MINUTES OF PUBLIC HEALTH COUNCIL

MEETING OF JUNE 9, 2010

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

THE PUBLIC HEALTH COUNCIL OF
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
Henry I. Bowditch Public Health Council Room, 2nd Floor
250 Washington Street, Boston, MA

Updated Docket: Wednesday, June 9, 2010, 9:00 AM

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1. ROUTINE ITEMS: No Floor Discussion

a. Compliance with Massachusetts General Laws, Chapter 30A, §11A ½ **(No Vote)**

b. Record of the Public Health Council Meeting of May 12, 2010 **(Approved)**

2. REGULATIONS: No Floor Discussion

a. Request for Promulgation of Amendments to 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII) **(Approved)**

b. Request for Promulgation of Amendments to 105 CMR 590.000: Minimum Sanitation Standards for Food Establishments to Comply with the Allergen Awareness Act (State Sanitary Code, Chapter X) **(Approved)**

c. Request for Promulgation of Amendments to 105 CMR 700.000 (Implementation of the Controlled Substances Act) Concerning Collaborative Drug Therapy Management **(Approved)**

3. PROPOSED REGULATION: No Vote/Information Only

Informational Briefing on Proposed Amendment to 105 CMR 590.000, State Sanitary Code, Chapter X: Minimum Sanitation Standards for Food Establishments, Requiring the Posting of Calorie Information (Proposed Rescission Due to Preemption Under Federal Health Care Reform Act)

4. PRESENTATION: No Vote/Information Only

"Public Health Hospitals - Meeting the Changing Health Needs of the Most Vulnerable"

The Commissioner and the Public Health Council are defined by law as constituting the Department of Public Health. The Council has one regular meeting per month. These meetings are open to public attendance except when the Council meets in Executive Session. The Council's meetings are not hearings, nor do members of the public have a right to speak or address the Council. The docket will indicate whether or not floor discussions are anticipated. For purposes of fairness since the regular meeting is not a hearing and is not advertised as such, presentations from the floor may require delaying a decision until a subsequent meeting.

PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on June 9, 2010, 9:20 a.m., at the Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Mr. John Auerbach, Commissioner, Department of Public Health, Ms. Helen Caulton-Harris, Dr. John Cunningham, Dr. Muriel Gillick, Ms. Lucilia Prates Ramos, (arrived at 9:25 a.m.), Dr. Meredith Rosenthal, Mr. Albert Sherman (arrived at 9:40 a.m.) and Dr. Michael Wong. Absent members were: Dr. Michèle David, Mr. Paul Lanzikos, Mr. Denis Leary, Mr. José Rafael Rivera, Dr. Alan C. Woodward and Dr. Barry Zuckerman. There is one vacancy. Also in attendance was Attorney Donna Levin, 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 summarized the agenda items that would be heard and noted that the order of items would change due to no quorum of Public Health Council Members being present at the start of the meeting. The Council heard the Informational Briefing on Proposed Amendment to 105 CMR 590.000, State Sanitary Code, Chapter X: Minimum Sanitation Standards for Food Establishments, Requiring the Posting of Calorie Information first since no vote is required. Ms. Suzanne Condon, Director, Bureau of Environmental Health followed this regulation with updates on the McDonalds Restaurant glasses recall and mustard gas incident.

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

RESCISSION DUE TO PREEMPTION UNDER FEDERAL HEALTH CARE REFORM ACT):

Ms. Suzanne Condon, Director, Bureau of Environmental Health, briefed the council on the proposed rescission on the previously approved regulations 105 CMR 590.000 in regards to posting of calorie information on restaurants menus.

"The Calorie Posting regulations were first introduced to Public Health Council on January 14, 2009, and were adopted on May 13, 2009 with an effective date of November 1, 2010. The regulations require that covered food establishments post calorie information on menus and menu boards. The Massachusetts regulations also require (among other things) that a licensed nutritionist or dietician complete a verifiable analysis of the calorie information posted. Staff proposes to rescind the Calorie Posting regulations based on federal preemption under the Patient Protection and Affordable Care Act. President Obama signed the Act into law on March 23, 2010."

Ms. Condon noted further, "The federal law contains an explicit preemption clause, which invalidates any state law or regulations that are not identical to the federal law…Since the DPH regulations contain provisions that are very different from the new federal requirements, the DPH regulations are preempted by the federal law…"

Staff's memorandum to the Council, dated June 9, 2010, as well as Ms. Condon, informed the Council that staff plans to proceed to public hearing as part of the process. Staff will return to the public health council, after the public hearing, scheduled for July 21, 2010 at 10:00 a.m. in the Public Health Council room at DPH to request that the Council rescind these regulations.

NO VOTE/INFORMATION ONLY

UPDATE ON MCDONALD RESTAURANT RECALL OF SHREK MOVIE CHARACTER GLASSES:

Ms. Suzanne Condon, Director, Bureau of Environmental Health updated the Council on the recall of glasses by McDonald's Restaurants. She noted that the glasses contain cadmium in the paint/glaze. She mentioned a similar situation years ago with McDonald's glasses containing lead.

