MINUTES OF THE PUBLIC HEALTH COUNCIL

Meeting of August 12, 2015

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

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

Docket: Wednesday, August 12, 2015 9:00 AM

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1. **ROUTINE ITEMS:**
   a. Introductions
   b. Updates from Commissioner Monica Bharel, MD
   c. Record of the Public Health Council Meeting July 15, 2015 **(Vote)**

2. **DETERMINATION OF NEED (DoN)**
   a. Healthcare Enterprises, LLC, has filed a DoN for construction of a surgical freestanding ambulatory surgical center in Shrewsbury MA. No. 2-4952 (**Vote**)

3. **PRELIMINARY REGULATION**
   a. Informational Briefing on Proposed Amendments to 105 CMR 153.000 (*Licensure Procedure and Suitability Requirements for Long-Term Care Facilities*), to Establish a Hearing Process for Closures and Changes of Ownership of Long Term Care Facilities

   b. Informational Briefing on Proposed Amendments to 105 CMR 164.000: *Licensure of Substance Abuse Treatment Programs*.

   c. Proposed Amendments to 105 CMR 700.000: *Controlled Substances Act* related to use of the Prescription Monitoring Program

   d. Informational Briefing on Proposed Rescission of 105 CMR 525.000: *Newburyport Shellfish Treatment Plant*

4. **PRESENTATION**

   a. Ticks and Tick-borne Disease in Massachusetts

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

Public Health Council

Presented below is a summary of the meeting, including time-keeping, attendance and votes cast.

Date of Meeting: Wednesday, June 10, 2015
Beginning Time: 9:10 AM
Ending Time: 11:33 AM
Attendance and Summary of Votes:

Board Member	Attended	Item 1c Minutes of the July 15, 2015 Meeting	Item 2a Determination of Need No. 2-4952, Healthcare Enterprises, LLC
Monica Bharel	Yes	Yes	Yes
Edward Bernstein	Yes	Yes	Yes
Derek Brindisi	Yes	Yes	Yes
Harold Cox	Absent	Absent	Absent
John Cunningham	Yes	Abstained	Recusal
Michele David	Absent	Absent	Absent
Meg Doherty	Yes – Arrived at 9:57AM	Not present at time of vote	Yes
Michael Kneeland	Yes	Yes	Recusal
Paul Lanzikos	Yes	Not present at time of vote	Yes
Denis Leary	Yes – Arrived at 10:02AM	Not present at time of vote	Yes
Lucilia Prates-Ramos	Yes	Abstained	Yes
Jose Rafael Rivera	Absent	Absent	Absent
Meredith Rosenthal	Absent	Absent	Absent
Alan Woodward	Yes	Yes	Yes
Michael Wong	Yes	Abstained	Yes
Summary	**11**	**5 Approved, 3 Abstentions**	**9 Approved, 2 Recusals**

PROCEEDINGS

A regular meeting of the Massachusetts Department of Public Health's Public Health Council (M.G.L. c. 17, §§ 1, 3) was held on Wednesday July 15, 2015 at the Massachusetts Department of Public Health, 250 Washington Street, Henry I. Bowditch Public Health Council Room, 2nd Floor, Boston, Massachusetts 02108.

Members present were: Department of Public Health Commissioner Monica Bharel (chair); Edward Bernstein, MD; Derek Brindisi; John Cunningham, PhD; Meg Doherty; Michael Kneeland, MD; Paul Lanzikos; Denis Leary; Lucilia Prates-Ramos; Alan Woodward, MD; and Michael Wong, MD.

Absent member(s) were: Harold Cox; Michele David, MD; Jose Rafael Rivera; and Meredith Rosenthal, PhD.

Also in attendance were Margret Cooke, General Counsel at the Massachusetts Department of Public Health and Jennifer Barrelle, Interim Deputy Chief of Staff for Policy and Regulatory Affairs at the Massachusetts Department of Public Health.

