

## **PUBLIC HEALTH COUNCIL**

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, November 12, 2008, 9:00 a.m., at the Department of Public Health, 250 Washington St., Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Ms. Caulton-Harris (arrived at 9:50 a.m.), Mr. Harold Cox, Dr. Muriel Gillick, Dr. Michèle David (arrived at 9:50 a.m.), Mr. Paul J. Lanzikos, Mr. Denis Leary, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Dr. Alan C. Woodward and Mr. Albert Sherman. Dr. John Cunningham, Dr. Meredith Rosenthal, Dr. Michael Wong, and Dr. Barry S. Zuckerman were absent. Also in attendance was Attorney Donna Levin, DPH General Counsel.

Chair Auerbach announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance.

### **RECORDS OF THE PUBLIC HEALTH COUNCIL MEETING OF SEPTEMBER 24, 2008:**

A record of the Public Health Council Meeting of September 24, 2008 was presented to the Public Health Council for approval. Mr. Albert Sherman, Council Member, moved approval. After consideration, upon motion made and duly seconded, it was voted unanimously (Dr. Michele David not present to vote) to approve the **September 24, 2008 record** as presented. The record was distributed to the members prior to the meeting for review.

### **FINAL REGULATION:**

### **REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 270.000: REGULATIONS GOVERNING THE TESTING OF NEWBORNS FOR TREATABLE DISEASE:**

Dr. Laurel Smith, Medical Director, Department of Public Health presented the regulations to the Council for final approval.

Staff's memorandum to the Council, dated November 12, 2008, noted in part, "...The amendments will update the requirements for mandatory and optional screening provided by the Department's newborn screening program..." In 2005, the Federal Health and Human Services Secretary's Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children recommended implementation of a national uniform newborn screening panel

with the expansion of newborn screening to 29 conditions. This recommendation was endorsed by the Academy of Pediatrics and the March of Dimes as well as the American College of Medical Genetics. Massachusetts has been testing for all of these conditions since 1999 through the pilot studies but does not mandate screening for all of them. It should be noted that some of the 29 conditions are not specifically mentioned in the current Massachusetts regulations, but testing information on them is generated as by-products of testing for the disorders included in the pilot studies."

"The Newborn Screening Advisory Committee met several times over the past year to consider and develop recommendations to the Department concerning:

1. Whether screening for certain additional disorders should be mandated based on additional information available since 1998, including those disorders which are the subject of the pilot studies listed in the 1998 regulations; and
2. Whether there are any conditions, either currently offered through the pilot study or not currently screened for, that should be offered through the pilot study.

The Newborn Screening Committee recommended several changes in the mandated and pilot study disorders. These changes were based on the sound criteria developed in 1998 by the advisory committee, and after public hearings and were subsequently adopted by the Public Health Council and became effective in February of 1999. The Guiding Principles for Determining Disorders for Which Screening Is Mandated:

- There must be consumer involvement in determining what gets screened.
- There must be a public health purpose for the screen.
- There must be public acceptance of the purpose of the screen.
- There must be an accurate screening test.
- The disorder must be treatable.
- Early treatment must be beneficial.
- There must be a significant, life-challenging risk of morbidity if the disorder is untreated in newborns.
- The screen must be reasonably priced.
- The prevalence of the disorder must be significant.
- There must be resources for and access to treatment and counseling.
- Positive health benefits must outweigh the risks and burdens of screening and the treatment on newborns and relatives.

- There must be a mechanism for regular review of the scientific and medical rationale for the screen.”

Staff’s memorandum said further, “For pilot study disorders, the Newborn Advisory Committee found that the screen should be offered on a voluntary basis since not enough was known about the natural history of the disease or the existence or efficacy of treatment to mandate that parents have their newborns screened for the diseases, but that the study could provide enough information to know whether the disorder should be screened for in the future on a mandated basis.”

Summary of Proposed Amendments:

[Reviewed by the Public Health Council in August, prior to release for public hearings]

1. Section 270.006 (A): Lists the disorders proposed for mandated screening. All of the new proposed disorders for mandated screening have been offered under the pilot studies since 1998.
2. Section 270.006 (B): List the disorders for which optional pilot studies will be conducted. These include 5 disorders currently offered in pilot study for which not enough information is known to determine whether they should be mandated, and a disorder new to the list – severe combined immune deficiency.
3. Section 270.006 (C): Lists those disorders that are not tested for directly, but that may be identified during the screening process. These “by-product conditions” do not currently meet the criteria for mandated screening, but if found, will be reported to the attending physician and infants would be followed (like the practice for pilot disorders).
4. Section 270.006: The changes in mandated and pilot disorders are effective February 1, 2009 in order to allow sufficient time for the NENSP to prepare for the change in screening.
5. Sections throughout the regulations: The program’s name is changed from Newborn Screening Program to Newborn Blood Screening Program, and the testing is referred to as blood screening to distinguish it from newborn hearing screening.
6. Section 270.004: Includes new definitions for Mandated screening, Newborn Blood Screening Program and Pilot Study; and revised definitions for Attending physician, Screening and Specimen.