NO VOTE/INFORMATION ONLY

UPDATE ON MUSTARD GAS EXPLODING ON FISHERMEN:

Ms. Suzanne Condon, Director, Bureau of Environmental Health informed the Council that her Bureau has been working in concert with many Federal agencies (incident occurred on Federal waters) and state agencies to figure out how to best dispose of the 250 tons (180 cages) of clams that has been embargoed due to New Bedford Fishermen discovering mustard gas canisters and an explosive head in their nets. Several fishermen had been injured. It is assumed that the canisters were most likely dropped in the ocean after WWI or WWII. Testing is being done to determine if the clams contain the mustard gas or not because if not the clams may be safe enough to put back into the ocean. If they contain mustard gas the clams are hazardous waste and therefore the safest way to dispose of them must be determined.

NO VOTE/INFORMATION ONLY

REQUEST FOR PROMULGATION OF AMENDMENTS TO 105 CMR 480.000: MINIMUM REQUIREMENTS FOR THE MANAGEMENT OF MEDICAL OR BIOLOGICAL WASTE (STATE SANITARY CODE, CHAPTER VIII):

Ms. Suzanne Condon, Director, Bureau of Environmental Health, accompanied by Attorney James Ballin, Deputy General Counsel, Office of the General Counsel, presented a request for amendments to 105 CMR 480.000 to the Council.

Staff's memorandum explained, "The Pharmacy Needle Access Law (Chapter 172 of the Acts of 2006) required the Department, in consultation with the Department of Environmental Protection, to design, establish and implement, or cause to be implemented, a program for the collection and disposal of spent non-commercially generated hypodermic needles and lancets…The Public Health Council approved amendments to the medical waste regulations that included a ban on disposal of sharps in household trash effective July 1, 2010."

Ms. Condon said in part, "…We have made significant progress in expanding access to sharps collections throughout the State. We had collection sites available in a 104 municipalities. That represents about one-third of the State. We also worked with our HIV/AIDS office to ensure that certain providers absolutely had sharps disposal capacity available but despite all that, we still have many communities that had no options available to them and so our belief was that, by extending this for two years, waiting for the economy to come back, and working on regulatory or legislative solutions, we might be able to realize this better in two years." The proposed amendment would change the date in the current regulations where a ban on disposal of sharps in household waste was scheduled to take effect on July 1, 2010 to July 1, 2012.

Regarding public comments, staff's memorandum indicated, "Two people attended the public hearing on May 14, 2010, and only one of those two presented oral and written testimony. No other written comments were received during the comment period which ended May 21, 2010. The only comments received were from Waste Management of Massachusetts, Inc., which, has played an active role in Massachusetts in promoting needle collection programs and encouraging key stake holders to participate in a statewide solution to reduce injuries and health impacts from sharps disposed of in household trash. While not opposing the Department's proposed two year delay, Waste Management encourages the Department to continue its education campaign. It also requests that the Department establish a committee of appropriate stake holders to work with legislators and state leaders to develop a legislative

solution that mandates proper collection and disposal of sharps and places shared responsibility for costs of collection and disposal on manufacturers of sharps and drugs contained in injection devices."

In closing, Ms. Condon said in part, "…The Department believes that extending the deadline for two years will allow sufficient time to ensure that a statewide plan for sharps collection is in place before the disposal ban takes effect. During these two years, we will evaluate options to implement a statewide program, including possible additional regulatory requirements or a legislative solution."

Mr. Albert Sherman moved approval of the amendments to **Regulations 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII).** After consideration, upon motion made and duly seconded it was voted unanimously to approve the request for final promulgation of said Regulations that change the **effective date of a ban on home sharps disposal to July 1, 2012** instead of July 1, 2010. This approval includes the amendments attached as Appendix A (105 CMR 480.125: Home Sharps) which is attached and made a part of this record as **Exhibit No. 14, 948.**

A brief discussion occurred, please see verbatim transcript.

REQUEST FOR PROMULGATION OF AMENDMENTS TO 105 CMR 590.000: MINIMUM SANITATION STANDARDS FOR FOOD ESTABLISHMENTS TO COMPLY WITH THE ALLERGEN AWARENESS ACT (STATE SANITARY CODE, CHAPTER X):

Ms. Suzanne Condon, Director, Bureau of Environmental Health, accompanied by Attorney Priscilla Fox, Deputy General Counsel, Office of the General Counsel, presented a request for amendments to 105 CMR 590.000 to the Council for final promulgation. Ms. Condon noted, "The amendments implement three requirements of the Allergen Awareness Act (M.G.L.c.140,§6B): (1) Exhibiting a staff awareness poster in the restaurant staff area relative to food allergy awareness; (2) inclusion of an allergen consumer alert notice on

menus and (3) requiring additional food allergy awareness training for food protection managers.

Ms. Condon noted in her presentation as well as in her memorandum to the Council, dated June 9, 2010 the following information regarding the proposed regulations for approval:

- Major Food Allergen means (1) Milk, eggs, fish (such as bass, flounder, or cod), crustaceans (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; and (2) A FOOD ingredient that contains protein derived from a FOOD named in subsection (1). Major Food Allergen does not include: (a) any highly refined oil derived from a FOOD specified in subsection (1) or (a) Any highly refined oil derived form a FOOD specified in subsection (1) or any ingredient derived from such highly refined oil; or specified in the federal Food Allergen Labeling and Consumer Protection Act of 204 (Public Law 108-282).

- Food establishments that cook, prepare, or serve food intended for immediate consumption either on or off the premises shall comply with the Food Allergy Awareness Requirements.

