

## **PUBLIC HEALTH COUNCIL**

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, June 24, 2009, 9:12 a.m., at the Department of Public Health, 250 Washington Street, Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Mr. Harold Cox, Dr. John Cunningham, Dr. Muriel Gillick, Mr. Denis Leary (arrived at 9:30 a.m.), Mr. Paul J. Lanzikos, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Dr. Meredith Rosenthal, Mr. Albert Sherman, Dr. Alan C. Woodward, and Dr. Barry Zuckerman. Ms. Helen Caulton-Harris, Dr. Michèle David, and Dr. Michael Wong, 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.

### **RECORD OF THE PUBLIC HEALTH COUNCIL MEETING OF APRIL 8, 2009:**

A record of the Public Health Council Meeting of April 8, 2009 was presented to the Public Health Council for approval. Council Member Albert Sherman moved approval. After consideration, upon motion made and duly seconded, it was voted unanimously [Mr. Denis Leary not present; Ms. Caulton-Harris, Dr. David, and Dr. Wong absent] to approve the April 8, 2009 minutes of the Public Health Council meeting as presented.

For the record, Council Member Mr. Denis Leary arrived at the meeting at 9:30 a.m. during the Informational Briefing on Health Insurance Consumer Protection; he therefore was not present to vote on the minutes above.

## **PROPOSED REGULATIONS:**

### **Informational Briefing on Proposed Amendments to 105 CMR 128.000, Health Insurance Consumer Protection:**

Attorney Carol Balulescu, Director, Office of Patient Protection and Deputy General Counsel, presented the proposed amendments to 105 CMR 128.000 to the Council. Attorney Balulescu noted at the meeting and in her memorandum to the Council, dated June 24, 2009 "that minor changes are required by M.G.L. c.176R, which was enacted as part of Chapter 305 of the Acts of 2008; that 176R took effect on January 1, 2009; Chapter 176R requires health plans to recognize nurse practitioners, defined as registered nurses who hold authorization in advance nursing practice under M.G.L.c.112, § 80B, as participating providers. Each health plan must additionally provide benefits to insureds who receive covered services from nurse practitioners to the same extent that the health plan provides benefits for identical services rendered by other licensed health care providers and must include participating nurse practitioners in its provider directory. If a health plan requires the designation of a primary care provider, it must provide the opportunity to an insured to select a participating nurse practitioner as his or her primary care provider. Section 6 of chapter 176R required the DOI to promulgate regulations to enforce the provisions of chapter 176R that relate to insured health plans. DOI has already amended 211 CMR 52.00, which is the companion regulation to 105 CMR 128.000, to incorporate these changes."

Staff's memorandum notes further, "Although Chapter 176 did not amend any section of chapter 1760, under which OPP operates; there are several sections of 105 CMR 128.000 that are indirectly affected by the passage of chapter 176R. Most of the proposed amendments involve changing the term 'primary care physician' to 'primary care provider' as defined in chapter 176R. In addition, OPP needs to amend its regulation to incorporate one other change made by the DOI to 211 CMR 52.16: added a new reporting requirement for health plans: in addition to an annual report of the number of physicians that are disenrolled, health plans must also report the same information for nurse practitioners. OPP is proposing to update 105 CMR 128.600 to add this requirement, as well as add the

definition of 'primary care provider' and add references to nurse practitioners as necessary."

In closing, Attorney Balulescu stated, "M.G.L. c. 6A §16D(d) requires that the Office of Patient Protection submit proposed regulations to the Managed Care Advisory Committee (MCAC) for review and comment at least 60 days prior to final promulgation. OPP sent these amendments to the members of the MCAC on April 28, 2009. The Department plans to hold a public hearing on July 30, 2009. Following the hearing, the Department will return to the PHC to provide a review of the testimony, to present any changes proposed in response to the testimony, and to request approval for promulgation of the amendments."

