

PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on September 9, 2009, 9:15 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, Ms. Helen Caulton-Harris, Mr. Harold Cox, Dr. John Cunningham, Mr. Paul J. Lanzikos, Mr. Denis Leary (arrived at 10:40 a.m.), Mr. José Rafael Rivera, Dr. Meredith Rosenthal (arrived at 9:17 a.m.), Mr. Albert Sherman, Dr. Michael Wong, Dr. Alan C. Woodward, and Dr. Barry S. Zuckerman. Members absent were: Dr. Michèle David, Dr. Muriel Gillick and Ms. Lucilia Prates Ramos. 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 Administrative and Finance. He went over the docket for the day. For the record, Dr. Meredith Rosenthal arrived during Chair Auerbach's introductory remarks at approximately 9:17 a.m.

REGULATIONS: REQUEST APPROVAL TO PROMULGATE AMENDMENTS TO 105 CMR 128.000, HEALTH INSURANCE CONSUMER PROTECTION:

Attorney Carol Balulescu, Director, Office of Patient Protection and Deputy General Counsel, Office of the General Counsel presented the request to promulgate amendments to 128.000, Health Insurance Consumer Protection to the Council. She stated in part, "...The proposed amendments make minor changes to the regulation, to reflect the requirements of Mass. General Laws, Ch.176R, which requires health plans to recognize nurse practitioners as participating providers. Each health plan must additionally provide benefits to insureds who received 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

the 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. Most of the proposed amendments involve changing the term primary care physician to primary care provider, as defined in Chapter 176R, as well as adding the definition of primary care provider. In addition, OPP must amend its regulation to incorporate a change made by the Division of Insurance, which now requires health plans to report disenrollment information for nurse practitioners, as well as for physicians. As required by law, OPP sent these amendments to the members of the Managed Care Advisory Committee on April 29, 2009, and received no comments." Attorney Balulescu noted further that a public hearing was held on the proposed regulations on July 30, 2009, attended by two parties, the Massachusetts Association of Health Plans, and the Massachusetts Coalition of Nurse Practitioners, attended the hearing and submitted written comments in support of the proposed changes.

In closing, Attorney Balulescu said, "OPP requests approval to promulgate the amendments as shown on Attachment 1, which is unchanged from the version presented to the Council in June. Following the approval by the Council, OPP will file the amendments with the Secretary of the Commonwealth for publication in the Massachusetts Registry."

Mr. Albert Sherman made the motion for approval. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the **Request to Promulgate Amendments to 105 CMR 128.000, Health Insurance Consumer Protection**. A copy of the approved amendments is attached and made a part of this record as **Exhibit No. 14,935**.

Presentation: "Office of Patient Protection", by Attorney Carol Balulescu, Director, Office of Patient Protection and Deputy General Counsel

Attorney Balulescu said in part, "...The Office of Patient Protection was established in July of 2000. We administer Sections 13-16 of

Mass. General Laws, Chapter 1760. Our charge is to assist consumers with questions or concerns regarding managed care, to establish an Internet site for reporting of data, and establish an external review process. We share responsibilities with the Division of Insurance which is responsible for accrediting health plans and for the oversight of utilization review. OPP is responsible for the oversight of health plan internal grievance procedures for the internal appeals processes, for certain continuity of care provisions, and we also administer an external review process. Our jurisdiction does not extend to all of the health plans that insure individuals in the Commonwealth. We don't have any jurisdiction over most of the government funded plans: Medicare and MassHealth and persons who work for the federal government and have the Federal Employee Health Benefit Plan are not eligible for our services. The one exception to that is Commonwealth Care, the new subsidized health insurance that was part of Health Care Reform is subject to consumer protections in Chapter 1760. We oversee plans that are issued in Massachusetts..."

