MINUTES OF THE PUBLIC HEALTH COUNCIL

MEETING OF APRIL 14, 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

Docket: Wednesday, April 14, 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 March 10, 2010 **(Approved)**

2. PRESENTATION: No Vote/Information Only

"Health of Massachusetts"

3. REGULATION: No Floor Discussion/Vote

Request for Final Promulgation of Amendments to 105 CMR 120.000: Massachusetts Regulations for the Control of Radiation **(Approved)**

4. PROPOSED REGULATIONS: No Floor Discussion/No Vote/Information Only

a. Informational Briefing on Proposed Amendments to 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII)

b. Informational Briefing on Proposed Amendments to 105 CMR 700.000 ((Implementation of the Controlled Substances Act) concerning proposed changes to the Prescription Monitoring Program

5. PRESENTATION: No Vote/Information Only

"Serious Reportable Events in Massachusetts Acute Care Hospitals, January 1, 2009 – December 31, 2009"

6. PRESENTATION: No Vote/Information Only

"Healthcare Associated Infection (HAI) in Massachusetts Acute Care Hospitals, July 1, 2008 – June 30, 2009"

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 April 14, 2010, 9:05 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, Dr. John Cunningham, Dr. Michèle David, Dr. Muriel R. Gillick, Mr. Paul J. Lanzikos, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Dr. Meredith B. Rosenthal, Mr. Albert Sherman (arrived at 9:35 a.m.), Dr. Michael Wong, Dr. Alan C. Woodward and Dr. Barry S. Zuckerman. Absent Members were Ms. Helen Caulton-Harris and Mr. Denis Leary. 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.

RECORD OF THE PUBLIC HEALTH COUNCIL MEETING OF MARCH 10, 2010:

Dr. Michael Wong moved approval of the minutes of March 10, 2010. After consideration upon motion made and duly seconded, it was voted unanimously to approve the **minutes of the meeting of March 10, 2010** as presented.

ANNOUNCEMENT:

Council Member Dr. Alan Woodward announced that the Massachusetts Medical Society is having the **Sixth Annual Public Health Leadership Forum, Clearing the Air: Energy Practices and Human Health** on Wednesday, April 28, 2010, 8:00 a.m. to 12:30 p.m. to discuss energy use, followed by a discussion with

attendees to identify concerns about energy policy and practices and opportunities for action. He invited the Public Health Council members to attend.

PRESENTATION: "HEALTH OF MASSACHUSETTS", By Kristin Golden, Director, Policy and Planning, Commissioner's Office and Bruce Cohen, PhD, Director of Research and Epidemiology, Bureau of Health Information, Statistics, Research and Evaluation:

Ms. Kristin Golden made introductory remarks, explaining the logistics of the report. She noted that the goal was to produce a statewide health report that highlights DPH work, compiles information in one place, provides baseline data (not intended as a definitive research study), explores the breadth and depth of health topics, includes outside experts' perspectives and topics critical to health such as community assets. She noted the visually attractive layout which was done by a professional designer. The report contains a variety of graphics and the policy perspectives of leading public health experts. The report has 14 chapters which highlights the breadth and depth of data and analyses of DPH programs, covering over 100 subjects such as Air Quality, Alcohol use, Asthma, Bullying, Cancer, Community Assets, Early Intervention, Falls, Mortality, Obesity, Poverty, Second-hand Smoke, Serious Reportable Events, Teen Births, Violence, Water supply and Wellness etc…The report was written by nearly 100 staff of DPH.

Dr. Bruce Cohen addressed some of the key findings of the report. He noted many Massachusetts indicators are better than those of the US and are getting better: breastfeeding, cancer deaths (including breast cancer and prostate cancer), colonoscopy, falls in nursing homes, fire deaths, heart disease deaths, insurance access, life expectancy, mortality lead poisoning, smoking and second hand smoke. Other areas have seen increases or no change: Asthma (adult), autism, Chlamydia, c-sections, diabetes, drug and alcohol use, falls, gestational diabetes, hepatitis, obesity, syphilis and traumatic brain injury. He noted that the report highlights disparities in each chapter by race, ethnicity, gender, age, geography, and socio-economic status.

Dr. Cohen noted some highlights from selected chapters of the report. "…Chapter Two highlights community assets and resources so that we truly understand the context of the interventions that we are trying to do. The model of improving individual well being and the quality of our community life is one that I think Public Health will be grappling with in the 21st century. We include data from a variety of DPH resources and external sources. We include traditional information about resources from the Board of Registration, looking at primary care and physician ratios. We also include information about health structure, community health centers and providers…Most of the data is presented by region with less drill down at sub-regional levels. In addition to the traditional concepts of resources, we are very fortunate to tap into two surveys, a community asset survey and a work place survey, to begin to look at resources that we have in our communities, that help us better understand and plan for addressing public health problems and these data highlight the findings from those two surveys and we also use information from sister agencies. Information on farmer's markets is from the Mass. Department of Agriculture…."