A discussion followed. Attorney Balulescu summarized the functions of the Office of Patient Protection (OPP) for the Council noting "the office fields about 1,000 telephone calls a year and assisted consumers in recovery in excess of a million dollars in claims every year." Answering a question about how consumers know about the office, Attorney Balulescu noted "that the OPP regulations require that, any time a health plan issues a denial, and it is required by law to issue it in writing, that it refer people to the Office of Patient Protection." The Council asked Attorney Balulescu to come back with a presentation at the meeting that she will be bringing back these regulations for promulgation.

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

#### **Informational Briefing on Proposed Rescission of 105 CMR 950.000 (Criminal Offender Records Checks):**

Attorney Sondra Korman, Deputy General Counsel, presented the informational briefing to the Council on 105 CMR 950.000. Attorney Korman briefed the Council on the proposed rescission of the DPH regulations governing Criminal Offender Records Checks (CORI) 105 CMR 950.000 et seq. In accordance with the Governor's Executive Order 495, Section 2 signed on January 11, 2008, the Executive Office of Health and Human Services (EOHHS) promulgated new regulations, 101 CMR 15.000 et seq., which establishes a consolidated set of policies and procedures for the review of the criminal history records of candidates for employment

within EOHHS, its agencies, and vendor programs. The EOHHS CORI regulations became effective for DPH hires on May 1, 2009; they will become effective for DPH's vendor hires on July 1, 2009."

Attorney Korman noted in her memorandum to the Council and stated in part, "As set forth in Executive Order No. 495, separate agency regulations resulted in some confusion among the vendor-service community. Further, the regulations were perceived to impose unnecessary obstacles to employment opportunities for qualified, rehabilitated individuals with criminal backgrounds. After a lengthy review process, the EOHHS CORI regulations have been revised." Some of the major revisions are summarized below:

- Amends the policy statement to reflect the dual purposes of the regulations: 1) protection of vulnerable populations served by EOHHS and its agencies and 2) provision of fair opportunities for, and reintegration of, qualified, rehabilitated offenders into the workforce;
- Retains Table of Offenses to establish which crimes are relevant to hiring decisions within human services positions;
- Streamlines, updates crimes list for clarity, consistency, and readability;
- Ensures that CORI checks are conducted only where relevant to duties and when prospective employee has been deemed otherwise qualified;
- Provides standardized template (Hiring Review Form) that employers must complete documenting appropriate consideration of risk and rehabilitation;
- Eliminates Lifetime Presumptive Disqualification and Discretionary Disqualification categories;
- Eliminates the mandatory requirement for written determination by a CJO or QMHP for candidates with Table A;

- Eliminates the required second tier review by Agency Commissioner for candidates with convictions or pending offenses in Table B (less serious offenses);
- Retains the second tier Commissioner review only for the most serious offenses listed on Table A; Commissioner may seek written determination by a CJO or QMHP, at agency expense;
- Adds a new 10/5-year look-back period: employers may not consider convictions for Table B Felony crimes that occurred more than 10 years ago; or Table B misdemeanor crimes more than 5 years ago;
- Reinforces CHSB requirements that job applicants must be given information relative to right to dispute accuracy/relevance of CORI.

In closing, Attorney Korman stated, "The next steps are that, since July 1 is coming up soon, we have to remove all the web-based information regarding the current regulations. There is going to be ongoing training and bulletins and guidelines that are going to be issued by EOHHS for our vendor agencies during the roll-out period. The effective date for this is July 1, and we are going to come back to the PHC for a final vote in August for rescision of the 105 CMR 950.000 regulations."

Discussion followed by the Council. Chair Auerbach clarified, "This is a decision that really has been made by EOHHS. It is not really a DPH decision, but because we had previously created a regulation with the old policy, we need to rescind that in order to be consistent with the decision that has been made already." Mr. José Rafael Rivera stated, "...I appreciate the fact that more access to training and information about how to train and interpret a CORI is going to be out there. I am concerned that vendors are still not going to know how to read and understand a CORI. It happens today... Is there something the Department can do to ensure that vendors really know how to read and understand a CORI...?" In response to Mr. Rivera, Chair Auerbach noted that the Department will take his comment to heart and will work on strengthening CORI training with the sections of the Department that oversees and contracts with community agencies. Mr. Harold Cox noted that the CORI system is a failed system. Chair Auerbach noted

that the Public Health Council is not the place where the issues in the CORI system will be worked out, that they are complicated and significant and hopes they will be attended to in other settings.