- No later than October 1, 2010, such food establishments shall comply by prominently displaying in the employee work area a **poster** approved by the Department of Public Health, no smaller than 8.5 by 11 inches, relating to major food allergens. The poster shall include major food allergens, health risks of food allergens, procedures to follow when a customer states that he or she has a food allergy and emergency procedure to follow if a customer has an allergic reaction to a food. Free posters are available from DPH and will be available to download from their website.

- Such food establishments shall include on all printed **menus and menu boards** (including drive-through menu boards) a clear and conspicuous notice requesting a customer to inform the server before placing an order, about the customer's allergy to a major

food allergen. The notice shall state: "Before placing your order, please inform your server if a person in our party has a food allergy". This requirement is **effective no later than October 1, 2010.** See regulations for specific requirements on menu boards including font size requirements and further that in lieu of placing the notice directly on the indoor/outdoor menu board itself, a notice may be posted adjacent to the menu board or at each point of service where food is ordered.

- By February 1, 2011, such food establishments shall have on staff a certified food protection manager who has been issued a Massachusetts certificate of allergen awareness training…The food protection manager must view the DPH issued food allergy awareness training video available at no cost, however, there is a $10.00 fee to obtain the certified certificate for food protection managers. The certificate will be valid for five years and should be posted next to the food establishment permit. The certified food protection manager is responsible for ensuring that employees are properly trained in food allergy awareness as it relates to their assigned duties.

- See regulations for exemptions to these regulations, certain institutions are exempt such as public and private schools, education institutions, summer camps, childcare facilities and other child care programs approved to participate in USDA Child Nutrition programs, food service operations in institutional settings in which food is prepared or/served to a specific population such as hospitals, non-profit organizations, elderly nutrition programs, charitable food facilities and temporary food establishments operated by non-profit organizations (i.e., school bake sales). Caution: certain areas of these institutions may be subject to these regulations or part of the regulations, for example, hospital cafeterias that serve the public may need to comply with these regulations.

- The regulations do not apply to retail food stores that do not conduct food service activities such as cooking, preparing and serving. Areas of the store that conduct these activities are

subject to the regulations.

Some of the changes made after the public hearing and comment period (since the last version of the proposed regulations were presented to the Council) include: The regulations apply now not only to Innholders and Common Victuallers but to all retail food establishments with food service operations that cook, prepare, or serve food intended for immediate consumption either on or off the premises; posters developed by industry and approved by the Department of Public Health will be permitted; the word "covered" has been deleted from the definition of menu and menu board; require notice on menu boards (or adjacent too) as well as on menus as recommended by the PHC; the original effective date of implementation was July 1, 2010, now there are various dates for different requirements to allow for orderly implementation.

Staff's memorandum notes that the proposed amendments were initially presented to the Public Health Council on February 10, 2010. A public hearing was held in Boston on March 12, 2010. The Department received written comments from approximately 20 individuals and organizations and oral testimony from four of the twelve people who attended the public hearing. The period for written testimony closed on March 26, 2010. Ms. Condon stated in part, "Many of the comments received from the food industry representatives indicated opposition to the proposed amendments, supporting greater flexibility in how covered restaurants and grocery stores make allergen information available to consumers and in how training is conducted. Some industry representatives also raised concerns about the economic impact of the Massachusetts regulations. Members of the public, public health experts/advocacy groups, and local boards of health were generally supportive of the proposed regulations, and offered suggestions on how the regulations could be strengthened. The proposed amendments were revised in response to comments received, and reflect a balanced approach that addresses legitimate concerns of both the food industry and public health experts and advocates…"

A brief discussion followed; please see the verbatim transcript for full discussion. Chair Auerbach repeated that the Council wants to make sure staff notifies hospitals that their areas open to the public like cafeterias are not exempt from these regulations. During discussion, Attorney Priscilla Fox, Deputy General Counsel, noted that the regulations are complicated and some parts of the regulations may apply to certain areas of institutions like hospitals. Ms. Condon noted that staff is in close contact with the 35,000 or so entities that will be impacted by this and that lots of information will get out to everybody.

Dr. Michael Wong made a motion to approve the regulations. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the request for **Promulgation of Amendments to 105 CMR 590.000: Minimum Sanitation Standards for Food Establishments to Comply with the Allergen Awareness Act (State Sanitary Code, Chapter X).** A copy of the approved regulations is attached and made a part of this record as **Exhibit No. 14,949.**

Note: Ms. Condon praised Ms. Priscilla Neves, Director, Food Protection Program for her 26 years of dedicated service to the Department. Ms. Neves is leaving the Department to work for the Federal government. She will be greatly missed! Commissioner Auerbach concurred and said in part that "She has been the one on the front-lines during food outbreaks protecting the public…" Commissioner Auerbach also thanked Ms. Condon for her dedication to her job and working so many long hours on so many issues.

REQUEST FOR PROMULGATION OF AMENDMENTS TO 105 CMR 700.000 (IMPLEMENTATION OF THE CONTROLLED SUBSTANCES ACT) CONCERNING COLLABORATIVE DRUG THERAPY MANAGEMENT:

Dr. Grant Carrow, Director, Drug Control Program, accompanied by Dr. Alice Bonner, R.N., Director, Bureau of Health Care Safety, and Quality, and Attorney Howard Saxner, Deputy General Counsel, Office

of the General Counsel presented amendments to 105 CMR 700.000 to the Council for approval.