Commissioner Bharel called the meeting to order at 9:10 AM and made opening remarks before reviewing the agenda. The Commissioner's remarks included the following items:

Updates from Commissioner Monica Bharel, M.D., MPH

Commissioner Bharel: I am very pleased to introduce the new Associate Commissioner for the Department, Lindsey Tucker. Lindsey is the former Principal Assistant to the Commissioner of the Department of Vermont Health Access, which is responsible for the state's publicly-funded health care programs and reform efforts, including Medicaid and the health insurance marketplace. She also served as the Deputy Commissioner and was the founding chief executive of Vermont's health insurance marketplace. Prior to her years in Vermont, Lindsey worked at both the Blue Cross Blue Shield of Massachusetts Foundation and Health Care For All. We are excited to add Lindsey to our team, and know we will benefit from all of her leadership and healthcare experience.

Additionally, I would like to introduce Antonia Blinn, who is serving in the newly created position of Director of Performance Management and Quality Improvement at DPH. Antonia previously worked at the Massachusetts League of Community Health Centers, leading quality and process improvement initiatives designed to increase smoking cessation rates, reduce patient wait time, and improve immunization and cancer screening rates. She also lead efforts to design and facilitate a curriculum on quality and process improvement to align with organizational strategic goals. Her expertise will be invaluable for us all.

During last month's presentation on the Department's mosquito surveillance and response activities, Dr. Catherine Brown noted that the state could expect to detect its first case of mosquito-borne illness very soon, and outlined DPH's risk levels and response plan. Since that meeting, the first instances of West Nile Virus have been detected in communities in Massachusetts and the Department's response plan has been put into action. As a result of this surveillance work, DPH has identified 14 communities as moderate risk (Belmont, Boston, Brookline, Cambridge, Chelsea, Everett, Malden, Medford, Melrose, Newton, Revere, Somerville, Watertown, and Winthrop) and appropriately communicated proper precautions we all can take.

I am excited to announce that the Drug Formulary Commission met last week to begin work on its new, expanded mission. While not a new Commission, Chapter 258 of the Acts of 2014 increased the Drug Formulary Commission's responsibilities by tasking them with preparing a drug formulary of interchangeable drug products for opioids that have a high chance of abuse and/or misuse. Opioid abuse is a public health epidemic and the work before the Commission is critical to our efforts to develop solutions aimed at preventing and treating addiction. I know that this is a significant undertaking and I appreciate the willingness of the Commission members to be part of the fight against the opioid crisis in Massachusetts. We anticipate that the Commission will release an initial draft formulary in the early winter.

Further highlighting the Governor's, Secretary's and my commitment to fighting the opioid epidemic, DPH released updated opioid-related death data to the public.

This data shows an increase in the number of confirmed opioid deaths, as well as a rise in the number of estimated deaths. In the first three months of 2015 alone, an estimated 312 lives were lost to opioid overdoses. Clearly this is a crisis that is not going away. Under the leadership of the Baker Administration, we recognize that there isn't a one-size-fits-all solution, and we are fighting this disease on the prevention, intervention, and recovery fronts. But key to these efforts to prevent, treat and cure addiction is improved data and data analysis. I want to highlight that this release is based on work our team has done in developing and implementing a new predictive modeling technique to provide estimates of opioid overdose deaths that include confirmed cases and those that are probable but not yet confirmed by the Medical Examiner. Analysts continually improve and revise both the model and the estimates as more final determinations become available. New and updated data will be released on a regular basis.

The Commissioner announced a change in the agenda, resulting in the Informational Briefing on Proposed Amendments to 105 CMR 153.000 (*Licensure Procedure and Suitability Requirements for Long-Term Care Facilities*), to Establish a Hearing Process for Closures and Changes of Ownership of Long Term Care Facilities being presented first.

1. Informational Briefing on Proposed Amendments to 105 CMR 153.000 – *Licensure Procedure and Suitability Requirements for Long-Term Care Facilities*

Lauren Nelson, Director of Policy and Quality Improvement for the Bureau of Health Care Safety and Quality presented to the Council on proposed amendments to the long term care facility regulation that would establish a hearing process for closures and changes of ownership of these facilities. She was joined by Sherman Lohnes, Director of the Division of Health Care Facility Licensure and Certification.