**PROPOSED REGULATIONS: INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 220.000, IMMUNIZATION OF STUDENTS BEFORE ADMISSION TO SCHOOL:**

Larry Madoff, MD, Director of Epidemiology and Immunization, accompanied by Ms. Kathleen Shattuck, Epidemiologist, Bureau of Infectious Disease presented the informational briefing to the Council on 105 CMR 220.000. Dr. Madoff said in part, "I am here to present proposed changes to the School Regulations, essentially to bring them up to date with existing regulations, recommendations and current practices....These regulations are proposed to be changed effective the fall of 2011 and phased in through 2017, and our hope is that this will allow plenty time for schools and others to adapt to these regulations. The regulations will require two doses of MMR (measles, mumps, rubella) for entry into Kindergarten, seventh grade and college, and for health science students; also, two doses of varicella vaccine (prevents chicken pox) at entrance to kindergarten, seventh grade, college and for health science students; a single dose of Tdap (tetanus, diphtheria and acellular pertussis) for entrance into seventh grade...There are some minor changes including criteria for immunity in college students (for MMR: birth in the United States before 1957 is sufficient proof of immunity except for health science students and for Varicella: in addition to vaccination and past history of disease, add birth in the United States before 1980 except for health science students) and some minor revisions of definitions of what a 'Certificate of Immunization' constitutes and 'Preschool' just a name change for the Department of Early Education and Care."

Staff's memorandum to the Council, dated June 24, 2009 indicated further that "the ACIP (The Advisory Committee on Immunization Practices) has updated its mumps vaccination recommendations to include 2 doses of a mumps-containing vaccine for school-age children and college students in place of the 1 dose previously recommended.

Currently in Massachusetts only 1 dose of mumps vaccine is required in addition to 1 dose of rubella and 2 doses of measles. The ACIP now recommends that all children receive 2 doses of varicella vaccine routinely given at ages 12-15 months and 4-6 years. Currently in Massachusetts, only 1 dose is required for school-aged children (2 doses are required for those who received their first dose at age 13 years or older) and there are no requirements for college students. The ACIP published new recommendations for routine Tdap vaccination of adolescents and adults in place of TD booster. Currently in Massachusetts only tetanus and diphtheria (TD) are required for 7<sup>th</sup> grade entry and college students, but not pertussis."

In closing, Dr. Madoff noted "Pediatricians have been following these updated recommendations for some time and we expect the impact on schools to be minimal."

Discussion followed by the Council first on dates of implementation. Staff noted that plenty of time is given in the implementation process to allow school nurses time to create the new form and understand the new requirements. Discussion continued on the process for recommending immunizations and whether it is transparent or not and whether the decisions are being made based on what is best for public health not just the financial costs and further whether recommendations should be made nationally so they are consistent across state lines. Dr. Madoff noted that most states do not require all recommended vaccines like Massachusetts. Discussion continued around many issues which resulted in the Council posing questions for public input. Please see the verbatim transcript for full discussion. During the meeting, corrections were made to 105 CMR 220.600, adding Community Colleges to the list of post secondary schools in the regulations and changing 'institute of higher education' to 'post secondary institution.'

During the public comment period, staff will assess:

- What grace period do we need for students transferring into schools from out of state and out of the country in terms of them providing proof of immunization?

- What is the best time for schools to process immunization verification September 2010 or January 2010?
- What are the advantages and feasibility of requiring additional ACIP recommended vaccines to the current list and when will they be required?