7. Section 270.006(B) (3): Language is deleted that referred to the approval of a research protocol because it was approved and implemented in 1999 and continues today.
8. Section 270.007 (A): Clarification of instruction on time to take specimen.
9. Section 270.008: Clarification that for out-of-hospital births, parents receive the bill for the testing.
10. Section 270.010: New section on follow-up of newborn blood screening to require attending physicians to provide information on diagnosis and long-term outcomes for purposes of quality assurance, ongoing evaluation of the effectiveness of the program and the determination of those disorders that should be screened for.
11. Section 270.011 – New section on confidentiality that states the current policy of the program to maintain confidentiality of testing results.

Staff noted that two public hearings had been held in Boston and Worcester on October 3<sup>rd</sup> and 7<sup>th</sup>. No one presented oral testimony or provided written comments. Minor additional suggestions were made by the New England Newborn Screening Program (NENSP) and the Newborn Screening Advisory Committee at its meeting of September 15, 2008. NENSP operates the Massachusetts Newborn Screening Program for the Department via an Interagency Service Agreement with the University of Massachusetts Medical School (UMMS). These additional revisions follow:

1. 270.006 (C) (2) (w) and (3) (c): Lists of by-product disorders were revised to include carrier status for those by-product disorders that may be detected through the mandated or pilot screens.
2. 270.007 (A): Language was changed to include the treating health care practitioner and to indicate that the attending physician or treating health care practitioner orders the collection of the specimen, but does not actually collect the specimen.

There was a brief discussion and then Dr. Muriel Gillick moved for approval of the amendments. After consideration, upon motion made and duly seconded, it was voted unanimously [Mr. Albert Sherman abstained; Dr. Michele David not present to vote] to approve the **Final Promulgation of Amendments to 105 CMR 270.000: Regulations Governing the Testing of Newborns for Treatable Disease**. A copy of the amended regulations is attached and made a part of this record as **Exhibit No. 14, 915**.

**EMERGENCY REGULATION: REQUEST TO PROMULGATE EMERGENCY AMENDMENTS TO 105 CMR 100.000: DETERMINATION OF NEED REGULATIONS:**

Ms. Joan Gorga, Director, Determination of Need Program, presented the Emergency Regulations to the Council for approval. Ms. Gorga said in part, "...We are here today to request the Public Health Council's approval of staff's recommendation for emergency amendments to 105 CMR 100.000, Determination of Need. The proposed amendments implement certain provisions of chapter 305 of the Acts of 2008 "An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care), which was signed into law by Governor Patrick on August 10, 2008... Additionally, the proposed amendments enable the Determination of Need Program Director to direct that filings required by the regulation be submitted in electronic format and for technical corrections...." Ms. Gorga explained the proposed changes to the Council.

Proposed Revisions (excerpted from staff's memorandum to the Council, dated November 12, 2008):

"Chapter 305 amends M.G.L.c.111 by extending Determination of Need (DoN) jurisdiction to two previously-exempt types of health care projects: outpatient projects with a capital expenditure in excess of \$25 million, and physician-owned ambulatory surgical centers that are Medicare-certified..."

"Any Ambulatory Surgery Center (ASCs) that seeks Medicare certification, including those that are wholly physician-owned, must now obtain a license from the Department and, prior to applying for such license, receive approval for a DoN..."

"Chapter 305 contains grandfathering provisions in regard to these two changes. For outpatient projects in excess of \$25 million, the statute provides that any project that seeks approval of final architectural plans by February 10, 2009, is exempt from DoN Review. For ASCs, the law provides that any ASC that was in operation or under construction as of August 10, 2008, is exempt from DoN Review."

Staff noted further that Chapter 305 requires further Department action in regard to the additional regulation of ASCs. The licensure requirements for those physician-owned ASCs that are currently in operation will be presented to the Council at a future date in the form of amendments to 105 CMR 140.000,

Licensure of Clinics. In addition, the Department is in the process of updating its DoN guidelines for review of ASCs. As is its practice with respect to DoN Guidelines, when the guidelines have been revised, staff will present the draft to the PHC, solicit public comments, and then return to the Council for final approval of the amended guidelines.

Attorney Carol Balulescu, Deputy General Counsel explained the filing process to the Council and the staff memorandum also states, "Following PHC approval and 30-day notice to the legislature as required by §25F of M.G.L.c.111, the Department will file the amendments with the Secretary of the Commonwealth for emergency promulgation. Emergency amendments take effect when filed, and remain in effect for three months. During the three month period, the Department must comply with all hearing and notice requirements of M.G.L. c.30A. Staff intends to conduct the public comment hearing on December 5, 2008 and hopes to return to the PHC in January or February to report on testimony and any recommended changes to these proposals. Following final action by the PHC, the Department will be able to file final regulatory documents with the Secretary of the Commonwealth before the expiration of the three-month period and thereby make permanent changes to 105 CMR 100.000." Staff explained that these regulations needed to be done on an Emergency basis so that the statutory effective date of the provisions could be met.