Dr. Cohen said in part, "…I could have chosen any chapter to highlight. The wealth of information here is phenomenal. Where do we go from here? This herculean effort probably will not be repeated on an annual basis, but I think this gives us a good place to start thinking about how we can take off from this report and maybe drill down to topics that emerge from this report, maybe to look at more geographic detail or choose a particular topic. I think it can be used externally, extensively, to help inform researchers and policymakers, and communities about the breadth of our activities, and give folks a place to start to understand the data and research that we do, and hopefully this will stimulate internal communication so we can do more integrative projects across the department…"

Chair Auerbach stated in part, "…I would add that part of the thinking behind designing this type of report is understanding the different ways that people receive information, which the Council has been very clear in terms of pointing out to us that we need to

continually adapt the kinds of reports that we do to reflect the demands of the public for certain kinds of information and so we have increased our use of blogs and Twitter on the internet and our ways of getting information out…It matters how the information is presented. It matters whether it is clear and whether it is attractively available. It matters if it is easy to link to other resources. And what we are hoping is that we are able to reach additional populations who are interested in the subject, that they will be able to use the information for a wide variety of purposes and that would include planning at the agency level, planning at the community level, writing grants, thinking about topics that maybe they haven't thought about before. It serves the purpose of having people in the Department who work on different areas, understanding how their information can all complement each other in ways that may push ahead our understanding of issues that are complicated issues and it really reflects what we have been hearing from the Council, which is that we need to go deeper into the issues that are coming before you as health issues, and not simply observe them, but try to understand why they are happening and what can be done in terms of addressing some of those health issues, by looking at such things as community assets that have to be addressed if we are going to be dealing with the issues rather than thinking simply about the clinical visit that may have highlighted a problem or diagnosed a particular concern…"

Discussion followed by the Council. Please see verbatim transcript for full discussion. Council Member Paul Lanzikos suggested that the report be disseminated to high schools and colleges as an educational model of how to extrapolate data from various sources and communicating it in a meaningful way to their audiences and readers. In addition, he suggested it be disseminated to the business community through the Chambers of Commerce and they could further disseminate the information into the community. This could be done electronically or samples, he said. Council Member Dr. Alan Woodward suggested copies be send to each legislator's office so they can have a data resource that they can access easily in decision-making and also to every community, every town or city relative to their health departments.

Ms. Golden responded that on the DPH website, the report will be available by chapter and so a person can just print the chapter(s) that they want and each chapter will have links to other relevant reports to the subject matter. The Department also has MassCHIP, which is an online data engine that allows people to drill down to very granular levels and certain indicators, to get raw data.

No Vote/Information Only

REGULATION: REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 120.000: MASSACHUSETTS REGULATIONS FOR THE CONTROL OF RADIATION:

Mr. Robert Gallagher, Acting Director, Radiation Control Program, presented the request for approval of final amendments to 105 CMR 120.000 to the Council accompanied by Ms. Suzanne Condon, Director, Bureau of Environmental Health and Attorney James Ballin, Deputy General Counsel, Office of the General Counsel. Mr. Gallagher stated in part, "…These amendments implement many new requirements imposed by the U.S. Nuclear Regulatory Commission…We want to emphasize particular requirements for the packaging and transportation of radioactive materials in addition to changes in the definition of byproduct material and additional revisions to maintain compatibility within NRC requirements. These amendments also adopt new security requirements contained within the Nuclear Security section of the Federal Energy Policy Act of 2005. The proposed amendments address inconsistencies within these regulations. For example, we are going to be requiring extra equipment to be maintained in the same fashion as mammography equipment. The proposed amendments add training and experience requirements imposed by the NRC for medical use of radioactive materials. They also adopt requirements imposed by the NRC regarding the packaging and transportation of radioactive material for compatibility with international transportation requirements."

He continued, "After the public hearing, some additional revisions to the proposed regulations were made in response to the public comments. As I mentioned, the public hearing was held on February

12, 2010. The comment period ran through February 19, 2010, but we did collect and accept late comments. In all, we received seven sets of written comments during and shortly after the comment period. At the public hearing, four members of the public attended with two providing oral testimony…Two parties made comments suggesting we replace the term 'qualified expert' with the term 'qualified Medical Physicist' in a number of sections of the regulations. This recommendation was not made as this would not be compatible with the regulations of the NRC. Two parties made comments that we replace section (E) of 105 CMR 120.435 in its entirety with section (A) of 105 CMR 120.594 (A) to clarify event reporting criteria and to promote consistency with section 500 Use of Radionuclides in the Healing Arts. These comments have been accepted and section (E) of 105 CMR 120.435 has been amended. Two parties made comments concerning the new requirement to adjust decommissioning funding plans at intervals not to exceed three years. Some licensees will not have the budget authority to immediately implement the new schedule and that they be allowed a further two years to realign their financial controls to accommodate the new cycle. This change was not accepted due to compatibility requirements with NRC regulations. And one party suggested that we reconsider the ten milligram per year annual dose limit. This will be considered for future regulatory revisions."