Attorney Balulescu further explained, "...If a health plan does issue an Adverse Determination, which is again a medical necessity denial, they have to comply with the requirements of the law in terms of what they set forth in that Adverse Determination. They can't simply say, the claim is not medically necessary and leave it at that. They have to identify the specific information upon which the Adverse Determination is based. They have to discuss the insured presenting symptoms or condition. They have to specify any alternative treatment options, reference and include applicable clinical practice guidelines and review criteria and, most importantly, they have to provide a clear, concise and complete description of the carrier's formal internal grievance process and the procedures for obtaining external review with the Office of Patient Protection. If the first answer from a health plan is no, the members do have a right to file an internal appeal, or file a grievance with the health plan. We use the terms interchangeably, and a carrier has to respond in writing within thirty business days for most grievances. They also have to have a process for handling expedited grievances. A grievance of an Adverse Determination, a medical necessity denial, has to be

reviewed by a same or similar specialist in at least one level of the review. An adverse Determination, if ultimately the health plan is still saying no, an Adverse Determination is eligible for the external review process, administered by the Office of Patient Protection. If the health plan fails to meet the time lines, then the grievance is automatically resolved in favor of the member, and this does happen occasionally.... For expedited cases, the law sets forth different requirements. If somebody is an inpatient at the time that their claim is denied, the case has to be resolved prior to their discharge from the hospital, which is very important. It means that a health plan cannot deny care and, in effect, kick-out a patient. A patient is entitled to the final disposition of the grievance before discharge."

She noted that another important function of the office is assisting consumers who have general questions or problems with managed care. The office has a managed care ombudsman (Stephanie Carter) and a nurse reviewer (Joanne Petty-McGinn) who deals with these questions by consumers and resolve issues between them and the health plans. The office helped recover in excess of a million dollars in claims for people.

A brief discussion followed by the Council. Please see verbatim transcript for full presentation. Dr. Woodward said in part, "...OPP is a small piece of the most comprehensive managed care patient bill of rights (Chapter 141) enacted in the country and is a model for other states. It makes sure that patients get what is appropriate and what is defined in their contracts in a fair and equitable way." Chair Auerbach stated to Attorney Balulescu, "Clearly you and your staff are making an enormous difference in terms of protecting the rights of the residents of this state, including people in the most challenging and vulnerable time of their lives." Thank you to you and your staff."

NO VOTE/INFORMATION ONLY

**RECONSIDERATION OF VOTE CONCERNING EMERGENCY
PROMULGATION OF AMENDMENTS TO 105 CMR 700.000
(IMPLEMENTATION OF THE CONTROLLED SUBSTANCES ACT)
AUTHORIZING ADMINISTRATION OF VACCINES BY
DESIGNATED HEALTH CARE PROFESSIONALS:**

Dr. Grant Carrow, Deputy Director, Bureau of Health Care Safety and Quality and Director, Drug Control Program presented the proposed amendments to 105 CMR 700.000 to the Council. He was accompanied by Attorney Howard Saxner, Deputy General Counsel, Office of the General Counsel, who worked on the specific language of the regulations.

Dr. Carrow said in part, "...The emergency regulations are part of the Department's efforts in preparing and planning for the H1N1 virus this fall. The goal is to expand the number of vaccinators to meet the increased demand for influenza vaccine that is anticipated this fall (need to distribute between six and nine million doses of seasonal and H1N1 vaccine) in a short period of time..."

Attorney Howard Saxner followed and said in part, "The Council at its previous meeting of August 12, 2009, approved for emergency promulgation, a set of regulations that would allow the Commissioner to designate certain groups of health care professionals who would be allowed to administer vaccines under a couple of conditions: (1) the prevention of pandemic or novel influenza virus and (2) that the Commissioner made a determination that there were not sufficient health care professionals to permit timely administration of the vaccine. The reason we had to do this was because under Chapter 94C of the M.G.L. limits the number of health care professionals who can administer vaccines and other controlled substances. The concept behind it was to allow the Commissioner of Public Health, by order, to designate certain health professionals groups that would include dentists, pharmacists and paramedics to administer vaccine. As protections for the public in doing this, the persons doing this would have to be licensed or certified health care professionals and they would have to administer only in accordance with the Commissioner's order. The Commissioner's order would govern such things as storage and handling of the vaccine, record-keeping and administration of the vaccine. In addition, there would have to be an order of a licensed practitioner in order to go ahead with it.