Discussion followed by the Council. Dr. Muriel Gillick stated, "My understanding is that these new regulations would result in the same – the existing DoN process being applied to other kinds of facilities such as the outpatient, but does not have any change in the nature of that process. I had asked previously whether that is in fact what is specified by the new law because I think, as we have discussed previously, there are some limitations of the DoN Process...legislative limitations...I was wondering whether it was in fact the case, the new law signed into effect in August requires that the existing process be the one that be applied to these new facilities?"

Ms. Joan Gorga, Director, Determination of Need responded, "I don't believe the law speaks to that. I believe there probably was an assumption that the existing process would be used, since it did not specify another process. I would indicate that there are nine Factors of DoN Review, and there is the opportunity to discuss duplication of services within those existing factors. I would not say that the DoN process is completely absent of a discussion of need." Deputy General Counsel Attorney Carol Balulescu, added, "The amendment to the law was an amendment to the definition section rather than to the body of the DoN statute. I wouldn't necessarily read into that, that there was intent that the process itself would be changed." Chair Auerbach added that it was possible for the Council to take a position and recommend it to the

Legislature that would allow a different approach to DoN Review. Dr. Gillick said, "Right, I guess that would certainly be what is required for the DoN process, as applied to existing facilities. My question was essentially, if there was a loophole for these new facilities that would allow for the opportunity to extend the process, not suggesting that it does nothing, but suggesting that it might be able to do more without Legislative mandate, and related to that, whether adopting these regulations would preclude going that route because we would be saying yes to the existing process, but for these other facilities." Dr. Alan Woodward, Council Member said, "...I think it was in August that we modified the DoN slightly, and we actually added a couple of words that might tighten that up, but it was one of those things that we had suggested might be brought back to this body for consideration, and I think, if there is a public hearing on the Chapter 305 changes, it might be a time to also discuss with the Council how we better look at the reality of need, and the cost effectiveness of expansions such as this" Chair Auerbach noted the limitations of DoN staffing.

Council Member José Rafael Rivera noted that wherever money is mentioned, like the 25 million dollars it should state [year of the dollars] in the regulations. Ms. Gorga said the dollars are mentioned in the staff summaries. Chair Auerbach said he sees Mr. Rivera's comment as a friendly amendment. Ms. Gillick said her comments earlier on outpatient centers apply also to ASCs. Discussion continued and Ms. Gorga noted that she was putting together an advisory board to review the ASC guidelines.

Council Member Paul Lanzikos inquired about the optional electronic submission request in the proposed regulations. Attorney Carol Balulescu said it was noted only one time in the regulations in interest of time. Mr. Lanzikos replied, "...Where the submission of applications is sort of central, you might just want to make that one reference there..." In addition, he noted that once the department decides to go electronic he hopes they will eliminate all the paper copies going to other agencies and require only electronic applications." Lastly, he inquired, "When staff decides to require electronic submission will the applications be posted on the DPH web site for public viewing?" Ms. Gorga noted that some of the applications are very large and that she would have to consult with the web staff to see if it is possible. Chair Auerbach stated, "We will make every effort to make that available."

**For the record**, Dr. Michéle David arrived at the meeting at this point, during Mr. Lanzikos' questioning of electronic submission policy at approximately 9:50 a.m.

Mr. Albert Sherman moved approval of the proposed DoN Emergency Amendments with Mr. Rivera's amendment. After consideration upon motion made and duly seconded, it was voted: (Chair Auerbach, Ms. Caulton-Harris,

Dean Cox, Mr. Lanzikos, Mr. Leary, Ms. Prates Ramos, Mr. Rivera, Mr. Sherman and Dr. Woodward in favor; Dr. Gillick opposed; and Dr. David abstained) to approve the **Promulgation of Emergency Amendments to 105 CMR 100.000 - Determination of Need Regulations** with Mr. Rivera's amendment requiring the year be noted in the regulations for any monies noted. A copy of the Emergency Amendments are attached and made a part of this record as **Exhibit No. 14, 916**.

Chair Auerbach noted for the record, the historical significance of the vote just taken on the DoN Regulations above and previously that year on the DoN Regulations, making changes to the regulations for the first time in 20 years. He said in part, "That earlier change, it really represents an enormously different approach to the DoN process, and much more of an incorporation of a regulatory review and consideration of a wide variety of different applications moving forward, and I know that creates an enormous burden for the DoN office, but I think that the public value from those changes is also quite significant, and I think that I want to commend the Council for making those changes and for participating in the process that represents such meaningful change."

#### **PRESENTATIONS:**

**" A COMPREHENSIVE OPIATE OVERDOSE PREVENTION PROGRAM USING NASAL NARCAN", By Dr. Alex Walley, Medical Director, Bureau of Substance Abuse OD Prevention Program, Ms. Sarah Ruiz, Bureau of Substance Abuse Services:**

Ms. Sarah Ruiz made introductory remarks to the Council, noting that this project has been a collaboration of three areas of the Department, the Commissioner's Office, Bureau of Substance Abuse Services, and the HIV/AIDS Bureau and acknowledged Andy Epstein of the Commissioner's Office for being the driving force behind this project. She noted that opiate poisonings have become the leading cause of injury death in Massachusetts, surpassing motor vehicle accidents. She indicated that the increase is attributed to primarily prescription opiate pain killers and as the dependency forms the person switches to heroine, that is more available and lower in cost in Massachusetts - nationally met amphetamine is used. Another factor is Schedule 2 opiate prescriptions have doubled. Cuts in substance abuse services in 2001-2004 have also contributed to the problem.