Mr. Gallagher concluded, "In summary, the Department respectfully requests final adoption of 105 CMR 120.000 as amended. If approved, the Department will file 105 CMR 120.000 as amended with the Secretary of the Commonwealth for publication on April 30, 2010 in the Massachusetts Register."

After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Final Promulgation of Amendments to 105 CMR 120.000: Massachusetts Regulations for the Control of Radiation.** A copy is attached and made a part of this record as **Exhibit No. 14, 946.**

PROPOSED REGULATIONS: NO VOTE INFORMATION ONLY

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 1O5 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 Mr. Steven Hughes, Director, Community Sanitation Program and Attorney James Ballin, Deputy General Counsel, Office of the General Counsel presented the informational briefing on proposed amendments to 105 CMR 480.000. She noted in part, "…In July of 2006, the Massachusetts Legislature passed the Pharmacy Needle Access Law. It was very important to this Department in terms of trying to reduce disease transmission, largely in relation to substance abuse, HIV AIDS population and others, and the mandate that we received was for the Department of Environmental Protection to work in partnership with us and in conjunction with other relevant state and local agencies 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. Ms. Condon noted that the chronic disease group generated two million used needles per week in the home."

Staff's memorandum to the Council dated, April 14, 2010 informed the Council, "During the last two years, the Department has made significant progress in expanding access to sharps collection sites throughout the state. In the spring of 2008, 23 sharps collection kiosks were distributed to municipalities and an additional 15 kiosks were awarded to other cities and towns in 2009. Sharps collection sites are available in 104 Massachusetts communities and 34 sites are operated in conjunction with community health centers. The Department also participated in a national dialogue with key stakeholders that were facilitated by the Product Stewardship Institute. Participants included sharps manufacturers, pharmaceutical and retail pharmacy representatives, waste management companies, advocacy and community service groups, representatives from a sharps collection program in Rhode Island, and legislative officials. Despite progress made at three national

meetings, no voluntary agreement among stakeholders was reached for a state wide sharps collection program."

Staff's memorandum noted further, "The MDPH Community Sanitation Program is proposing only one change to the Minimum Requirements for the Management of Medical or Biological Waste (105 CMR 480.000). The proposed amendment would change the date in the current regulations when a ban on disposal of sharps in household waste was scheduled to take effect from July 1, 2010 to July 1, 2012. The reason for changing the effective date of the sharps disposal ban is that statewide access to sharps collection centers is still in the implementation stages and convenient and affordable disposal options are not yet available in all communities… 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. The Department intends to hold a public hearing on this proposed amendment in May and return to the Council to request final approval of the proposed amendment at the Council's June 9th meeting."

Discussion followed by the Council. Dr. Alan Woodward suggested three things (1) suggested implementation in areas of the state where drop off Kiosks are available within two to five miles, (2) suggested that since many of the Kiosks have needle removers have people dispose of the needle only not the large syringe to save space and further a person can mail in a lot more needles in a package without the syringes attached, and (3) instead of going a time consuming Legislative route use a regulatory process instead to get this process done.

Staff responded to these suggestions. Ms Condon said she would talk to the Department's Occupational Health Surveillance Program because they monitor needle stick injuries to discuss removing the needles from the syringe suggestion and Ms. Condon stated further that staff plans on trying the regulatory route first and plans on making suggestions to the Commissioner about it. However, she said

legislators who attended these stakeholder meetings on this issue were very willing to move forward and file legislation if needed.

Mr. Paul Lanzikos asked about experiences in other states and internationally on this issue. Ms. Condon replied that only California has done a lot of work on this issue but has been criticized for moving forward with a ban without a plan in place. Ms. Condon said, "We are trying to get the plan in place before the actual ban takes effect because there are a lot of states right now wrestling with the same EPA directive that we are and there hasn't been one single place that has come-up any great model except for the state of Rhode Island, which has been working with a Waste Management Company and seems to have found a way to solve this by working with the pharmacies and some others…" Dr. Michael Wong stated, "Western Europe has been a big leader in community sharps disposal programs for more then ten years, some are actually funded by the countries themselves through legislative and then regulatory means and these are expensive programs. Anyone can find these disposal units anywhere in a public area and they are very secure…"

Ms. Condon noted, "We have a couple of pharmacies that have housed Kiosk placement, paid for by the generator of the needles. They put their sticker on it and advertise their brand of lancets and in exchange they either pay for the Kiosk or pay for the disposal."

Chair Auerbach noted for the record that the Department has moved forward on this, having 100 communities with disposal facilities now compared to a few years ago when there was zero in place. He said further, "We have gotten to a place where we are able to have a serious discussion about how to do this in a practical way that will work for the people of the Commonwealth."