Attorney Saxner continued, "...At the August meeting the Council raised the question as to whether medical and nursing students should also be allowed to administer vaccines if designated by a Commissioner's order. Staff reviewed the issue and reached the conclusion that, at least making an allowance for this possibility would be a good idea and so we have written that into the proposed regulations (presented today) as Attachment B. As protections for the public, it would require students be duly enrolled in an approved or accredited program leading to licensure, and that the student be administering in accordance with any policies of that program. In addition, the student would also have to be authorized and supervised by a licensed and qualified health care professional." Attorney Saxner noted that language was added to Attachment B allowing the designated health professionals, per the Commissioner's order, to administer seasonal flu vaccine as well as the H1N1 vaccine.

Dr. Grant spoke about the guidelines for implementation of the emergency regulations. He said in part, "What those guidelines do is add dentists, paramedics, and additional pharmacists as potential vaccinators. The draft guidelines provide immunization clinics with the right to determine which individuals may administer vaccine in their programs and those clinics may also require vaccinators to have additional training or competency evaluation. The guidelines may be changed at any time throughout the flu season by the Commissioner, depending on emerging conditions..."

Dr. Grant noted that the guidelines changed the age-limit from 18 years old down to 12 years old for administering shots by a pharmacist and expanded training options for pharmacists. The guidelines authorize paramedics to administer vaccine and they will continue to be overseen by the ambulance service medical director and continue to act under the statewide treatment protocols. The guidelines provide that training for immunization can be provided by the ambulance service based on either the Office of Emergency Medical Services or DPH standards. The guidelines authorize dentists to administer immunization under the auspices of established immunization programs in the state, and the training will be conducted by health care facilities or professional schools, DPH itself,

or under the auspices of the Massachusetts Dental Society. He noted that the guidelines have requirements for training programs to administer vaccines and require the documentation of said training. It was noted that medical students will have to be in their third or fourth year and for nursing students the requirement that they completed their vaccination training and their schools would assert to their proficiency.

Discussion followed by the Council. For the record, Ms. Jean Pontikas, Interim Director, Bureau of Health Care Safety and Quality and Dr. Larry Madoff, Director, Division of Epidemiology and Immunization, Bureau of Infectious Disease, Prevention, Response and Services joined the discussion. It was noted by Dr. Madoff that the decision to limit administering vaccine to third and fourth year medical students was based on clinical competency. Dr. Woodward noted that the reasoning behind adding the seasonal flu to the regulations is because seasonal and H1N1 vaccines can be given simultaneously by the additional providers which would be an efficient use of resources. Chair Auerbach clarified further, the Departments reasoning regarding medical students. He stated, "We are really at cutting edge of rethinking how we incorporate a range of different people in training, as well as health care professionals in the vaccination effort, and for that reason, we wanted to be somewhat cautious. We wanted to be sure that we would assure the public that we are doing this in a careful and considered way..." Ms. Helen Caulton-Harris asked for clarification on who would choose vaccinators in the communities and if the groups of vaccinators are to be expanded – would the Public Health Council be acting on that.

Chair Auerbach responded as follows: "...Even though it is not required by the regulations I would not feel comfortable about expanding the number of health care workers that would be allowed under this order beyond the three that we have highlighted namely the paramedics, pharmacists and dentists without coming back to the Council for a full discussion...I would pledge to do that before going beyond that...We want to clarify that the clinic organizer has complete control over who is allowed to vaccinate..."