## **No Vote Information Only**

### **Regulations for Promulgation:**

#### **Request for Reconsideration of Amendments to Licensure of Clinics (105 CMR 140.302) and 105 CMR 130.370 (Licensure of Hospitals) Relating to Retention of Patient Records:**

Dr. Paul Dreyer, Director, Bureau of Health Care Safety and Quality, accompanied by Attorney Lisa Snellings, Deputy General Counsel, Office of the General Counsel presented changes to 105 CMR 140.302 and 105 CMR 130.370. Dr. Dreyer stated in part, "During the May 13, 2009 meeting, Dr. Woodward raised a concern that the language that referenced, 'Episode of Care', in the medical record retention amendments that were proposed might result in the destruction of old records that had current clinical significance. There was some discussion about that issue and I think staff's response was, we would address it through sub-regulatory means. We looked at the issue further and we have come to the conclusion that it needs to come back to the Council for a more formal vote. What we are proposing is that the Council adopt Dr. Woodward's suggestion, that the language, 'Episode of Care' be deleted from both the hospital regulations and from the clinic regulations... Staff concurred with Dr. Woodward that the language might result in the destruction of records that have current clinical significance and further that the language might create a system that would be administratively burdensome to the institutions."

After consideration, upon motion made and duly seconded, it was voted unanimously to **Rescind the May 13, 2009 approval of amendments to the hospital and clinic licensure regulation relating only to retention of patient records (105 CMR 130.370 and 105 CMR**

**140.302).**

After consideration, upon motion made and duly seconded, it was voted unanimously to **delete the phrase “related to the episode of care” from 105 CMR 130.370 and 105 CMR 140.302 and approve promulgation of the revised amendments.** A copy of the Staff’s memorandum, dated June 24, 2009 and revised amendments are attached and made a part of this record as **Exhibit No. 14, 927.**

Note: The other amendments to the hospital and clinic licensure regulations approved at the May 13, 2009 meeting were final upon publication in the Massachusetts Register on June 12, 2009. These amendments to sections 105 CMR 130.370 and 105 CMR 140.302 have not yet been published in the Register. These approved amendments take effect upon being published in the Massachusetts Register on or about July 10, 2009.

**PREVIOUSLY APPROVED PROJECT APPLICATION NO. 4-3B14 OF TUFTS MEDICAL CENTER, BOSTON – REQUEST FOR SIGNIFICANT CHANGE:**

Ms. Joan Gorga, Director, Determination of Need Program, presented the Tufts Medical Center application to the Council. She said in part, “...Tufts Medical Center is before you this morning for a significant change to Approved Project No. 4-3B14, a Proton Beam Radiation Therapy unit, which was approved in December of 2006 as an expansion to Tufts Radiation Therapy Service. Proton Beam therapy is similar to other forms of radiation therapy, which work by aiming ionizing particles at the target tumor but proton beam therapy has an advantage over conventional radiation therapy because its ability to accurately target tumors spares healthy tissue in vital organs. As a result, higher doses of radiation can be used with Proton Beam Therapy. Proton Beam therapy is used most often to treat tumors involving the optic nerve, spinal cord, and other tumors where conventional therapy would damage surrounding tissue. At the time of approval, the holder expected approval by the Food and Drug Administration of the unit in late 2007, and installation and licensure of the unit in 2008. Due to circumstances beyond the control of the holder, namely delays experienced by the manufacturer, Still River Systems are

years behind schedule. The unit under development by Still River is unique. It utilizes one quarter of the space and approximately one quarter of the cost of existing proton beam systems. The authorization for the approved DoN will expire in 2009, and the holder has applied for a three year extension of the period of authorization."

Ms. Gorga continued, "When the technology is approved by FDA, which is expected this winter, the first clinical test unit will be shipped to the first hospital on the waiting list and clinical testing will take place in early 2010. Then the first unit will undergo a commissioning process. Once the first unit is fully commissioned, the other units will be prepared and shipped to the hospitals on the waiting list. Tufts Medical Center is third on the waiting list and, based on current projections, the earliest that the equipment would be installed, tested and operational at Tufts would be 2012. Therefore, Tufts has requested a three-year extension of the authorization period until December of 2012. There are no changes to the maximum capital expenditure or changes to the gross square footage for the project. Staff has found that the holder demonstrated that the delay is beyond its control and staff also found that the request complied with the procedural requirements for a significant change."