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 700.000 (IMPLEMENTATION OF THE CONTROLLED SUBSTANCES ACT) CONCERNING PROPOSED CHANGES TO THE PRESCRIPTION MONITORING PROGRAM:

State Representative Peter J. Koutoujian addressed the Council in support of the Proposed Changes to the Prescription Monitoring Program. He said in part, "…In 2005, 22% of our state budget was spent on substance abuse and addiction related services. That is a significant amount of money for treatment and probably not enough on prevention and many people are readmitted many times…Our current approach to substance abuse is flawed and obviously it is not working….Between 2002 and 2007, over three thousand people died in Massachusetts due to opiate related overdoses and over one hundred thousand missions to DPH funded abuse programs in 2007 and those numbers don't seem to be diminishing….When we are investing this level of our limited resources in fighting prescription drug abuse, we must make an investment in preventing it from occurring. I commend DPH for the proposed regulations to enhance the current Massachusetts Prescription Monitoring Program. I am not alone in acknowledging it has been a long and arduous journey to get to this point, but it is reassuring and I am very pleased to see the progress that we have made recently, particularly under this leadership, and your leadership, and even more reassuring to see the changes right here in the pipeline, poised to go. It is because of the cooperation and openness of Commissioner Auerbach, Secretary Bigby, and the Governor, that we have been able to move forward on these much needed enhancements….The transition to an on-line system will help us transition forward to more real time information, which I think is the ultimate goal in order to prevent prescription drug abuse as it is happening in real time. Proactive reporting system, DPH analyzing and sending reports to prescribers and pharmacies on their patients who may be drug seeking, I think is a great way to address this issue, as well. Increased reporting frequency for timely access to information, both proactive reporting and increasing reporting frequency will move us closer and closer to a real time system, which needs to be our ultimate goal."

He continued, "…I think the expansion of the schedules monitored is an incredible advancement on this, creating medication histories on schedules two through five….For example, over prescription of anti-psychotic drugs in nursing homes is a very significant issue that we should be watching. It is a large issue and could potentially be

avoided by expansion of the schedules of drugs monitored, resulting in an improvement of health care quality as well. Other drugs that would be captured would be the anti-psychotics, vicodins, OxyContin, Ketamine, valium, anabolic steroids, benzodiazepines, and codeine cough syrups. These are things that should be captured by your Department. I think the interstate operability so out of state providers can have access to this information if needed to prevent patients from crossing state borders to doctor shop [is needed]."

In closing Representative Koutoujian said in part, "I thank the Department and the Council for all of your hard work that you have done and will be doing to put this together, and I look forward to working with the Department of Public Health and the Council in order to push our Prescription Monitoring Program forward so that we can better prevent prescription drug abuse in the Commonwealth."

Chair Auerbach responded, "Thank you Mr. Chairman. We appreciate that you have been very concerned about this issue and your working with us to think about this issue and working with us to think about the ways that we can move ahead on this issue and address some of the problems that you have identified and your impact I think is reflective in the actual regulation that we will be considering today because we have heard very clearly from you, this was a time to act. We needed to address some of the problems that have existed and we are confident that this regulation will be part of addressing the various concerns that you and other legislators embrace."

Representative Koutoujian added in part, "…This will literally save lives, and it will save us a lot of money, and it will prevent a lot of problems for physicians and pharmacists and so many others, and this devastating problem, we can start to maybe get our arms around it and address it in a more comprehensive way."

Dr. Alice Bonner, Director, Bureau of Health Care Safety and Quality, presented the proposed changes to the Prescription Monitoring Program to the Council. Dr. Bonner noted that the CDC has asked states to meet the following goals: decrease unintentional drug poisoning, morbidity, mortality, and costs and there are two ways

that state should do this (1) by having health care providers request a report from the state PMP on the prescribing of opioids to the patient by other providers (a Solicited Report) and (2) the State should actually send reports to providers on patients treated with opioids by two or more providers if there are signs of inappropriate use (an Unsolicited Report). Ms. Bonner noted that only about 50% of states provide unsolicited reports to providers like Massachusetts.

Dr. Bonner noted some statistics, "Two people die everyday in Massachusetts from addiction-related disorders. In 2007, 638 deaths occurred and the numbers are increasing. For every opioid-related overdose in 2007, there were 47 non-fatal incidents also related to opioids in Massachusetts hospitals. Of all of the individuals prescribed a Schedule II controlled substance, about 2900 or .5% fall into this category of potentially going from provider to provider and pharmacy to pharmacy which represents 45,000 prescriptions in that period of time (3% of the prescriptions). In a ten year period, there has been a 43% increase in doctor shoppers, significant numbers."