At the conclusion of the presentation, Commissioner Bharel asked the members if they had any questions about these proposed changes for Ms. Nelson or Mr. Lohnes.

Dr. Woodward: It talks about that they only have to submit draft closure plan to the Department after the hearing, and then that the Department will approve or comment within 14 days. Typically, one of these closures would come to PHC so 14 days is a short timeframe, no?

Mr. Lohnes – In regard to nursing home closures, I do not believe there is a requirement for those to come before the Public Health Council currently. The timeline we have set up, though, takes into account a CMS requirement that there be a notice to residents 60 days before closure. We then worked backward from that. So, what we're doing is requiring initial notice at the 120-day point, and then there would be a draft closure plan from the facility that would be required before the public hearing. So there would be something for the public, residents, and staff to look at for the hearing. Subsequent to the hearing, we DPH would review and comment on the closure plan. The facility would then need to respond to our comments.

Dr. Woodward – So this [timeline] starts back at 120 days, I didn't see that. That gives you the notice period for the hearing, which is 90 days, right?

Mr. Lohnes – Correct, the closure hearing has to occur at least 90 days prior to the anticipated closure date.

Dr. Woodward – So then at that time there is notice at DPH, and then 60 day notice of a final decision [by the Department] follows.

Mr. Lohnes – That is correct. That way, there is actually meaning to the hearing.

Mr. Lanzikos – I have a couple of points and questions. Currently, while the Council does have some statutory authority over regulation of these facilities, that [authority] has largely been delegated to staff. As we're looking at all of the regulations moving forward, I would like for this to come into question. [In this instance] I'm not so much concerned about closures, because I think that is more of an administrative and orderly process, but I am [concerned] about transfers of ownership and relocations. I think that is something increasingly that there has been a lot of activity in the past four or five years. Prior to that it was latent, but now it is

having a lot of policy and cost implications. While I know it is not within the purview of the regulation before us, as we are looking at the broader scope of regulatory oversight I'd like the Council, the Commissioner, and staff to reexamine the proper role of the Council, particularly with transfers and relocations.

I have two questions: For proposals involving a partial closure, such as closure of a wing of a facility – would those come under this regulation or are those handled administratively?

Mr. Lohnes – For the partial closure of a facility, that is something that is handled administratively but notification to affected residents would need to occur before those residents could change rooms. That comes under federal regulations and Attorney General regulations.

Mr. Lanzikos – Would that notification follow the process of this regulation, or is it separate from this regulation if it's a partial closure?

Mr. Lohnes – That would be separate from these regulations. The closure of a partial unit would not be included in these regulatory changes, as they apply to closure of the full facility. Generally, when we see the closure of part of a facility it is due to low census and they are closing that unit to consolidate.

Mr. Lanzikos – But it has the same implications for those people residing in the unit the same way a full closure would, doesn't it?

Mr. Lohnes – Those [affected] residents would still need to receive notice before they could move to another room in that facility, or before they could be transferred to another facility. They are still required to provide notice to those residents and find adequate placements.

Mr. Lanzikos – The criteria and standards that are used for partial closures: are those part of the regulatory framework or are those purely administrative?

Mr. Lohnes – There are regulatory requirements to notify residents before transfer.

Mr. Lanzikos – Before we have final promulgation [of these regulatory amendments] I woud like to see [regulatorily] how the partial closure differs from the full closure. And my last point: several places in the presentation, the word "approval" was used. Not to get too semantic, but I want to clarify that there is consideration of approval or potential denial, particularly for transfers, and that this is not just a rubber stamp approval issued. There is serious consideration of these changes, and the potential for modification and possibly denial before approval.

Commissioner Bharel paused questions and comments from council members to welcome Representative Denise Garlick from the town of Needham, and House Chair of the Joint Committee on Elder Affairs. The Chair would like to make a statement about these proposed

regulatory amendments, and as is customary we will take the Chair out of turn. So, I would like to welcome Madam Chair to the podium.