In closing, Ms. Ruiz noted that the Department has been restoring treatment programs with the support of the Legislature and the Patrick Administration. And further that the goals of the Substance Abuse Services Bureau is (1) prevention of the problem in the first place and increased access to treatment

(2) if an overdose occurs prevent it from becoming a fatal overdose with the Naloxone Distribution Pilot and expanded treatment using buprenorphine.

Dr. Alex Walley, Medical Director, Bureau of Substance Abuse OD Prevention Program, General Internist at Boston Medical Center and Medical Director of the Boston Public Health Commission Methadone Clinic, followed and said in part, "...One of the big parts of our prevention message and our education message is to encourage people to engage public safety when an overdose occurs, to get help, and while they are waiting to get help, we give them strategies and also give them intranasal Naloxone (the anecdote to an overdose), which they can give to the person who is overdosing and hopefully, can prevent their fatal overdose...so this is like an epi pen, or like using glucose in a diabetic who has overdosed on insulin."

Dr. Walley indicated, "This is a public health pilot...We are distributing a prescription medication to bystanders, not to the people who are actually going to receive the medication. Our hope is after exploring the results of this pilot, we can, in the future, look at more codified policy. The distribution of this medication is based on a standing order by the Medical Director for distribution of Naloxone within the parameters of the pilot. It is modeled after the Boston Public Health Commission program, which was launched in September of 2006...The way the program is set up at the sites is, people are able to come back to us and report their experience with using Naloxone and experience with overdoses. We have done 319 refills and a 179 overdose reversals have been reported. The bystander group is made up of friends, family, professionals and active users, over fifty percent of them have actually seen an overdose themselves, before they came into this program. Overdose is not that rare of an event. It is a pretty common event and people want to know what to do when it happens and have something to do when it does..."

Mr. Barry Callis, MSW, Prevention Education Unit, HIV/AIDS Bureau addressed the Council. He said in part, "...The initial pilot that Alex referenced earlier began through the Boston Public Health Commission in September of 2006 and through the addition of five additional sites beginning in December of 2007, this has really been the strength in mounting this particular pilot. It is collaboration between the AIDS Bureau and the Bureau of Substance Abuse Services. We have an internal working group to make sure that the pilot programs are supported on this are informed and managed according to privacy and confidentiality laws...This pilot capitalizes upon our currently funded IDU serving programs in core cities that are experiencing a disproportionate number of fatal overdoses in Massachusetts. There are staffs in our programs, primarily directors and coordinators of these programs, who are designated and approved to be the only individuals to enroll bystanders in the project. We thought that this was very important, to make sure that we made sure that staff had the

skills and capacity to do this added piece of work. They provide overdose education, identification and response to an overdose, and that includes the use of Naloxone, and there is a curriculum. All of the staff attended a full day training on the 16<sup>th</sup> of November, just a year ago, on this curriculum. We set up reinforcement training for all new staff to be trained as the programs began the pilot...All of the reversals are collected on a new data collection form, and they are returned to the Department monthly. This is so that we are able to monitor the number of refills, the number of overdoses and reversals that are being seen. We are working with the Boston University School of Public Health Data Coordinating Center in managing the data. All of our staff, including internal staff of the Department, has access to the data on a regular basis, just so that we are monitoring the progress of the pilot..."

In closing Mr. Callis said in part, "...In working together across the AIDS and Substance Abuse Bureaus, we are learning about one another's data collection systems. We are supporting the pilot sites with quarterly in-person meetings. We are doing monthly conference calls, as well as the contract managers for those programs attending those sites more regularly to monitor the progress of the site...Programs are deepening their working relationships with first responders, public safety, local media, substance abuse treatment networks, and we are expanding into new social networks of users that we currently didn't have access to before. We are increasing treatment and treatment readiness and, most importantly, we are working with folks with dignity and support for self determination for improved quality of life."

Current participants in the pilot program are: Boston Public Health Commission, the AHOPE Needle Exchange Van, Tapestry Health serving North Hampton, Springfield and Holyoke, CAB Health and Recovery serving Lynn, Peabody, Gloucester and Salem, Seven Hills Behavioral Health, serving the Greater New Bedford and Fall River communities; AIDS Support Group of Cape Cod, serving Hyannis and Provincetown, Cambridge Cares About AIDS, serving Cambridge and the surrounding communities. It was noted that folks from outside these communities can enroll in the pilot by contacting any of the programs.

Discussion followed by the Council. Please see the verbatim transcript for full discussion. Council Members Mr. Jose Rafael Rivera, Mr. Dennis Leary, Dr. Michele David and Dr. Alan Woodward noted their support for the pilot program. Dr. Alan Woodward, an emergency physician, noted that the half-life of Naloxone is quite short and that folks treated with it still have to go to the emergency room or they could still die. He also said, "An unintended consequence may have people believing that they have a safe anecdote at hand and cause them to experiment further". Dr. Walley responded that this has not been occurring but "staff needs to be vigilant about delivering this with education that this is a life-threatening emergency that needs medical

attention..." Chair Auerbach noted that, "Andy Epstein was the person who began the effort to develop a pilot in Boston, designed the program and enrolled every single person. And when she came to DPH, she took the lead in terms of developing the program here..." He thanked Andy Epstein, Michael Botticelli and Kevin Cranston, the directors of the bureaus that were involved in the implementing the pilot program.