Dr. Bonner noted further, "…The goals for our planned enhancement are to leverage the technology that we have to increase and improve use of PMP reports for patient health and safety. We know that if we provide tools that are easy to use, that providers will access them, like an on-line system. It is a big difference, versus not having that type of system. Having availability to data at the point of care allows much more of a focus on prevention…Our second goal is to provide more complete data in support of clinical decision-making for improved medication management at the point of care and thirdly, to provide more complete information for epidemiological analysis of both medical and non-medical use of controlled substances, and that allows us to do both in-state regional trending and also interstate and to reduce morbidity and mortality from misuse and abuse of controlled substances."

Dr. Bonner explained the proposed changes to the PMP regulations: expand collection of Schedules from just Schedule II to Schedules II through Schedule V; Require a customer ID for all schedules II-V; pharmacy reporting frequency be increased from monthly to weekly reporting; Require reporting by out-of state mail order pharmacies;

provide reports to providers on prescription histories of their patients; and allow by codifying Interstate data sharing; and focus Medical Review Group (MRG) expertise on unsolicited reports.

Dr. Bonner explained these proposed changes in greater detail during her presentation; please see the verbatim transcript for the complete discussion and/or staff's memorandum to the Council dated April 14, 2010 to the Public Health Council. Regarding the on-line system, Dr. Bonner noted that the on-line system will be available to providers in two ways (1) a web portal and (2) through the electronic health record and further to protect privacy interests of patients, these records will only be available to providers for their specific patients and to law enforcement when there is an open investigation. Law enforcement will not have direct access but will have to request the information from the PMP staff; providers will have direct access only for their patients. There are penalties for misuse of the PMP data (i.e., revoking of licenses and registrations). There will be ongoing auditing and monitoring of the system.

Dr. Bonner noted that the public hearing on these proposed changes is scheduled for May 25th at DPH central office, 1:30 in the Public Health Council Room, 2nd floor, 250 Washington Street, Boston, MA. Staff wants to get the word out on the PMP on-line system to encourage use. Staff plans to have a program for third party payers on June 3, 2010 and for providers on June 12, 2010 with more training to follow.

Discussion followed by the Council. Dr. Alan Woodward suggested that the online electronic health record use biometrics instead of a name and password to enter the system and that the system should have a warning system that comes up instead of a list of patient data. Maybe use a color code in red, green, or yellow to warn the provider quickly to be careful. Dr. Bonner responded that these suggestions will be looked at; and said further that pilots of the program will take place in four or five hospital systems.

Discussion continued around the PMP information providing the primary care provider with the opportunity to discuss the situation with the patient in the context of their health and maybe link them to

care. Mr. José Rafael Rivera said he thought this would save a lot of lives and further said the communities need to be involved to change the norm that this is the way to go. Dr. Bonner responded that the Department has been talking to community groups and advocacy groups on this and agreed that on the community level is where these groups can address the broader issues of drug abuse. She said "We want to have names and addresses for all of the community advocate groups that we can loop into this and that perhaps community health centers can play a big role."

Chair Auerbach added, "…In terms of thinking about this issue, The Bureau of Substance Abuse Services here at DPH is the lead bureau on this with Michael Botticelli as the Director…Mr. Rivera I think you are pointing out that we can't simply have a regulation on this and that there needs to be this overall approach to prevention as the first step, to linking people to treatment as the second step and then where that isn't done, then we need other tools, as well. The Department has funded a number of grassroots coalitions around the state to work on this issue and we are committed to that spirit of this issue, that this isn't a criminal justice issue but fundamentally a health issue, where prevention is our best approach." Chair Auerbach stated that Mr. Botticelli will be invited to attend the PHC meeting when these regulations come back for a vote to provide that larger context to the issue.

Discussion continued and Dr. Michael Wong noted that substance abuse issues cannot be talked about in a silo but must be integrated with the mental health issues that go along with substance abuse. It needs to be an integrated process. Chair Auerbach noted that Commissioner Leadholm and the Department of Mental Health will be included in discussions about this during the public comment period to see if there are any additional comments or tweaking of the regulation that we have that input. Mr. Lanzikos asked about funding of the program. Dr. Bonner noted that funding comes from a variety of sources such retained revenue accounts and grants. Dr. Muriel Gillick, a palliative care physician, stated in part, "…I think we need to be very cautious in routinely labeling individuals who get opioid prescriptions from more than one provider as drug seeking. We, not infrequently, see patients with advanced cancer, who have severe

pain that is being managed largely by their oncologist, but also by their primary physician. Those individuals may be hospitalized because of a pain medicine and then , when all that doesn't work, they see me in Palliative Care consultation, it is possible that their medicines will be changed again. We need to make sure that we are paying adequate attention to perhaps the other side of the issue." Dr. Gillick further asked, "…What is the evidence that diversion is causally related to the increase in opioid-related mortality that has been seen in the state"? Dr. Bonner replied that there is little evidence and that is the reason they are interested in obtaining better outcomes data and want to continue to fund research on the matter. Chair Auerbach responded in part, "We need to make sure there are safeguards in there so that patients who genuinely need pain medication do not have barriers to access and we think we can design this so that will not happen."