Representative Garlick – I intend to stay and hear all the comments of the Council, but wanted to give a few comments. I wanted to be on the record as saying I also share the concern for safety and quality care everyone in this room has for our most vulnerable residents – our seniors. I wanted to reiterate what we've heard from the presentation that this legislation was passed in July of 2014, and I know it is a very complicated process to bring regulations forward and I want to commend the Commissioner who made this a top priority and allows us to be here in August, and have this process begin. I would like to respectfully request that the Public Health Council do everything in its power to keep us on the most expedient course moving forward. I know we have the public comment period and that you need to hear the regulation again after that. And I would also recommend to the Public Health Council that, to the best of your ability, you ensure that DPH will have adequate inspectors and the resources they need to ensure they are enforcing this [regulation]. As the Commissioner said, as the Chair of the Joint Committee on Elder Affairs, I come as a representative of my colleagues for whom in their communities there have been closures or transfers that have caused considerable consternation and concern about new ownership, and I am also here as a registered nurse. So, I share all of these concerns with you and hope I can be helpful in the process.

Commissioner Bharel – Thank you, Madam Chair. Do we have any other questions?

Dr. Cunningham – I want clarification of an assumption that I have that may be wrong, and that is that physical relocations to another site would follow a separate process from a transfer of ownership?

Mr. Lohnes – Yes, a change of location of a nursing home would follow a different process from transfer [of ownership] procedure.

Mr. Brindisi – Circling back to the piece about requiring a public hearing for closure, I'm interested in what penalties or enforcement measures the Department take if the hearing process was not adhered to and the facility was in closure mode. What ability does the Department have to hold the owner to that process for closures?

Mr. Lohnes – That's something we would have to look at on a case by case basis, depending on the circumstances. There is an exception in the regulation for emergency situations. For example, we had a nursing home on the South Shore that suffered a fire last winter. In a situation like that, the closure regulations would not apply. For any other closure, we would certainly look at the situation and there are provisions in the regulation that look at abandonment of the facility as neglect. That would be something we would work with the Attorney General's Office on.

Seeing no other questions or comments, the Commissioner thanked Ms. Nelson and Mr. Lohnes for their presentation.

2. Record of the Public Health Council Meeting July 15, 2015 (Vote)

Mr. Lanzikos stepped out of the meeting at 9:36 AM, and rejoined the meeting at 9:40 AM.

Commissioner Bharel asked for a motion to approve the minutes from July 15, 2015.

Dr. Woodward then made a motion to approve minutes. Dr. Bernstein seconded the motion.

All voted in favor, except Ms. Prates-Ramos, Dr. Cunningham, and Dr. Wong who abstained as they were not in attendance for the July meeting.

3. Informational Briefing on Proposed Amendments to 105 CMR 164.000: *Licensure of Substance Abuse Treatment Programs*

Commissioner Bharel welcomed Jim Cremer, Deputy Director for the Bureau of Substance Abuse Services (BSAS), and Erica Piedade, Director of Quality Assurance and Licensing for the BSAS, for an Informational Briefing on Proposed Amendments to 105 CMR 164.000: *Licensure of Substance Abuse Treatment Programs*.

At the conclusion of the presentation, Commissioner Bharel asked the members if they had any questions about these proposed changes for Mr. Cremer or Ms. Piedade.

Mr. Lanzikos – I have a question on the 300 patient threshold: how is that census determined? Is it at any point in time, or 300 throughout the course of a year? And if a practitioner were operating under that [threshold], could they voluntarily seek licensure?

Ms. Piedade – The regulations require the licensure of large office based opioid treatment, or OBOT, programs that have over 300 patients. To answer your first question, whether a program meets the threshold is determined by the number of clients served concurrently, meaning over 300 at any point in time.

Mr. Lanzikos – But once they are licensed, they could operate under 300?

Ms. Piedade – They could operate under 300. Anyone could apply for licensure, whether or not above or below 300 clients.