Dr. Carrow noted in his memorandum to the Council dated June 9, 2010 and stated in part, "The Department's Drug Control Program (DCP) is returning to the Public Health Council to request final promulgation of proposed regulations that would permit a pharmacist to register with the DCP for the purpose of writing prescriptions and issuing medication orders. Such registration would be contingent upon the pharmacist and his/her supervising physician meeting the requirements of their respective Boards of Registration. The writing of prescriptions or issuance of medication orders would be in accordance with a collaborative practice agreement between the pharmacist and supervising physician."

Dr. Carrow further informed the Council, "that the law permits a pharmacist to enter into a written, collaborative practice agreement with a supervising physician, allowing the pharmacist to initiate, monitor, modify or discontinue a patient's drug therapy. The mutually developed agreement establishes individualized guidelines for the collaborative practice of the authorized pharmacist and supervising physician. The pharmacist would be required to have training and experience commensurate with the scope of the collaborative practice. The statute limits collaborative drug therapy management (CDTM) to the following settings: hospitals, long-term care facilities, inpatient/outpatient hospice settings, ambulatory care clinics, and community pharmacies (retail drug businesses) with physician supervision…There are differences as to what activities may be conducted by practice setting. For example, in a licensed heath care facility, a pharmacist in agreement may prescribe or dispense all controlled substances, however in a community or retail setting, by contrast, only Schedule 6 controlled substances may be prescribed or dispensed…I just want to reiterate that these are voluntary agreements…There is no requirement to engage in this activity at all on the part of any of the parties…"

It was further noted in staff's memorandum that the new law directs the Commissioner of Public Health to issue regulations authorizing a

duly licensed pharmacist to register with the Department for the purposes of engaging in CDTM and writing prescriptions in accordance with the collaborative practice agreement and regulations of the Boards of Registration in Pharmacy and Medicine. The law separately directs the Boards of Registration in Pharmacy and Medicine to issue rules and regulations to address the implementation of CDTM. Accordingly, the Boards of Registration in Pharmacy and Medicine have developed companion regulations. These regulations will (1) establish the qualifications for a pharmacist to enter into a CDTM agreement with a physician and (2) detail the requirements for a CDTM practice in a specific pharmacy practice setting (hospitals, long-term care facilities, inpatient or outpatient hospice, ambulatory care clinics and community (retail) pharmacies, in accordance with specific requirements of the law. The statute and proposed companion regulations establish special requirements for collaborative practice within the community (retail) pharmacy setting. A collaborating pharmacist is limited to: (1) extending drug therapy initiated by the supervising physician for 30 days (2) administering vaccines (3) modifying or discontinuing medication prescribed by the supervising physician for patients with specified disease states (e.g., asthma, diabetes, congestive heart failure, HIV or AIDS); (4) issuing initial prescriptions for schedule VI controlled substances only, for treatment of specified disease states, to the extent provided in the collaborative practice agreement. The patient must be referred, in writing, by the supervising physician to the collaborating pharmacist and the patient must provide written, informed consent to participation in the collaborative practice. The patient would have to be at least 18 years old."

Dr. Carrow noted, "The regulatory amendments would authorize the DCP to issue a Massachusetts Controlled Substances Registration (MCSR) to a duly licensed pharmacist who meets the applicable statutory and regulatory requirements. The proposed amendments are consistent with those in 105 CMR 700.000 for prescribing by other health care providers in the expanded role, including advanced practice nurses and physician assistants."

Staff's memorandum to the Council, dated June 9, 2010 lists the regulatory requirements a pharmacist registered with the Department and engaged in CDTM must meet:

Scope of Practice:

- As a licensee, the pharmacist meets all applicable requirements of the Board of Registration in Pharmacy;

- in addition to registering with the DCP, the pharmacist is registered with the U.S. Drug Enforcement Administration if the collaborative practice agreement allows for federally controlled substances to be prescribed;

- a prescription or medication order from a pharmacist may be issued, modified, or discontinued only in accordance with the collaborative practice agreement entered into with the supervising physician, and applicable regulations of the Boards of Registration in Pharmacy and Medicine;

- a pharmacist practicing in a retail setting is restricted to writing prescriptions for Schedule VI controlled substances only;

- a pharmacist may order and dispense a Schedule VI controlled substance for "immediate treatment";

- a pharmacist may issue an oral prescription; and

- within a licensed health care facility (i.e., hospital, LTC facility, ambulatory care clinic, hospice), a pharmacist may prescribe a controlled substance for a patient as a written medication order documented in the patient's medical record.

Recordkeeping Requirements of the Regulations:

- A pharmacist practicing under a collaborative practice agreement is required to keep a record of all controlled substances maintained for the purpose of immediate treatment or

administration; and

- a pharmacist who writes an initial prescription or modifies or discontinues a prescription is required to provide a copy to the supervising physician within 24 hours of issuance (unless more urgent notification is warranted).