NO VOTE/INFORMATION ONLY

PRESENTATIONS:

"SERIOUS REPORTABLE EVENTS IN MASSACHUSETTS ACUTE CARE HOSPITALS, JANUARY 1, 2009-DECEMBER 31, 2009:

"HEALTHCARE ASSOCIATED INFECTION (HAI) IN MASSACHUSETTS ACUTE CARE HOSPITALS, JULY 1, 2008 – JUNE 30, 2009:

Ms. Elizabeth Daake, Director of Policy Development and Planning presented the reports on SREs and HAIs, accompanied by Attorney Lisa Snellings, Deputy General Counsel, Office of the General Counsel at DPH. Ms. Daake said in part, "…Chapter 305 requires the Department to collect hospital-specific data on adverse medical events and medical errors. This is our second annual report on SREs, and the big change we had in the last year was in June of 2009, regulations were implemented to prohibit health care facilities from charging for services provided as the result of an SRE. As a result, our reporting process changed. Some excerpts from her presentation follow. Please see verbatim transcript for full discussion.

“The report focuses on acute care hospitals. Over ¾ of the SREs, 383 events took place in these hospitals….Non-acute hospitals in Massachusetts reported an additional 127 SREs, over 60% of which were falls…”

“The purpose of this reporting is not intended to punish hospitals, or to regulate these events. It is to help us understand how these events happen, to share best practices, and how they can be prevented in the future. So accordingly, hospitals have been allowed to respond to the SREs they have experienced in order to learn from one another’s experiences and that will be shared in an attachment that will be going up on the web site today and also this year, we interviewed some hospitals who wanted to share their success stories with us and incorporated them within the report.”

“[The report] has 28 discreet events grouped into six categories…Of the 383 SREs in Massachusetts acute care hospitals, 54% of these were environmental events, largely falls, which is similar to last year’s report.”

“We wanted to stress that it is misleading to draw conclusions about the overall quality of a hospital just based on the number of SREs. There can be a higher number of SREs because a hospital has a particularly strong reporting culture. It doesn’t necessarily mean that there is a quality concern there, and NQF itself actually acknowledges that not all SREs are preventable….Hospitals with more patients may have a larger raw number but it doesn’t mean that their rate of SREs is any greater than anyone else’s and we caution against using this data to compare one hospital to another. Its purpose is to look for earmarks for improvement and to share best practices and help us to identify trends over time…”

“Most hospitals reported between one and six SREs for the 2009 Calendar year. The mean was 5.0 versus 4.3 in 2008. We had an overall increase so that is not surprising. Only ten hospitals reported greater than or equal to ten SREs this year.”

“This report and its attachments will be published today on the web site. The attachment showing the hospital comments will be updated if we get additional comments as time goes on and also included in

the report are several success stories that hospitals shared with us, in terms of identifying and addressing SREs. At the national level right now, there is a lot of work going on and the NQF is reviewing the list of SREs and anticipates releasing a new list in early 2011", noted Ms. Daake in closing on the SRE report.

A brief discussion followed by the Council. Dr. Alan Woodward noted in part, "Have you done an SRE rate by event and then see if there are outliers. How do we do a loop closure on this data? If we started with the very precise definitions that are, deaths, falls with serious disability, that are pretty reliably going to be reported, that would be a useful way to see if there are outliers, whereas your overall compilation may show every one from zero to three, maybe you are going to find that someone is in one category as a 5 and everyone else is a .5. I don't know. I am just trying to figure out, how do we get something constructive out of this, that we can feed back and really have information that suggests to hospitals, you are an outlier or you are not an outlier in the same area. Where do you want to focus your efforts to improve?" Chair Auerbach stated, "…If other states are using the same definition as we are we could look at falls or wrong site surgery relative to other states."

Discussion continued around the no billing allowed for SREs data collected. Ms. Daake noted that the Department collects data on whether or not the hospital is charging for the SRE, not the amount saved. Chair Auerbach said, "We may want to think about how we could project the amount of funds that are saved – is there this financial incentive that gets created in order to avoid this? We will work on that."

Ms. Lucilia Prates Ramos asked if zero SREs are reported by a hospital does that mean they didn't report or that they had no falls? Ms. Daake said, yes, it could mean they had no serious disability or death as a result of falls because some hospitals are in absolute compliance.