Mr. Lanzikos – So, anyone could voluntarily apply for licensure if under 300, but it is required for sites serving over 300.

Ms. Piedade – That is correct.

Dr. Bernstein – I have three questions. First: is it possible to, or is there rationale for not, testing for suboxone? I didn't see that as one of the testing drugs. Because I think some people

maybe are not in the program, but still use suboxone so testing their urine for suboxone might be a way of maintaining security and safety.

Ms. Piedade – These are amendments to our current regulations, and I believe that our current regulations do require testing for buprenorphine.

Dr. Bernstein – My second question is about overdose prevention: would that include distribution of naloxone by these programs?

Ms. Piedade – Currently, we have been working with our licensees to promote co-prescribing [of naloxone] for at risk clients. It is not a requirement, but we have been promoting that and having it available for all of our treatment facilities.

Dr. Bernstein – My third question is about whether these agonist prescribers are also able to prescribe methadone, since agonist [therapy] does include methadone? Also, suboxone or buprenorphine is an agonist antagonist so it is confusing to have the word agonist there, and not agonist antagonist. I can see a number of these private, for profit programs that are already offering methadone could also offer another option for suboxone and reach the 300 [client threshold].

Ms. Piedade – So according to federal regulations, if you are going to administer methadone you have to be licensed as an opiate treatment program (OTP), you have to be certified by the Center for Substance Abuse Treatment (CSAT) as well as licensed by BSAS. We have 41 methadone programs, many of which do provide buprenorphine as part of their program. Some of them also have outpatient licenses that are collocated where they can [provide] Vivitrol, which is an antagonist. We're promoting as many either outpatient or OTPs that are out to have the full spectrum of FDA-approved medications to address opioid use disorder.

Dr. Bernstein – So will they have additional requirements?

Ms. Piedade – No. Again, these are amendments to the current regulation. Within the parameters of the federal regulations, we already regulate methadone treatment programs. So, when we say OTPs we generally mean methadone treatment programs. So those 41 programs that exist that are ambulatory are already regulated by this regulation. {With these amendments], we just added the regulations for OBOTs serving over 300 clients that are not currently licensed by the Department. So, there are some OBOTs that are operating within licensed primary care centers, and some that are operating under a [BSAS] outpatient license and some that operate as part of a hospital. So this applies to the non-licensed corporate entities with sites serving over 300.

Dr. Woodward – How was the 300 client threshold established, and how many do you think are going to need to be licensed? Do you think this threshold discourages primary care providers from providing this treatment, or capping their service below the threshold?

Ms. Piedade – The legislature set the [threshold] of over 300. It would not stop primary care services already providing the service from providing it; they are licensed by the Department. But the law is very clear that it is [programs] not currently licensed by the Department. So we encourage access to buprenorphine as part of FDA- approved medication for opioid use disorder, and are not discouraging that at all. I think what we are doing is what we are required to do by the legislature and maintain balance between patient safety and patient access. So, I don't believe this will decrease access because there are plenty of primary care centers offering this service. We actually fund 18 OBOTs in primary care centers.

Dr. Woodward: So, how many additional entities do you think will be applying for this licensure?

Erica: That is a good question. Because we don't regulate large OBOTs we're not certain. We know of at least 5 in the state.

Mr. Brindisi – Is there a notification process to the municipality and/or the abutters of these facilities?

Ms. Piedade – That's a good recommendation. We know who has a DCP registration for prescribing buprenorphine so we can send out notification regarding the regulations. And, of course, we can make an alert available on our website so everyone would know that there have been added regulations that focus on the licensure of large corporate entities that prescribe buprenorphine.

Mr. Brindisi – Yes, I think if you could consider notification to municipalities so 1) they are aware of what is going on in their community and 2) so they can refer people there if necessary – municipalities get a lot of questions on this issue, especially as of late. And [notification] to the abutters as well so that they understand what is going on in their neighborhood.

Commissioner Bharel – That is a good suggestion, thank you.