Staff's memorandum indicated and Attorney Howard Saxner said in part, "A public hearing was held on April 6, 2010 in Boston, Massachusetts and the hearing record was kept open through April 9, 2010. Four professional organizations, two academic institutions, and one health care facility submitted written testimony. The four professional organizations and a health care facility provider presented oral testimony at the hearing. Except for the Massachusetts Independent Pharmacists Association, the testimony offered strong or general support for the regulations. The Massachusetts Society of Health System Pharmacists, the Massachusetts Pharmacists Association, and Massachusetts Independent Pharmacists Association shared the same recommendation, that the DCP regulations be amended to include current technology, so that pharmacists practicing under a collaborative practice agreement would be allowed to issue 'electronic prescriptions'. Staff believes that the current regulations provide authority to issue prescriptions electronically. Nevertheless, in response to these comments, the Department has proposed an amendment to make clear that electronic prescriptions are included under the definition of 'written prescription' ".

In closing, Dr. Carrow said, "…Our purpose here is to come before you to ask for your approval for final promulgation of the proposal before you. Upon your approval, the Drug Control Program regulations would be promulgated and published in the Massachusetts Register along with those from the Boards. The Drug Control Program would post on its web site an application form for pharmacists to obtain a Massachusetts Control Substances Registration. Then the Drug Control Program would begin accepting applications and issuing registrations to those pharmacists with collaborative practice agreement in place and, in that regard, the

Boards are working on developing a model practice agreement for use for anyone who wants to enter into such an agreement…"

Discussion followed by the Council, please see the verbatim transcript for full discussion. Dr. Muriel Gillick asked staff for concrete examples of how this would work in real life. Ms. Jean Pontikas, Director, Health Professions Licensure joined the panel and responded, "…I think that there will be opportunities in the community pharmacy setting, which is the setting that requires an explicit referral and consent by the patient for the collaborative drug therapy so that a patient who is on anticoagulation therapy might be referred to a community pharmacist by the supervising physician, enter into an agreement, and the physician would work with the pharmacist on monitoring the drug therapy and prescribing medications appropriate to that. The same would be the case for a situation where there is a diabetic patient, and there might be an opportunity for the patient to receive, or to have greater access to the therapy management if it is conducted by the pharmacist." It was noted that the law allows for laboratory results to go directly to the pharmacists to guide him/her in determining the appropriate dosing of the medication. However, the agreement in place between the supervising physician and the pharmacist would determine who receives the lab results and when the discussion on the lab results should occur. Chair Auerbach suggested another example would be a dosage being adjusted for a patient starting a new medication, having the symptoms monitored and then adjusted by the pharmacist in collaboration with the supervising physician instead of needing another trip to the physician's office. Dr. Carrow added that prior to these regulations, a physician would have needed to sign off before the medication could be changed, now with an agreement, the pharmacist can make the change and later have the physician review the change as needed.

Dr. Meredith Rosenthal commented, "This is relevant to the context of the Patient Centered Medical Home and the notion of team-based care in the context of the Chronic Care Model. I can picture this working in that model. There is a reimbursement model there that would support the pharmacist's work. In general, however,

pharmacists can't really be reimbursed for these activities under standard billing…Do you have a sense of the demand for the ability to operationalize team-based care with pharmacists?" Ms. Pontikas replied that "providers are prepared to implement this and have been waiting for this to occur and see it as a good opportunity to be able to extend more services, more readily, to the patients."

Dr. Michael Wong stated that he can see the potential Medical Home and patient benefits of this but has some of the same issues as Dr. Gillick. He noted his concern about patient records: Would changes by the pharmacists to the medications of a patient make it to the patient's medical record? Without direct entry into a patient's record electronically he doesn't see it happening, faxes get lost, they won't be working out of the same office as in a nurse practitioner situation. He said, "If this moves forward without direct entry into the electronic medical record, we are really going to run into problems." Ms. Pontikas responded that the regulations of the Board of Pharmacy and Medicine include a provision that requires that any change or modification to a prescription needs to be communicated to the physician within a 24 hour period and in the institutional setting it would have to be documented in the patient's record. She said further, "These are important issues to be considered and that the Boards can issue some additional guidance to the practitioners on what a best practice might be and further that these issues of logistics are ones everybody is grappling with everyday."

Mr. Albert Sherman raised transitions in care issues with regards to prescriptions. It was noted that Dr. Alice Bonner would be returning to the Council with more information on the Transitions in Care Task Force Recommendations. Ms. Lucilia Prates Ramos asked if there was a way to pilot this and delay full implementation. She is concerned about elderly consumers who don't speak English, getting lost in the shuffle between pharmacists and physicians prescribing medications. She said in part, "…I would hope that pharmacists and physicians would be very selective about the patients they decide to implement this with, but I know from experience of working out in the field and with the communities, that there is room for error, and I am concerned about that…" Ms. Pontikas clarified that a pharmacist

cannot issue prescriptions for a patient without there being an agreement in place between the patient's physician, the pharmacist, and the patient. Ms. Pontikas noted that this kind of program has been implemented in 44 other states successfully. Dr. Carrow noted the goals of the law: (1) to improve patient care and safety (2) to increase medication adherence, and (3) to reduce medication errors, adverse effects, and health care costs.

Discussion continued and Chair Auerbach noted that the law has been passed, signed by Governor Deval Patrick into law in January of 2009, requiring the Department to implement this program. "The legislature decided this was the law and we are simply putting into regulation what has been required by the law…" Mr. Bill Ryder, Regulatory and Legislative Counsel of the Massachusetts Medical Society (MMS) noted for the record that his organization was in favor of the statute in response to Mr. Sherman's inquiry of the MMS' position on this.