Discussion continued around the no billing of SREs data, Dr. John Cunningham suggested, maybe "collecting the aggregated cost in a year of uncompensated care". Dr. Meredith Rosenthal, noted that

"Counting monies not spent will be challenging" and offered to work on the issue with staff. Dr. Michael Wong noted, "I think the way this works is there is a charge and reclaim goes back to the payer of record rather than refraining from charging completely." Ms. Daake added, "What does it mean to not be paid for the consequences of these events? If a patient is upgraded to the ICU, what is the incremental cost? It is very difficult, in a hospital accounting context, as you all know, to separate those incremental costs." Mr. Lanzikos suggested that the Hospital Patient Family Councils receive the SRE reports and Chair Auerbach concurred. Ms. Lucilia Prates Ramos said to make sure the information is consumer friendly and understandable to the public.

HAIs Report

Ms. Daake began, "HAIs are infections that patients acquire during the course of receiving medical treatment for other conditions within a health care setting…As mandated by Chapter 58 of the Acts of 2006, the Hospital Licensure Regulations were amended to require acute care hospitals to report specific data beginning July of 2008. We released a preliminary report in April of 2009. This report we are now releasing covers the period of July 1, 2008 to June 30, 2009. As it is the first full year of collection reporting, readers should use caution in drawing specific conclusions…This data serves as a baseline and as an opportunity for learning. The data is reported by the hospitals to the National Health Care Safety Network and HSN, which is a CDC monitoring system that uses consistent national measures. Quality assurance reports are then created by MDPH epidemiologists and hospitals may make corrections. In the next phase there will be additional data validation process involving chart review and additional work with hospitals for detecting HAIs."

Ms. Daake noted further," Influenza vaccination data was collected for the most recent flu season and we anticipate an analysis of this data by the fall and she noted further that MRSA point prevalence studies were conducted twice, once in September of 2008 and once in September 2009 requiring all acute care hospitals to collect MRSA (Methicillin-resistant Staphylococcus aureus) nasal cultures and anticipate reporting on this in the Fall of 2010."

Dr. Alfred DeMaria, State Epidemiologist, Medical Director, Bureau of Infectious Disease, "…I am going to show you the result for this first year of data, and it involves what we refer to as CLABSI, Central Line Associated Bloodstream Infection and Surgical Site Infection with four procedures, two of which I will be presenting by hospital rates and two by aggregate rates, and we are presenting SIR, Standard Infection Ratios. This is becoming the national standard. Basically, it is the number of infections over the number expected from the national rate, and the number of procedures done in a particular facility. It is just a way of standardizing the results, something we do very frequently for vital statistics and so forth. Seventy-three hospitals reported. They are stratified by teaching, non-teaching and major teaching, and we have a large number of community hospitals in the data set. This is a variable group of hospitals. The definition of line-related bacteremia is very strictly defined. We are using the HSN definitions, which have evolved over 40 years. It is very complicated…And they are stratified by criteria one, two, and three, depending on the type of organism and the clinical condition of the patient. We are looking at Intensive Care Units, which differed in type, size, acuity of patient, and patient mix. There were 257 central line associated bloodstream infections during the one year reporting period, and this applies to lines put in, in the ICU and followed in the ICU. The line utilization data is very important and the ICU type is very important. You will see that in the full report. We are giving you today the statistical outliers compared to the national rate and a lot of our hospitals are in the average range but we want to do better than the average, the line data is lower statistically, 95% below which is good…"

Dr. DeMaria spoke about further measures reported to MDPH through the NHSN database, in addition to the CLABSI in intensive care units noted above they collected data on Surgical Site Infections (SSI) related to Hip arthroplasties, Knee arthroplasties, Coronary artery bypass graft (CABG) procedures, and Hysterectomies (vaginal and abdominal). He noted, "The CABG and hysterectomy SSIs are reported in aggregate in this report, but will be hospital-specific in future years. He noted further that Surgical Site Infections (SSI) are infections that are directly related to an operative procedure. SSIs

develop within 30 days after an operation or within one year if an implant was placed and the infection appears to be related to the surgery. Deep incisional and organ/space SSIs result in the greatest personal cost for patients and families. These are the SSIs that hospitals are currently required to report to MDPH. More than half of SSIs are not identified until after the patient leaves the hospital. The CABG, Knee arthroplasty, and hip arthroplasty data represent 7 months of surgical procedures. In these cases, there has been a full year of follow-up for SSI with implant. Once the full year has passed for all of these procedures (end of June 2010), the data will be analyzed and posted. During CABG surgery, a healthy vein or artery usually taken from the patient's own blood vessels in the leg, arm or chest is connected or grafted to a blocked coronary artery. The wires used to close the incision stay in he patient's body permanently and for the purpose of NHSN are considered an implant. Procedures with implants are monitored for infection for one year. CABG surgery is specialized and only 14 Massachusetts hospitals currently perform these procedures. Massachusetts hospitals' infection rates for CBGB patients with 2-3 risk factors are lower than the national rates (the difference is statistically significant)."