Dr. Wong – To Commissioner Brindisi's comment: I know in my neighborhood here in Boston I know there was a discussion back and forth with a local housing district or community district with an OBOT that was interested in stepping into one of the commercial spaces and unfortunately there were not a lot of substance abuse intervention advocates present who could explain what buprenorphine is or what OBOT programs are and what they do to help individuals. I think I would suggest that not only would there be some kind of municipal announcement but actually having someone from the local department of health or even Massachusetts DPH BSAS present to field some of those questions. It was really a contentious discussion that went on and I was a bit appalled by some of the statements made by neighbors. The Commissioner recognized for the record that Meg Doherty joined the meeting at 9:57AM.

Determination of Need Application - Healthcare Enterprises, LLC, has filed a DoN for construction of a freestanding ambulatory surgical center in Shrewsbury, MA (VOTE)

Commissioner Bharel welcomed Eric Sheehan, Interim Director for the Bureau of Health Care Safety and Quality, for presentation of the Determination of Need application filed by Healthcare Enterprises, LLC for construction of a freestanding ambulatory surgical center in Shrewsbury, MA, and noted that Drs. Cunningham and Kneeland would be recusing themselves from this vote and would be leaving the room. Drs. Cunningham and Kneeland left the Council room at 9:58AM.

Denis Leary joined the meeting at 10:02AM, and was recognized by the Commissioner at 10:07 AM.

At the conclusion of the presentation, Commissioner Bharel asked the members if they had any clarifying questions on this application for Mr. Sheehan. Having no questions, the Commissioner called representatives of UMass and Shields to the table for their presentation.

Dr. Eric Dicson, President and CEO of University of Massachusetts Memorial Healthcare (UMass Memorial) – Thank you for considering our application. UMass Memorial is the safety net provider for Central Massachusetts. We are dedicated to delivering the highest quality, lowest cost healthcare possible for the citizens of Central Massachusetts, our primary service area, and especially the residents of Worcester County. Right now we are impaired in our ability to do that, because we have too much high cost, hospital-based operating room capacity, and too little low cost standalone ambulatory surgical capacity. As Mr. Sheehan nicely described today, what we are talking about is shifting some of that capacity from the high cost environment of the trauma center to a low cost environment, which is an ambulatory surgery center. Effectively in doing so, we are hardwiring in lower costs for people that are being cared for. This is an important part of our transition from what was classically a fee for service mentality paying the highest fee possible for a procedure to really managing the overall cost and quality for a population and moving into a more risk based ACO model. This is an important step in our transition to become a more population health-centric organization. I thank you on behalf of both [UMass Memorial and Shields] for considering this application.

Commissioner Bharel then asked if there were any questions from council members.

Mr. Lanzikos – My first question relates to patient projections that are narrative stats on page five [of the staff summary]. Could you provide a little better understanding of how the volume has gone from 8,000 [patients] in 2017 to almost 13,000 patients in 2018, and from there leveling off? Where are those patients currently getting their services, and why do those level off?

Dr. Dicson – So, right now we do 44,000 surgical cases per year at the medical center, two-thirds of those being ambulatory cases. At our level one trauma center we do 9,000 ambulatory cases. As you can imagine, that kind of operating environment is not ideal for

patients, due to parking, high copay, bumping because of emergency trauma cases that come in. So it's a tough environment for our ambulatory patients. Some of the volume will come from the trauma center cases, which will be moved over to this lower cost site that will be very nearby. All of our projected growth in ambulatory surgery is is expected to grow significantly with the aging of the population and the shift from an inpatient environment to an outpatient environment. So, this growth is due to shifting from one environment to another, and new cases due to changes in population growth. There will also be new doctors coming in doing those cases, especially in and around Worcester, potentially from St. Vincent's and other hospitals that would be shifting their cases.

Mr. Lanzikos – I understand the rationale on the growth due to demographics, but am focused on the increase from 2017 to 2018. My interpretation of what you just said is that some of those [patients] are getting their surgery in your inpatient [setting] and some are getting their surgery in maybe outlying surgical areas that you're going to bring closer to home?