Dr. Alice Bonner stated "…What hasn't been mentioned quite so much is the role of the pharmacist as an educator and as an extender of the physician education and the staff model education around these medication issues, all of the errors, and the patient's role in being empowered to understand the medications. As a clinical model, and you were talking about the Medical Home Model, that's a huge opportunity here to really enhance primary care by enhancing the team, and perhaps having a pharmacist who can take a little bit more time, not thinking so much of the retail setting but of some of the other settings…in the nursing home setting, the consultant pharmacists are tremendously valuable in clarifying a lot of these issues…As a model of primary care, I think the education piece is really important and what the pharmacist can do and there is some good literature from Canada and from the U.S. about significant results when pharmacists are a part of that team…"

Chair Auerbach summarized the Public Health Council's desires in implementation of these amendments: "The Council clearly has recommended that, in the implementation of this regulation, and the implementation of this law, particular attention and care be paid to

ensuring that these collaborative relationships are established only in proper situations, with good communication, with oversight by the physician, and with direct, timely communication and transfer of information where there has been any kind of a change in terms of the medication; and so, I guess maybe with those strong recommendations from the Council, I would ask if a Council Member would like to make a motion of the regulation as recommended."

Mr. Sherman moved approval of the amendments. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the **Request for Promulgation of Amendments to 105 CMR 700.000 (Implementation of the Controlled Substances Act) Concerning Collaborative Drug Therapy Management (CDTM).** A copy of the approved regulations is attached and made a part of this record as **Exhibit No. 14, 950.**

In closing, Chair Auerbach said, "Again, I would reinforce that I hear the Council saying, this is the law, they are going ahead, but there clearly are some reservations that I think would be worth our conveying with the same strength and concern that the Council Members have relayed today, and we would appreciate that; and maybe just periodically, if we could get just an update about how this is being implemented, it would be terrific."

RECORD OF THE PUBLIC HEALTH COUNCIL MEETING OF MAY 12, 2010:

Mr. Albert Sherman moved approval of the minutes. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the minutes of May 12, 2010 as presented.

PRESENTATION: "PUBLIC HEALTH HOSPITALS – MEETING THE CHANGING HEALTH NEEDS OF THE MOST VULNERABLE":

Mr. Philip McCauley, Director, Bureau for Public Health Facilities, made introductory remarks on the four public health hospitals, the Department of Public Health operates. He said in part, "…The

Department of Public Health operates four hospitals providing quality specialty care to a range of patients from Boston to the Berkshires at Lemuel Shattuck Hospital, Jamaica Plain, Tewksbury Hospital, Tewksbury, Massachusetts Hospital School, Canton, and Western Massachusetts Hospital, Westfield. While the work of the hospitals is distinct from the department's public health programmatic and regulatory activities, it is a significant part of DPH. In FY10, the hospitals accounted for 30% of DPH projected state spending, with a similar percentage proposed in Governor's Patrick's FY11 budget. The hospitals account for two-thirds of the Department's state-funded workforce. DPH hospitals face the same challenges as the larger health care system: Growing fixed costs, including the need to acquire technologically complex and costly treatment modalities, flat or declining revenues and funding bases, on-going efforts to increase quality and reduce medical errors and Healthcare-Associated Infections (HAIs), sustaining accreditation and regulatory compliance within a rapidly changing environment, and competing for labor, especially clinical caregivers, in a competitive and expensive markets. The four facilities are accredited by the Joint commission."

Ms. Maria Tricarico, Director of Nursing, Lemuel Shattuck Hospital (LSH), spoke on behalf of Mr. Paul Romary, Chief Executive Officer of Lemuel Shattuck Hospital, who could not make the meeting. Ms. Tricarico noted in part, "…LSH opened in 1954 and provides care for the inmates at the state's correctional institutions, Department of Mental Health patients, and the community. In FY09 LSH had 800 correctional institution patient admissions, 152 mental health admissions, and 595 community admissions. Ten community and 10 mental health beds had been reduced in FY10 due to budget cuts. LSH's core clinical expertise includes: acute care, including telemetric cardiac monitoring, PICC/central line placements, wound care, telemedicine, and run an accredited medical residency program that is affiliated with Tufts Medical Center and Lahey Clinic. Infectious disease specialization in HIV/AIDS, tuberculosis and Hepatitis C, Post acute inpatient care for seriously and chronically mentally ill (DMH), acute rehabilitation medicine, surgical services: general, orthopedics, vascular, gastroenterology, urology, ENT, thoracic, Multi-specialty outpatient department with 25 clinics and 'one-stop' primary and

mental health care, Hematology-oncology and hemodialysis for behaviorally challenging individuals, on-campus continuum of substance abuse services, complete on-site ancillaries and diagnostics: full clinical lab/pathology, CT scanner, mobile MRI, 2,000 agent Rx formulary, sleep studies, EKG/ECHO and EEG. LSH ambulatory care clinic visits totaled 14,508 in FY09 (does not include the Goldfarb Behavioral Health Care which closed in January 2009 due to budget cuts). This figure includes the Goldfarb Primary Care, Clozaril-Mass Mental HC, orthopedics, GI clinic and Hematology/oncology.