Chair Auerbach noted the emergency regulations approved at the August 12, 2009 meeting had not been filed with the Secretary of the Commonwealth purposely so that the ninety day effective date would begin on September 14, 2009. The Council needs to rescind last month's approved regulations so there are not two conflicting sets of regulations.

Dr. Alan Woodward moved to Rescind the Emergency Regulations Approved by the Public Health Council on August 12, 2009, 105 CMR 700.000. After consideration upon motion made and duly seconded it was voted unanimously to **Rescind the Emergency Regulations Approved by the Public Health Council on August 12, 2009 105 CMR 700.000 (Implementation of the Controlled Substances Act), Authoring Administration of Vaccines by Designated Health Care Professionals (Attachment A of the memorandum to the Public Health Council dated September 9, 2009).**

Mr. Albert Sherman moved to approve the **new language of Emergency Regulation 105 CMR 700.000 (Implementation of the Controlled Substances Act), Authoring Administration of Vaccines by Designated Health Care Professionals.** After consideration upon motion made and duly seconded it was voted unanimously to approve **Emergency Regulation 105 CMR 700.000 (Implementation of the Controlled Substances Act), Authoring Administration of Vaccines by Designated Health Care Professionals (Attachment B of the memorandum to the Public Health Council dated September 9, 2009).** This includes in brief the addition of (1) "or a medical or nursing student duly enrolled in an approved or accredited program for licensure and acting in accordance with the policies of that program" ...[and]..."authorized and supervised by a licensed and qualified health care professional" (2) add "or seasonal influenza" virus and (3) and minor clarifying language. Staff's memorandum to the Council dated September 9, 2009 and Attachments A and B are attached and made a part of this record as **Exhibit Number 14,936. Please see Attachment B for the full text of the approved language of 105 CMR 700.003(H).**

For the record, Dr. Gillick, Dr. David, Mr. Leary, and Ms. Prates Ramos were not present for any of the above votes.

DETERMINATION OF NEED:

COMPLIANCE MEMORANDUM: PREVIOUSLY APPROVED APPLICATION NO.4-4916 OF CARITAS PET IMAGING, LLC:

Ms. Joan Gorga, Director, Determination of Need Program, presented the request by Caritas Pet Imaging to add an additional host site to their PET service. Ms. Gorga said in part, "...I am presenting for your action, a request for significant change, filed by Caritas PET Imaging, for the Previously Approved Project No. 4-4916, a mobile positron emission tomography service. The holder is an affiliate of the Caritas Christi Health Care System and with two mobile vans presently provides PET services at ten host sites in Western Massachusetts, Greater Boston, and Southeastern Massachusetts. The staff summary indicated there were nine host sites because the staff thought one of them was not operational, but it is. There are ten host sites. The new host location is in Dartmouth, Massachusetts at Hawthorn Medical Associates, a large group practice which has referred over 250 patients per year for PET scans. The part-time, one day per week, Caritas service will replace an existing PET service providing similar part-time service. Later this year, St. Anne's Hospital will open a satellite radiation therapy service on the Hawthorn campus." Ms. Gorga noted that there would be modest increases to the MCE and the operating costs. Staff recommended approval of the request.

Dr. Alan Woodward asked for clarification of the 250 pet scans that will be done at this new location, whether they were being done by the mobile unit there now. Attorney Andrew Levine, on behalf of the applicant replied yes.