Chair Auerbach further noted, "For the first time, in 2007, we are seeing a leveling off of the number of opiate related overdoses. We were having between twelve and twenty percent increases each year, and we are down now, in 2007, to about a two to three percent increase, which is almost leveling off. We believe that a contributing factor is not just the prevention and treatment efforts that Ms. Ruiz was mentioning but also the impact of the Boston pilot, which was in existence in 2007, and as you noted, there were 74 reversals that were documented in that program and that may have been the difference in terms of our seeing that leveling off. The fact that we can potentially say that as many as 250 people's lives were saved as a result of the program, I think really is a testament to the effectiveness of this work, and to your dedication and willingness to take leadership on it. Thank you to all who have been involved."

### **No Vote/Information Only**

#### **"A Drop in Heart Attack Deaths and the Massachusetts Smokefree Workplace Law", by Thomas Land, Ph.D., Director of Surveillance and Evaluation, Massachusetts Tobacco Control Program, Eileen M. Sullivan, Director of Policy and Planning, Massachusetts Tobacco Control Program**

Ms. Eileen M. Sullivan, Director of Policy and Planning, Massachusetts Tobacco Control Program addressed the Council. She said in part, "Massachusetts implemented the Smokefree Workplace Law on July 5, 2004. Since then, there has been a significant drop in heart attack deaths. We believe that the decline in heart attack death is linked to the implementation of the law, and we are currently working to estimate health care cost savings...The law is considered comprehensive because it mandates that smoking is prohibited in all work sites with more than one employee. Enforcement of the law has been primarily conducted by local boards of health. In general, compliance with the Massachusetts law has been good. In 2007, we conducted an observational field study to determine compliance levels and found a rate of 94% compliance. Most of these violations were smoke migration from people smoking outside and the smoke drifting inside, not active indoor smoking. The real goal of secondhand smoke laws is to positively impact the health of residents. Until now, there has been no specific evaluation of health effects of the

Massachusetts Smokefree Workplace Law....Many communities began restricting smoking in the 1990s, particularly focusing on restaurants. By 2002, nine communities had comprehensive laws.”

Ms. Sullivan continued, “A shift began with the formation of Clear Air Works, a regional coalition, led by the Boston Public Health Commission and the Cambridge Public Health Commission. Rather than focusing on the hospitality industry, Clear Air Works focused on the need for all workplaces to be Smokefree, and for all employees, as well as the general public, to be protected from secondhand smoke. This regional approach was highly successful, and was soon being duplicated in other parts of the State, including the North Shore and Western Massachusetts. Boston successfully implemented a comprehensive law in May 2003, followed by Cambridge and Somerville enacting their regulations later that fall. Clean Air Works was critical for building momentum for state law, which was signed into law in June 2004, and went into effect July 5<sup>th</sup>, a mere 18 days later...Prior to implementation of the statewide Smokefree Workplace Law, 54% communities had already implemented similar comprehensive laws, 193 has weaker versions of Smokefree air laws, and a hundred had no laws for industry. We believed that the municipalities with stronger laws would see a positive health impact prior to other municipalities.”

Dr. Thomas Land, PhD, Director of Surveillance and Evaluation, presented the survey findings to the Council via a Powerpoint presentation. He showed slides presenting estimated deaths using the CDC’s SAMMEC (Smoking Attributable Mortality Morbidity and Economic Costs) model and then actual heart attack deaths in Massachusetts between 2000 and 2006. Both sets of slides show that the decrease in heart attack deaths is steady before 2004 and accelerates thereafter.

Dr. Land said in part, “If we step back and take a longer view of heart attack deaths, we see an important pattern emerge...It was our hypothesis that those towns with preexisting strong laws would show an earlier decline in heart attack than towns with weaker laws or no laws at all. The graph appears to bear out that fact. Heart attack deaths in Massachusetts dropped more rapidly in strong law towns than other towns. Perhaps most interesting of all is that, by the end of the study period, there is very little difference in the rate of heart attack deaths by type of local law. The question that remained is whether these drops could be linked to the Smokefree Workplace Law.”

“In the last few years, he continued, “a number of studies have shown links between secondhand smoke exposure and heart attack. There have been studies in Helena Montana, Pueblo Colorado, Italy, Canada, Scotland, and elsewhere. Some of the specific findings of these studies have been enlightening. The Scotland studies showed that limited exposure to secondhand

smoke can impact health, even among non-smokers. A recent analysis of eight separate studies estimated that the reduction in heart attack hospitalizations following the implementation of Smokefree air laws to be approximately 19 percent. In the context of the recent literature, a drop in deaths should therefore not be surprising...In aggregate, our analysis showed that there were sixteen percent fewer heart attack deaths in Massachusetts than expected after the state law was implemented. Unlike some other studies, the impact in Massachusetts was not immediate. There was approximately a one-year lag period before the decrease in heart attacks was realized. We assumed that this lag was due to the fact that many towns may have allowed for a warning period, to educate business owners before violations and fines were issued. As was noted earlier, only 18 days elapsed between the passage of the law and the implementation date. Given this short time period, it is not surprising that we see a lag between implementation and impact."