In closing Ms. Gorga stated, "Staff is recommending that the request for significant change be approved. Representatives of Tufts are here today to answer questions..."

Discussion occurred around the community initiatives benefits. It was noted that this application is unique, for if the FDA does not approve the unit at all, the community benefits will still be paid. Mr. José Rafael Rivera suggested that the community benefits be reassessed since much time has gone by since the initial approval and the needs of the community may have changed since then. All parties agreed (the Council, Ms. Gorga and the applicant agreed).

Ms. Ellen Zane, CEO and President of Tufts Medical Center noted for the record that the community health initiative funding has already begun for some of the projects specifically, the Asian-Access Program and for interpreter services.

Dr. Alan Woodward moved approval. After consideration upon motion made and duly seconded, it was voted unanimously to approve the significant change for **Previously Approved Project Application No. 4-3B14 of Tufts Medical Center** for extension of the authorization period on the Proton Beam Project for three years (**from December 15, 2009 to December 14, 2012**). A copy of the staff memorandum dated June 24, 2009 with supporting material and containing the conditions is attached and made a part of this record as **Exhibit No. 14, 928**.

**PRESENTATION: "ROUTINE SCREENING FOR HIV IN MASSACHUSETTS", BY KEVIN CRANSTON, MDIV, DIRECTOR, BUREAU OF INFECTIOUS DISEASE, PREVENTION, RESPONSE AND SERVICE, AND LAUREN A. SMITH, MD, MPH, MEDICAL DIRECTOR FOR THE DEPARTMENT OF PUBLIC HEALTH:**

Mr. Kevin Cranston said he was present to announce a change in policy regarding routine screening for HIV in clinical settings. He reported significant reductions in annual incidence of HIV, a 25% reduction in the total numbers of newly diagnosed persons with HIV over the last five years and deaths are at a relatively low rate of 300 deaths per year from a high of over 1400 deaths earlier in the epidemic. He noted that the improvement is due to antiviral therapy and that there are still over seven hundred new infections per year and an unacceptable number of deaths among persons with HIV and AIDS.

Mr. Cranston said further, "The central problem that we and the country have been facing is an unacceptably high number of individuals who, when they first learn their HIV status, are close to or already have an AIDS diagnosis. Our Massachusetts data for the last three years indicate that fully 31% of individuals recently diagnosed with HIV had an AIDS diagnosis within two months of that initial diagnosis, and there are significant health disparities around HIV/AIDS with other subset populations, notably among non-U.S. born individuals. There, the proportion of lateness to care is fully 39%."

Dr. Lauren Smith added in part, "...If you know your status, you are more likely to change your behavior and that allows for a decrease in transmission and you are more likely to get appropriate care early that will

lengthen the time or prevent the advancing to an AIDS diagnosis...A third of our folks who are HIV positive progress to an AIDS diagnosis within two months - that is highly problematic and a real call to action that we do something differently."

Mr. Cranston noted, "In response to the CDC recommendations, issued in 2006, Commissioner Auerbach convened a broad-based panel of clinicians, legal advocates, HIV positive consumers, bioethicists, academics and governmental representatives that met, starting in February of 2008 through April of this year to review our response to the CDC recommendations..." He mentioned that the Department is conducting four routine screening pilots which are still ongoing. The pilots are at Baystate Medical Center, Springfield, Dorchester House Multi-Service Center, Codman Square Health Center, and Harvard Vanguard Medical Associates, Kenmore. He said there was consensus among the panel regarding routine screening itself and the supports the Department could put in place to enable that routine screening to take place. However, there was not strong consensus on the role of written informed consent. He said they felt they could move forward with many aspects of recommendations from the panel."