Ms. Tricarico stated further, "…Our philosophy is to try and stop the cycle of recidivism that most of these patients experience. They get ill. They pop-up in different areas of the health care continuum, many times in emergency rooms, which is extremely expensive. It is also not efficient or effective. We try to take a comprehensive approach, where we look at all the issues that is impacting on this person and address them in a coordinated way so that, when we discharge them, they are truly discharged to a better setting, and to a better condition than they were in, so they are not popping up in emergency rooms in other care centers. A little more than a third of our patients display disruptive behaviors. About 18% need one-to-one supervision during admission, which is very expensive. More than half of our patients, across all units, are on anti-psychotic medications. Over half of them have some kind of infectious disease. About forty percent of them have to be on isolation while they are in the hospital and require private rooms, and all of the precautions, and about more than two-thirds, require IV medications in various combinations."

In closing Ms. Tricarico said, "I think the story that I would like to end with, that centers on our ambulatory care and how we provide care to our patients, I remember, walking through the clinic and seeing a somewhat older woman, who was clearly a person who lived on the streets because she was carrying bags and everything. She looked confused. I asked her what she needed. She said she needed to see someone because she had been raped. I brought her to an examining room and told people what was going on, and asked

her what happened, and it turned out that this was the 28th time this woman had been raped on the streets. Sexual assault is a hugh factor for those living on the streets, particularly women, and I said to her, BI is right down the street, and they have a fabulous Rape Crisis Center. How about if I arrange to transfer you there and come with you, and she said no, I don't want to go there, and I said, why not? That's their specialty. And she said, because there I am a crazy homeless person. Here, I am a person."

Ms. Katherine Chmiel, Chief Executive Officer, Massachusetts Hospital School (MHS), Canton, presented the MHS data to the Council. She noted in part, "…There are three things going on at MHS. We are a pediatric hospital. We have a school program that is run by the Department of Elementary and Secondary Education, and we also have a Board of Trustees that functions very differently in this state-run environment. Our Board functions as a private non-profit. Many of the wonderful things I will talk about are privately funded. The State provides for the care and the medical treatment, the Department of Education for the children's education and then we have this wonderful board that provides the sparkle and magic that happens at Mass. Hospital School. "

Ms. Chmiel noted, "…We have a summer program that runs for seven weeks, where children from the community who are not patients at MHS can come and, they call it camp, but it is truly a summer program, where the nursing staff, the physicians and the physical therapists, all of the MHS staff provide very safe and a lot of fun activities for the kids, while they are also receiving some very good treatment and good rehabilitation services."

"We have a very powerful pain management program", She said, "As you can imagine, these children who suffer from some of these horrific illnesses, conditions like cerebral palsy and spina bifida, there are a lot of contractions to their limbs and their bodies. We have a program that is amazing in that these kids can learn how to relax and they can actually without medication, learn how to manage some of the horrific pain that they have. We have a full case management program, where we work very closely with families. We don't just

treat children there. We treat usually an entire family. We have a very strong focus on independent living for the older kids. As they start to get older, we have a program; it's a unit where the focus is not so much on caring for them. The nurses there are specially trained in that they teach them how to direct their care. They teach them how to become more independent, to speak up for themselves because, when they do go out into the community, they have personal care attendants. They are going to need to learn how to tell people what they need, and how they need things done. We have a fabulous Rehab engineering program, on site with about a hundred children that we care for. There are 75 inpatients and about 25 day students, that come to the school. We too, suffered from the budget reductions last year and we had to shut down a 14-bed unit. Our rehabilitation engineering department customizes wheelchairs and speech devices that the children need for mobility. About 50% of our children have, as a primary diagnosis, cerebral palsy on the extreme end of the spectrum. All of these children have illnesses or conditions on the extreme end."

Ms. Chmiel continued, "…About 27% of our kids have metabolic or neuromuscular disorders. The metabolic disorders are very rare, and I can't pronounce most of them but mitochondrial disorder comes to mind. These children suffer from these horrific illnesses, and have a lot of co-morbidity. Seven percent have spina bifida and 10% have muscular dystrophy. In cases of the children with muscular dystrophy, the focus of our care for them is quality of life because their life expectancy is about 19 to 20 years of age. In their late teens, we start to see increases in their cardiac problems, respiratory problems and we often lose them. Six percent of these children are victims of some of the gang violence that we see on the news, the gunshot wounds or horrific automobile accidents or diving, swimming accidents. The children also have co-morbidity: co-occurring seizure disorders, respiratory problems and diabetes…It is not a big focus of what we do, but we do have about half of the children that have mental health issues. Seventy-seven percent of them have a DSM diagnosis of mental retardation and they are followed by DDS."

Ms. Chmiel said further, "…We believe that we have a very high quality service that we provide in a very cost effective manner. We generated about nine million dollars in revenue back to the General Fund of Massachusetts in Fiscal Year 2009. We are quite cost effective and we do a wonderful job with these kids." She noted that a private school serving medically intensive children charges about $385,000 dollars a year for a 365 program."

In summary, Ms. Chmiel said, "They say that MHS is the best and least restrictive environment for the children because: Children who are referred have not been successful in traditional community/home based settings, some children are 'stuck' in costly, restrictive, acute care settings, MHS has an open campus with a strong medical focus that keeps the children healthy so that they can thrive in the on-site school program and over 140 recreational programs. MHS has a Therapeutic Leave Program which allows children to go home as often as every weekend and during traditional school vacations. They focus on Independent Living Skills and Community Mobility."