Dr. Land noted further, "Beginning one year after the implementation of the statewide law, the decrease in heart attack deaths, that could be associated with the statewide law, varied by type of local law. In towns with prior strong laws, the decrease was only eight percent. For weak and no law towns, the decrease was 18 percent and 17 percent respectively. For strong Law towns, much of the decrease in heart attack deaths occurred prior to the statewide law. For weak and no law towns, the bulk of the decrease occurred afterward. When we translate this information into deaths, we determined that there were 577 fewer deaths than expected annually in Massachusetts, following the implementation of the statewide law...In total, there were 866 fewer heart attack deaths than expected in Massachusetts between July 5, 2005 and December 31, 2006."

Dr. Land commented, "Besides heart attacks, the U.S. Surgeon General has linked more than a dozen causes of death to secondhand smoke exposure. We plan to evaluate the impact of the Massachusetts Smokefree Workplace Law for all of them, beginning with causes like heart attack and then chronic conditions like COPD. Preliminary analyses show that three additional causes of death have similar data patterns; cardiac arrest, cerebral hemorrhage, and cerebral infarction, or stroke...And finally, with the decrease in deaths and hospitalizations linked to the Smokefree Air Law, we are currently working to quantify the result in savings. At the same time, we will keep in mind that any savings highlights the fact that tobacco control efforts are an integral part of cost containment strategies for health care in the Commonwealth."

Chair Auerbach added, "Just a fascinating study and a very meaningful one in terms of understanding how public policy and regulatory change can have an impact on health. I want to start the discussion acknowledging Dean Cox's role in this particular undertaking because he was the convener of Clean Air Works

and the leader of the effort to try to change those regulations. Thank you for that work Dean Cox. Do you have any initial comments or thoughts about seeing the good results from your efforts?"

Council Member Dean Harold Cox replied by complimenting Commissioner Auerbach for his integral role in the project too. He said in part, "This is really very interesting data and it certainly justifies the pain that all of us experienced with this...I like the data, but it still raises important questions that we should really think about any time we think about what the impact of these kinds of policies have on improving the lives of people, and one of those certainly has to do with what gives you the confidence that the change in policy is really what actually impacted the decrease in the heart attack deaths?" Dean Cox said he wondered about the time frame that is needed from the passage of that kind of policy to seeing the result. He wondered how certain populations had been impacted by the policy such as the workers in bars and when you look at deaths do we see these results among different racial groups.

Dr. Land responded, "What give us the confidence that this is a real effect that is due to the Smokefree Workplace Law, and I think that the answer to that is two-fold. One is that, it fits very nicely in with the literature that currently exists, that has been emerging in the last several years. Most of the medical analysis that was done and released this summer showed that there was a 19% decrease in hospitalizations across a large number of studies, in countries across the world, and our finding of sixteen percent actually may be somewhat of an underestimate because so many of the towns had strong laws prior to the statewide law. We think that the figures fit nicely together, so that we would expect a similar drop in hospitalizations as we would see in deaths, but it also is that we patterned our study after all the existing studies. We took into account over a dozen alternative explanations that were included in our analysis and some of these were contributing factors, such influenza outbreaks and pollution levels in the state, but they did not decrease the impact of the statewide law that we saw. I think those were the two factors that give me confidence that this is a real effect." In reply to the time frame question for seeing the results of the policy change, Dr. Land reiterated his statement during his presentation that lag time would be expected after such a short time between passage of the law and implementation of it. Regarding workers in bars, the death certificate information doesn't indicate where the event occurred so he could just say generally that they feel the information applies to these workplaces. The study was patterned after the Italian study and to split the data into such small pieces like different racial and ethnic groups that it would be unlikely to find significant effects. He noted that in the future, they may be able to look at the race and ethnic groups now that they have more data on the implementation dates for local laws (received from Mass Municipal Association and Massachusetts Association of Health works).

Dean Cox acknowledged that Eileen Sullivan, Director, Policy and Planning, Massachusetts Tobacco Control Program was the person who guided the work during the Clear Air Works campaign. Discussion continued, Dr. Muriel Gillick, Council Member suggested that the Council look at other states surrounding Massachusetts “as a potential bit of confirmatory evidence, that have same climate, that didn’t have such laws in effect, which also didn’t see the drop in acute myocardial infarction.” Council Member Dr. Alan Woodward suggested looking at other states that have passed strong similar laws to Massachusetts to see if there is a similar time-wise trend for more confirmatory evidence. He asked, “What are the next policy changes that we should implement? And What is the next step to reducing tobacco use in this state, and is Boston going in the right direction as discussed in today’s newspaper?” Ms. Sullivan replied in part, “The place right now where we have a great deal of concern, and it is very much an educational approach, is the exposure of secondhand smoke in housing, and we have a number of educational initiatives that we have begun looking at; educating landlords, as well as residents. The drop that we have seen is adults in workplaces. This doesn’t impact the secondhand smoke exposure on children.” Chair Auerbach noted that on November 17<sup>th</sup>, there will be a special program starting that targets veterans, their families and veteran survivors in Massachusetts for assistance with nicotine replacement therapy. Mr. Paul Lanzikos, Council Member added, “I would just like to take advantage of the impetus of the study and the excitement coming around, for a little advocacy that I hope, within the next couple of years, what we are going to be seeing is the ban of the sale of tobacco products in environments that are involved in health care, particularly pharmacies and in public buildings. I hope that this can stimulate efforts like that in a fairly short period.”