Mr. Cranston said, "Our goal here is to come into maximum compliance with the CDC recommendation...The opt-out screening recommendation is currently prohibited in Massachusetts by M.G.L.Ch. 111, §70F. It requires a distinct written informed consent to perform an HIV antibody or antigen test and in addition written informed consent to release the results of the test.

Staff is releasing the following clinical advisory out to all clinicians in the Commonwealth (in brief):

- DPH recommends the screening of all patients, regardless of their risk history or clinical presentation, between the ages of thirteen to sixty-four
- Patients with Tuberculosis be screened for HIV (i.e., co-infection of TB and HIV can change treatment)
- Patients seeking testing and treatment for sexually transmitted diseases be screened for HIV

- Pregnant women should be screened for HIV during the routine prenatal test and again during the third trimester (i.e., prevent transmission to newborn)
- Recommend a streamline consent process using the model brief consent language (only a few sentences are needed)
- No additional prevention counseling is needed
- DPH developed revised brochure length materials for patient education to serve the role of informed process (available in English, Spanish and Portuguese and being developed in Vietnamese, Haitian, Creole, and French)
- Coding guidelines for billing for a routine screening is available and a Frequently Asked Questions sheet is available clarifying what Chapter 111, §70F requires and does not require
- Clarified laboratory regulations or the consent form needing to follow the patient with the specimen to the laboratory by saying: an institution simply needs to have a procedure in place that lets the laboratories know that consent has been obtained
- There is an Implementation Guide which walks the institutions through the multiple models (patient-initiated, counselor-initiated, and physician-initiated testing).

In closing, Mr. Cranston said the information will be available on the website [www.mass.gov/dph/AIDS](http://www.mass.gov/dph/AIDS) and will be mailed out to primary care and urgent care providers.

A brief discussion followed, whereby Dr. Muriel Gillick asked about false positives and false negatives for screening a general population. Mr. Cranston replied in part, "Our state rules require all screening tests for HIV infection to be followed up with a confirmatory serum-based test currently the Western Block test, which has extraordinarily high specificity, to the point that we are able, where an individual may receive distressing information about a preliminary or presumptive positive result, we are able, within a relatively short period of time, to be able to provide a definitive diagnosis with the confirmatory test." Mr. José Rafael Rivera asked if there have been any changes in needle sharing behaviors. Mr. Cranston responded, "We are very pleased to report, part of the reduction in incidence in HIV has been pretty dramatic reduction in the incidence of HIV

amongst known injection drug users, who at one point in the epidemic represented close to 40% of new diagnosis and, in our most recent data, represent fewer than 15% of new diagnoses, largely, as a result of extraordinary efforts from our prevention providers, both doing needle exchange programs in the four sanctioned areas; Boston, Cambridge, Provincetown, and Northhampton with legal needle exchange programs, plus a broad array, about 18 other programs doing risk reduction education, both sexual and drug use education, and distribution of materials such as cottons, cookers, alcohol wipes, bleach kits, to enable individuals who don't have access to a sterile syringe to at least be able to sterilize a syringe before use, and particularly in needle exchange programs... We set as a collective goal, to reduce incidence to single digits in the coming years."

## **NO VOTE/INFORMATION ONLY**

### **Action Steps/follow-up:**

- Follow-up presentation by Carol Balulescu on the OPP Office, at the meeting in which she returns with the final draft of the regulations
- Training on CORI – strengthen our training through contracted agency meetings (work with sections of department that oversees community agencies (Work with Kevin Cranston and Michael Botticelli) [Auerbach asked Andy Epstein to work on this with him])
- Inform Susan Lett that the Council desires that she bring back to the ACIP board that immunizations should be decided on a national basis so that they are consistent from state to state (per Alan Woodward)
- Previously Approved Project Application No. 4-3B14 of Tufts Medical Center requests for a significant change application was approved. Applicant agreed to review their community health

initiatives to see if still relevant after the time lapse (José Rafael Rivera to Gorga)

The meeting adjourned at 11:45 a.m.

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John Auerbach, Chair

LMH