Mr. Paul Lanzikos made the motion to approve the request. After consideration, upon motion made and duly seconded, it was voted unanimously [Ms. Helen Caulton-Harris and Mr. Albert Sherman not

present and therefore did not vote on this item] to approve the **Request by Previously Approved Application No. 4-4916 of Caritas PET Imaging, LLC** for a significant change to add an additional host site, Hawthorn Medical Associates, 535 Faunce Corner Road in Dartmouth, MA a multi-specialty physician practice. This amendment is subject to the following condition:

1. All conditions attached to the original and amended approval of Project No. 4-4916 shall remain in effect.

CATEGORY 1 APPLICATION: NO. 4-3B79 OF YOVILLE HOSPITAL/SPAULDING REHABILITATION HOSPITAL – TRANSFER OF OWNERSHIP REQUEST:

Mr. Bernard Plovnick, Consulting Analyst, Determination of Need Program, presented the Spaulding Rehabilitation Hospital, Cambridge, Inc. request for transfer of ownership of Youville Hospital. Mr. Plovnick indicated that the project followed the Alternate Process for Transfer of Ownership of the Determination of Need Regulations, 105 CMR 100.600 et seq. and satisfies the requirements. The Office of Health Equity conducted a review of the interpreter and outreach services available to limited and non-English proficient (LEP) patients at the Hospital. As a condition of approval, OHE recommended and DoN staff agreed that the applicant have in place the elements of a professional medical interpreter service. In conclusion, Mr. Plovnick stated, “Based upon our review of documents submitted by the applicant, and the Suitability Review conducted by the Division of Health Care Quality, we found the applicant to be in full compliance with the requirements of the ultimate process for Transfer of Ownership and recommend approval.” It was noted that there were no Ten Taxpayer Groups registered in opposition to this project and staff did not conduct a public hearing.

A brief discussion followed by the Council. Mr. David Stordo, President of Partners Continuing Care and Spaulding Continuing Care Network and representing Mr. Daniel Lahey, President of Youville Hospital responded to questions by the Council. The Council asked if

this request is prompted by financial distress at Youville Hospital. Mr. Stordo responded, "...The short answer to the question is, yes, Youville sustained some significant operating losses secondary to changes in how Medicare reimburses such hospitals and, given the types of patients who we have been admitting there over the years, it made it untenable for Youville and its current owner, Covenant Health System, to continue the operation...We will achieve some management efficiencies that should mitigate some of the operating losses, certainly not eliminate them entirely...Given the capacity constraints at our academic medical centers, the Mass General and Brigham and Women's Hospitals, a lot of the patients who we are caring for at Youville and in some of our other entities are patients who would not be able to leave the acute hospital if we weren't willing to provide the care in the alternative setting at a lower cost...From a broader system perspective, it makes sense for us to sustain those losses in one entity in order to allow for the patient flow throughout the system..."

Per the DoN guidelines, the hospital's primary service area for chronic disease services encompasses the northeast region of the state and for acute inpatient rehabilitation services, its service area extends to the state as a whole so the Board of Trustee Membership meets DoN criteria.

Dr. Michael Wong moved for approval of the transfer application. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the request for **Transfer of Ownership of Youville Hospital**, a long term care hospital with 180 beds (100 chronic care, 80 rehabilitation) through the sale of its assets to Spaulding Rehabilitation Hospital Corporation, a private, nonprofit corporation of which **Partners HealthCare, Inc.** is the sole corporate member, with no maximum capital expenditure and no incremental operating costs. The staff summary is attached and made a part of this record as **Exhibit No. 14,937**. This Determination is subject to the following condition:

1. To ensure optimal and timely provision of competent medical interpreter services and outreach to the limited and non-English

proficient (LEP) patients, Spaulding Hospital – Cambridge shall implement the recommendations of the Office of Health Equity (OHE) as outlined in section III of the staff summary.

Notes for the record: Ms. Caulton-Harris returned to the meeting during discussion on the Youville application at approximately 10:35 a.m.. Mr. Denis Leary arrived at the meeting at approximately 10:40 a.m. in time to vote on the Youville application. Mr. Sherman was not present to vote on the last item, the Youville application.

Mr. José Rafael Rivera noted for the record that September is Substance Abuse Recovery Month and that everyone should take the opportunity to celebrate the good work of the people in recovery and those who support people in recovery.

No Follow-up Action Steps.

The meeting adjourned at 10:45 a.m.

John Auerbach
Chair

LMH