as herd immunity, but also, it may have an impact when we have a pandemic, which is not if but when." Dr. Michael Wong noted in part, "The effectiveness or attenuation of the disease is something that needs to be highly pushed. Looking back at the pandemic of 1918, it is pretty clear that those who survived were folks who had high titers of influenza virus that were not present immediately, but present sort of a year or two prior, that clearly provided them with some kind of protective immunity." Dr. Zuckerman noted that we might want to add into the message that there is a difference between a cold and the flu.

Ms. Mary Clark, Director, Bureau of Emergency Preparedness shared highlights of the pandemic preparedness. Some highlights of her presentation follow: "...Since late 2003 or early 2004, the Department has been working with 15 Public Health Emergency Preparedness Coalitions, planning and preparedness around Pan Flu and other hazards. We work with two tribal entities in the state. There are 75 acute care hospitals that we are working with, 60+ community health centers, and 550 long term care facilities that we are working with on the pandemic flu planning."

Ms. Clark noted, "These are the assumptions that we, in the Department have been working on, and we work with local public health and we work at the state level. Outbreak for Pandemic will occur simultaneously throughout Massachusetts, the U.S. and the world. We anticipated that the initial wave will be up to eight weeks. Projected number will spread across the epidemic curve, with the peak midway. The Health Care sector, and other sectors, will be quickly overwhelmed because of the numbers of individuals they take care of, there will be workforce shortages across all of the sectors, which will affect access to supplies, equipment, individuals being able to work, a variety of things that will affect us across the Commonwealth and across the country at the same time, which heightens the challenges of the planning for an event like this...We are anticipating a pandemic which would affect approximately 30% of the Massachusetts population. They would become ill, which would be about two million people for the Commonwealth. Of those, 80,000 would require hospitalization, with the vast majority not requiring hospital-based care, but needing possibly care from their physician's office or in an alternate care setting in their community, and we anticipate approximately one percent of the individuals who were infected would die."

Ms. Clark said her bureau has continued with quarterly meetings of the Pan Flu Forum; developed a Pandemic Operations Plan for the State, is working with the Department of Education, the National Guard, with the Massachusetts Emergency Management Agency and others who have responsibility in terms of a pandemic. This plan is continually updated; the Department and all the agencies of the EOHHS Secretariat have developed Continuity of Operations Plans and Continuity of Government plans and these are kept up to date; enhanced local health capacity to respond with grants from the CDC, used to foster mutual aid agreements to share resources and assets because no one community will be able to respond alone; provide planning templates and support to help local communities develop consistent pandemic and hazard plans across the Commonwealth; enhance surveillance systems so we have as early a warning as possible when trends or issues come up; development of the Mass Virtual Epidemiological Network (MAVEN) an on-line system that we are rolling out to local public health communities, which will allow them to provide a case report to the state in a more timely way and for the state to get back to them; using

federal funding to try to enhance the lab reporting and capacity, both for influenza reporting and testing and electronic laboratory reporting; pulled together people from public health, hospitals, community health centers and others to plan primarily for a surge around the pandemic (how to handle the patients coming in for hazards and pandemic flu).

Ms. Clark noted further things her bureau is working on: Hospital bed and Emergency Room capacity reporting on-line; emergency telephone communication systems; working with at risk communities and individuals who would need additional assistance in an emergency; training for personal care attendants so they know how to care for their clients during a pandemic; working on a voluntary registry template so individuals can sign-up for help through their Local Emergency Management Group; gathering information about the Medical Reserve Corps, and the Mass. System for Advance Registration (MSAR).

For the record, Council Members Wong and Zuckerman left the meeting at the close of Ms. Clark's presentation (11:35 a.m.) Mr. Sherman left during Attorney Levin's presentation at 11:50 a.m.

Attorney Donna Levin, DPH General Counsel, addressed the Council, She said in part "…The question is, will there be different standards of care in a pandemic? Health Care providers are asking about the question of liability. What standard of care will they be held too? They are concerned not only about their own liability but also how we deliver care ethically in these kinds of circumstances. They are looking for guidance, and some consistent approach, and it is really very hard to get to. So that is where the concept of Altered Standard of Care comes in…The argument is that 'Standard of Care' is a legal term it is due to the circumstances of the time…The use of this term is a way to recognize and emphasize that the circumstances will be so different, that they will be beneath the 'Standard of Care'. It reflects in advance some guidance of these circumstances, and there are three advantages to using this term. One, It's stronger for health care providers. Two it's a strong message for the malpractice bar that we are at a consensus here, and three, it is guidance to judge the liability in the event of subsequent litigation.

Attorney Levin continued, "…It is possible to waive statutory or regulatory requirements….In most states, this kind of residual law, common law is for health care providers and is not based on the statute." She spoke about a working group that pondered five different scenarios focusing on distribution of scarce resources and staff, recognition of allocation and prioritization, seizure of assets, and health care provider issues and provider liability. And she said, "Based on the stakeholder discussions and deliberation of the group, we drafted guidelines and I repeated those in the back of your handout, and here are the

goals, and one goal speaks to determining the process for the development of these priorities and the allocations; for example, who gets the antiviral, what priorities, specific protocol for the delivery of care. What are the criteria to be used and the care guidelines, like priority of care, ratio of care...it is important that it is based on science, clinical knowledge and judgment, that there are equitable treatments, that there is no discrimination, that we use physician discretion. The delivery of care will change. The scope of practice for health care practitioners will change. There will be care delivered in non-health care settings, and there is a note that patients' rights and civil liberties will be honored to the extent possible, but that is secondary to goal of maximum number of lives saved and that goes back to provider liability...Isolated and alone, all these standards of care would not be sufficient to address all the issues; but in conjunction with the legislation that we have been working on,[we should be able to do this]. How will these guidelines be implemented? There is a Declaration of Emergency by the Governor and by order of the Commissioner of Public Health and then going out with orders that we had prepared in advance to deal with these circumstances..."

Discussion followed by the Council. Council Member Dr. John Cunningham stated, "I would call it, Public Health Emergency Standards of Care because it is only when we declare a Public Health Emergency and this becomes your standard of care, so it is not really altered, It is what it is." Attorney Levin said she would add that suggestion to her list. Dr. Meredith Rosenthal, Public Health Council Member noted, "I want to remark that these principles should apply to an ethical Public Health System period. In our current fragmented system of financing we don't recognize that treatment decisions for one patient affect the available resources for the patient down the hall. Care that strives for equity and maximizes population health; can we not agree that should be the Standard of Care at all times?" Council Member Harold Cox thanked the staff for their work.

The meeting adjourned at 12:00 p.m.

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John Auerbach, Chair

LMH