## **NO VOTE/INFORMATION ONLY**

**Note:** Dr. Muriel Gillick and Ms. Helen Caulton Harris left the meeting just prior to the presentation below at approximately 11:10 a.m.

### **“Health Profile of Massachusetts Adults by Sexual Orientation Identity”, by Stewart Landers, Kerith Conron, and Matthew Mimiaga**

Mr. Stewart Landers, Senior Program Director, Interim Director, Bureau of Community Health Access and Promotion, addressed the Council: “We have done this work because there have been other studies based on other research, indicating health disparities between Gay, Lesbian, Bisexual populations and Heterosexual populations in several areas, including health care access, mental health, tobacco, alcohol and other drug use, sexual health and violence victimization, and we believe that these data can be useful in helping to inform a Public Health policy agenda, identifying where disparities exist and helping to

identify what types of interventions could be useful in reducing or eliminating those disparities.”

Dr. Kerith Conron, Harvard School of Public Health and consultant to the Department of Public Health presented the report findings. She said in part, “We use logistic regression to estimate models that compared differences in health outcomes between sexual orientation groups, while adjusting for age, sex, race, ethnicity and educational attainment. Logistic models produce odds ratios, which compare the odds of an event in one group compared to the odds of an event in another group; and so, most of what we will be presenting to you today are odds ratios. ... We were interested in the possibility of effect modification by sex. What that means is we thought there might be a difference between sexual orientation group membership and the health outcome based on the sex of the participant. We tested for those and found differences. We present to you odds ratio separately for men and women...We ended up with 94% of eligible people being included in the sample that we are going to present findings from today.” Some of the statistical highlights follow:

- Most people in the state identify as Heterosexual or Straight. About two percent identify as Lesbian/Gay, and about one percent as Bisexual
- A large number of young people, 18 to 24 years of age identify as Bisexual
- A large proportion of the Gay/Lesbian population are males and a larger proportion of the Bisexual population are female
- A larger proportion of the Gay/Lesbian population has more than a four year college degree

Mr. Matthew Mimiaga, Harvard Medical School and the Fenway Institute and consultant to Department of Public Health spoke on health care access:

- Bisexuals were less likely to report having health care insurance and were less likely to report having a regular medical provider and were less likely to report having been for a dental cleaning in the prior twelve months as compared to the Straight population
- Gays, Lesbians and Bisexuals were more likely to report having fair or poor health in comparison to Straight or Heterosexuals
- Gays and Lesbians, in comparison to Straights, were more likely to report a disability related activity limitation. Similarly, Bisexual women, in

comparison to Straight women, were more likely to report a disability

- With respect to weight, there are sex stratified differences. Gay men were less likely to report being obese compared to straight men and Lesbian women were more likely to be obese, in comparison to Straight women
- With respect to chronic health conditions, heart disease in particular, these are lifetime diagnoses, Bisexuals were more likely to report having been told that they had heart disease than Straight, Heterosexuals. In contrast, Gays and Lesbians were more likely to report that they had asthma, compared to Straight Heterosexuals
- For lifetime HIV testing, Bisexuals, in comparison with Straights, were more likely to report having ever been tested for HIV. For Gay men and Straight men, again, Gay men were more likely to report lifetime HIV testing and, similarly, Lesbian women were more likely to report HIV testing, in comparison to Straight women

Dr. Conron reported on mental health, substance abuse, sexual assault and intimate partner victimization:

- Gays, Lesbians and Bisexuals were more likely to report feeling tense or worried for more than fourteen out of the past thirty days, than their straight peers
- Bisexuals were more likely to report feeling sad or blue more than fourteen days out of the last thirty than their Heterosexual peers. They were also much more likely to report that they seriously considered suicide within the past twelve months than their Straight peers
- The odds of being a current smoker or a former smoker, versus being a never smoker, were greater among Gay and Lesbian people, compared to their Straight peers. Gays and Lesbians were more likely to report binge drinking and also more likely to report any use of any illicit drug within the past thirty days than their Straight peers
- The odds of current smoking versus never smoking were also greater among Bisexual men and women, compared to Heterosexuals. We present you with odds ratios that are stratified simply because they were slightly different in magnitude for men and women

- Bisexual women were much more likely to report eliciting drug use in the last thirty days than Straight women
- Both the Gay and Lesbian population and the Bisexual population were much more likely to report a lifetime experience of sexual assault than their straight peers.
- Bisexual women were much more likely than Straight women to report lifetime experiences of physical intimate partner violence, while there was no difference between Bisexual and Straight men