Mr. Derrick Tallman, Chief Executive Officer, presented the Western Mass. Hospital data to the Council. He said current services include: inpatient services: Alzheimer's Behavioral, Pulmonary (Ventilator Patients and those in need of 24 hour Respiratory Therapy), Neurological, MS, Huntington's, ALS, Transitional: End of Life, Respite and Waiting for Discharge. Outpatient Dental Services to Uninsured and Underinsured are provided. Level of care by Patient Days is Respite 272 (1%), Acute 737 (3%) and Chronic at 23,447 (96%). Eighty-eight percent of Home Admissions are due to respite services. Mr. Tallman noted that many patients are rejected by other facilities due to disruptive behaviors, need for one to one supervision, substance abuse, history of incarceration (e.g., CORI, SORI), medical complexity (number of diagnoses and consultant services), some patients too young for most SNF placement, are a fall risk, or require intensive use of ancillary services.

Ms. Sandra Akers, Chief Executive Officer, Tewksbury Hospital, presented the data on Tewksbury Hospital to the Council. She said in part, "Tewksbury is the largest of the Public Health hospitals.

Tewksbury Hospital's mission is to provide complex behavioral and medical care for people who cannot be successfully treated at other facilities. Current Hospital census is 336 (220 medical patients served in their 7 acute/chronic units) and 116 Mental Health and Forensic patients from DMH in four locked psychiatric units. Our clientele are difficult patients with behavioral challenges, who get stuck in acute care systems, the majority of time, at a much higher cost to the Commonwealth than what we are providing care for. The hospital currently operates at 98% capacity (after closure of two medical units from prior 9c cuts). Other Services Tewksbury Hospital provides include: Chronic rehabilitation for post-acute patients with Brain Injury, Huntington's Disease, Spinal Cord Injuries, Multiple Sclerosis, Muscular Dystrophy, and Pick's Disease, Rehab and chronic medical management for DDS clients with behavioral, medical, and neurologic illness that cannot be managed in the community, Chronic Hemodialysis treatment for patients who have behavioral challenges and chronic medical illness. Longer-term antibiotic and wound care for complex bacterial infections, often in the face of substance abuse and persistent mental illness. Tewksbury is a bridge to the community for medically compromised substance abusers who need medical, psychiatric, and substance abuse treatment and further provides Intermediate Psychiatric and Forensic care for DMH clients of the Northeast area."

Ms. Akers continued, "…Eighty-two percent have been denied admission to three or more private facilities before they get to Tewksbury. We are clearly the safety net hospital for the Commonwealth. Seventy-seven percent of patients have a major mental disorder in addition to medical illness, 13% of patients have a MR diagnosis, 67% of patients have a neurological diagnosis, 17% of patients have Huntington's Disease, 18% are brain injured and require medium term rehabilitation, or are unable to find community placement, and have inadequate funding for private/commercial rehab, 20% of patients have active substance abuse on admission, 12% have deep tissue infection (endocarditis or osteomyelitis) caused by recent IV drug use. We have an entire unit devoted to care of males whose behavior and positive SORI/CORI makes them

incapable of placement anywhere else in the Commonwealth ...Patient admissions has doubled every year for the last four years."

In conclusion, Ms. Akers stated, "Tewksbury is a great place, and despite what occasionally you will see in the newspapers. We are home to eight other vendor programs on the campus of Tewksbury, including several substance abuse programs and adolescent programs for young boys, and it is a wonderful place."

A brief discussion followed by the Council. Please see verbatim transcript for full discussion. Dr. Muriel Gillick asked the facilities if it would be possible in the future for the hospitals to develop more palliative care programs and address advanced care planning for their patients. Ms. Akers of Tewksbury replied that they now have a nurse certified in palliative care on staff and have completely changed and revamped their advanced care planning program. Ms. Tricarico said that LSH has a palliative care team, who takes referrals from all of the hospitals and that they provide palliative care education to all of their nurses.

NO VOTE/INFORMATION ONLY

FOLLOW-UP ACTION STEP:

- Periodically, update the Council about how the Collaborative Drug Therapy Management (CDTM) regulations are being implemented (Auerbach to Carrow, Pontikas, Saxner, Bonner)

LIST OF DOCUMENTS PRESENTED TO THE PHC FOR THIS MEETING:

- 1a) copy of letters of meeting notice to A&F and Secretary of State
- 1b)Copy of the draft minutes of May 12, 2010
- 2a) Amendments to 105 CMR 480.000, staff memo dated 6/9/10 with appendix A (amendments)
- 2b) Amendments to 105 CMR 590.000, staff memo dated 6/9/10 with appendices A (amendments) & B (public comments)

- 2c) Amendments to 105 CMR 700.000, staff memo dated 6/9/10 with Attachment A (amendments) and B (public testimony) and a copy of companion regulations 247.CMR 16.00 and 243 CMR 2.12
- 3) Amendments to 105 CMR 590.000 (Informational Staff Memorandum to the PHC
- 4) Presentation, copy of Powerpoint slides

The meeting adjourned at 12:00 noon.

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John Auerbach, Chair

LMH