Dr. DeMaria continued, "…Both vaginal hysterectomy and abdominal hysterectomy are reported. Infections related to hysterectomy can be detected for up to 30 days. There are 66 HAIs related to both types of hysterectomy surgery reported in this period. Massachusetts hospital deep tissue organ space SSI rates for abdominal hysterectomy were statistically lower than the national rate; rates for vaginal hysterectomy procedures were not significantly different. Hip arthroplasty is surgery to the hip joint where the diseased or damaged hip joint is removed and replaced with an artificial implant called prosthesis. Knee arthroplasty is a surgical procedure where the diseased or damaged part of the knee is removed and replaced with prosthesis. There are 78 HAIs related to hip and knee arthroplasty reported during their reporting period (July 2008 through January 2009). Massachusetts hospital deep infection SSI rates for patients with 0 or 1 risk factors are statistically below the rates that would be expected for both hip and knee arthroplasty, based on national rates for these procedures. Only New England Baptist had

hip arthroplasty SSI infection rates that were statistically different from the national data, statistically lower. New England Baptist Hospital's rate was significantly different from the expected, statistically lower and Saint Vincent Hospital's rate was significantly different from the expected, statistically higher. Other hospitals had similar or higher SIRs but didn't have enough procedures to put them outside the range, and we have contacted them and they have recognized their problem and have not reported any new infections since July of last year."

Ms. Eileen McHale, Coordinator, Health Care Associated Infection Planning, Bureau of Health Care Safety and Quality presented Race/Ethnicity Data to the Council. She stated in part, "…Reporting race and ethnicity data is certainly a priority for the Massachusetts Department of Public Health, and understanding what it means is really important to us. The current method of reporting for our acute care hospitals is for the National Health Care Safety Network and they have limited ability to do this because it is not a requirement for participation. Nevertheless, January 1, 2009, we required acute care hospitals to begin reporting this information using the customized NHSN fields. This required each hospital to go into the system and set-up fields to enter all the specified data defined by the Division of Health Care Finance and Policy. Training was provided for hospitals prior to the implementation on this. Our initial focus on this has been on ensuring the quality of the HAI measures at the facility level, but one of our next steps is going to be to move forward to evaluate and to set-up a formal process to really go back and look at the race/ethnicity data, be sure that all the fields have been set-up appropriately by hospitals."

Ms. McHale further noted that a data cleaning process was developed by MDPH epidemiologists, since the HAI data is self-reported data, they look at the data and highlight items that may need a second look from the hospital and the hospitals themselves are able to review and edit their own data. She spoke about the two Infection Control nurses hired by the department and their role: They served as a consultative resource to hospitals on the implementation of HAI reporting and developed a protocol to monitor best practices with hospitals and they visited each acute are hospital and provided

technical assistance on the new reporting requirements and helped the hospitals identify areas for improvement. They developed protocols for inspection of the hospitals. They will conduct infection prevention focus surveys and this has been incorporated as part of the regulatory process. Ms. McHale spoke about receiving federal grant money to enhance statewide coordination of HAI activities and improve the quality of the data that is be being reported to the NHSN. The third part of the grant funding is for states to move forward and develop and implement collaborative learning to validate the data."

Ms. McHale noted that they submitted a five-year action plan on how they propose to address HAI over the next few years and noted their next steps: Pilot their data validation protocol in development with JSI; Enhance their collaborative learning and partnering with the Coalition for the Prevention of Medical Errors to do this; Facilitate reporting from other health facilities: In June 2010, free-standing ambulatory surgical centers will be required to begin reporting surgical site infection information to the NHSN on surgical site infections from hernia repairs; Talking to free-standing dialysis centers about reporting and the potential for a pilot with dialysis centers; and Speaking with extended care facilities (long term care and rehab facilities); Think of better ways to target this information to consumers; and Lastly, work on defining best practices for training and certification of professionals in health care associated infection prevention.

Chair Auerbach said in conclusion, "…We look forward to learning more from this experience in understanding how we can have the largest impact. It really sounds like the work you have done is on the cutting edge of understanding how to reduce hospital infections and then measuring our progress."

NO VOTE/INFORMATION ONLY

FOLLOW-UP/ACTION STEPS:

- Invite Michael Botticelli, Director, Bureau of Substance Abuse Services to the meeting when the PMP returns for a final vote for

context on SAS services. (Auerbach)

- Consult with Commissioner Leadholm, DMH for any comments on the proposed PMP regulations (Auerbach)

- Online health record system for PMP use biometrics instead of a name and password to enter the system and consider a color coded warning system pop-up (Woodward, Bonner)

- Consider having public just drop-off at Kiosks only the needle and not include the syringes and the same for mail returns. (Woodward, Condon)

- Think about how to project the amount of funds saved by not allowing payment for SREs (Auerbach, Rosenthal, Daake)

- Send aggregated SRE reports in a consumer friendly format to hospital Patient Family Councils (Lanzikos, Auerbach, Prates Ramos, Daake)

The meeting adjourned at 12:10 p.m.

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John Auerbach, Chair

LMH