In summary, Mr. Landers stated, "There were some areas we explored, where we found no sexual orientation differences, that included prostate specific antigen testing, lifetime mammography, three year cervical cancer screening, diabetes, and twelve month intimate partner violence victimization, compared with lifetime that Dr. Conron just reported on, however we have found sexual orientation disparities in access to health care; self-reported health status, chronic health conditions, including heart disease and asthma, mental health, including depression and anxiety, substance abuse, including tobacco smoking, sexual health and violence victimization. Overall, Gay, Lesbian and Bisexual adults evidenced poorer health and greater risk than Straight adults across several health domains, and in particular we found that an emphasis on the health needs of Bisexuals is indicated by our findings and we encourage the bureaus across the Department to think about ways in which these disparities could be further addressed. I realize that some of the programs are looking at some of these issues..." Mr. Landers thanked Commissioner Auerbach and Kevin Cranston for their support of the project and the Bureau of Health Information, Statistics, Research and Evaluation Staff and BRFSS staff.

Discussion followed by the Council. Council Member Dr. Michèle David noted, "I was intrigued by one aspect of the study, that shows that the Gay/Bisexual community has a very high attainment of college, but still have access to healthcare difficulties, and usually the data shows there that usually the people who are college graduates can access health care. Do you have any explanation for that?" Dr. Kerith Conron responded in part, "...Insurance is often linked to the legal status of one's relationship to partners is a significant factor that might influence whether or not a person has access to care. Prior negative experiences trying to receive care would also present barriers to having a regular health provider, for instance..." Council Member José Rafael Rivera inquired if the question about access to substance and mental health services was asked in the study. Ms. Conron replied, "There were a number of questions asked about substance abuse treatment utilization and some questions asked about overall health access and experiences obtaining care, and we are planning to pursue analysis of those items." Dr. Alan Woodward asked if the question is access

versus utilization – “it may be education in getting people to utilize some of the resources they actually to have access to”.

Dr. Conron noted further, “I want to do more targeting of adolescents, particularly around tobacco use, and much more outreach and education about intimate partner violence in same sex settings, as well as sexual assault perpetration by same sex peers. We know, from a local study done of participants in a Gay/Straight Alliance Group here in Massachusetts that Bisexual women were much more likely to report that they had been sexually abused by a dating partner. While in some senses, we think of sexual assault victimization as being perpetrated by unknown adults, what we actually know from the larger data is that peers and siblings are often likely to be perpetrators, and we need to do a better job at creating environments where kids feel that they can disclose victimization regardless of the sex of the perpetrator.”

Chair Auerbach added, “...I don’t think we have seen data before that had confirmed that Gay, Lesbian and Bisexual people are at significantly greater risk of heart disease and asthma. This is very troubling and I know that, you know, in trying to think about what could explain that, just from the data that you shared, and certainly such things as higher rates of smoking and weight related issues could be factors, and I know you didn’t study this...it makes me think that one other factor, as we looked at the issue of infant mortality and the disparities that exist among Black women, in particular, there has been a growing body of literature that suggests that elevated anxiety levels create hormonal changes or other kinds of physiological changes, that can contribute to poorer health outcomes, simply from the experience of discrimination, that then results in greater anxiety and a variety of different complications, and I think that the studies are suggesting a higher level of infant mortality. So, it would seem to make sense that other groups that also face discrimination might experience the same level of discrimination-related anxiety that then could also contribute to poorer health outcomes. I know that you couldn’t have looked at that but it does seem like an area that we may want to pay more attention too...After we found significant patterns of health disparities among people, based on race and ethnicity, particularly in the Black Latino community is that we, at the State, needed to develop policies and programs that reflect customized attention to those populations. I think that your findings also would lead us to conclude that we need to develop the same sort of customized, adapted services towards Gay, Lesbian and Bisexual populations, given the disparities that you are highlighting.”

Council Member Dean Cox noted how important he felt the survey was and it leads him to think about how to address these concerns for the Gay, Lesbian and Bisexual communities. He noted in part, “...Maybe this is another item for our committee to actually have a fuller conversation around what is the agenda and

in what ways is the Department beginning to think about addressing these kinds of concerns, here within the Department and around the state.”

**FOLLOW-UP ACTION LIST:**

- Rethink DoN approaches [Gillick to Gorga, Balulescu]
- In proposed DoN regulations add inflationary dollar amounts (years) to \$25,000,000 figure and ambulatory centers [Rivera, Gillick to Gorga, Balulescu]
- Electronic Submissions of DoN Application Requirements versus paper submissions should they be revisited [Lanzikos to Gorga] and possibility of applications on the web
- Check with states nearby with no smoking laws in effect to see if they have seen a drop in acute myocardial infarction [Gillick to Land] Check with nearby states with smoking laws in effect to see similar time-wise trend for more confirmatory evidence [Woodward to Land]
- End sale of tobacco in pharmacies and public buildings [Lanzikos]
- Follow-up Studies on Gay, Lesbian and Bi-sexual populations to determine if programs are needed to offset health affects caused by discrimination

The meeting adjourned at 11:40 a.m.

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John Auerbach, Chair

LMH