Dr. Dicson – There is significant surgical migration of patients in Worcester County to outside settings to get ambulatory surgery because there is inadequate standalone ambulatory surgical capacity. And this really fractionates the care of our patients. So we may have patients on blood thinners cared for by our team that are referred for something simple like a urological procedure or a knee surgery. They are then shifted to a different group of physicians that are caring for them with no connection back to their primary care doctor, and especially for the example of patients on blood thinners this lack of continuity of care within providers is bad for the patients.

Mr. Lanzikos – I appreciate the value of that. I wonder if there is any concern among staff that the transfer of patients from other existing surgical centers might affect their volume and their cost effectiveness, and possibly ability to continue operation? Are we jeopardizing any other outlying services?

Dr. Dicson – That is a fair concern. I would say that yes, we do expect – not from other surgical centers but from hospitals – a shift in volume to the ambulatory surgery center. That is a necessary shift that has to occur in healthcare in order to bring the cost of care down. So, even for us at UMass Memorial this is not an easy transition. I think other organizations are going to have to make that same shift over time. You cannot have ambulatory surgery done in centers that cost 20, 30, 40 percent more than a standalone ambulatory surgical center. I think there will be some pain at some other providers, but I think it's a necessary pain we all must go through in order to offer high quality care for less.

Mr. Lanzikos – Could we have staff weigh in on whether there will be any disruption to the point where we could disrupt access to services unintentionally.

Commissioner asked if Mr. Sheehan or Dr. Dicson had any information on that at this time.

Dr. Dicson – All of the hospitals in that region, with the exception of St. Vincent's, are either owned by UMass Memorial Healthcare or affiliated with UMass Memorial Healthcare and we do not anticipate that any of those hospitals will be jeopardized because of that. The one [hospital] that is not owned by us or affiliated with us has a very high operating margin, has a very high altitude to be able to push the envelope.

Mr. Sheehan – DPH does not believe that patient access to care will be negatively impacted in this region, because of the system efficiencies that are outlined by the applicant.

Mr. Lanzikos – My other question has to do with the closure of operating rooms across three sites. How did you come to the determination that it made optimal sense to close a few at each of these sites rather than at one site? It would seem to me that the net operating margins, the savings would have been greater if you closed them all at one location.

Dr. Dicson – We have three campuses doing ambulatory surgery now, and it was really about where we thought the volume would shift from these and where we thought the inefficiencies existed in operating room capacity. So, at the Memorial campus for example where there are six operating rooms there's over 10,000 cases performed, many of which are appropriate for the ambulatory surgical center.

Mr. Lanzikos – My other question is regulatory – the operating rooms are being closed. If they needed to be activated in the future, and I'm assuming they are not going to be physically torn down and will still be there. What is the regulatory process to potentially bring these back into service?

Mr. Sheehan – The Determination of Need program, as one of the conditions we outlined for the three operating rooms that are currently out of service, [will require the hospital] to request an advisory opinion on whether or not any of the 3 out of service operating rooms could open.

Mr. Lanzikos – I understand that. What about the ones that are going to be closed as part of this approval? Could they ever come back into service?

Atty. Levine – The operating rooms would be gone, so that the hospital would not have rights to reopen those. So that space, once they are surrendered, would no longer be eligible to be reopened for operating purposes unless a determination of need was filed to add capacity and subsequent licensure. They would have to start the process again.

Dr. Woodward – Shields has primarily been involved in the imaging business to date. It seems like a new venture, and I assume it was for capitalization of this project and I know you've had a joint venture previously.

Mr. Tom Shields, President & CEO of Shields Healthcare – Primarily, we're well known for imaging, but our experience dates back 35 to 40 years ago to many aspects of healthcare,

including nursing homes, dialysis, radiation therapy, PET/CT, and most recently [ambulatory surgery] with the surgical center in Dedham with New England Baptist Hospital which has been operating for about a year and a half. We've had a joint venture with UMass Memorial that dates back close to 20 years. It has been a great joint venture, has been quality driven, is efficient, and is growth oriented. It's centered on a great patient experience. I think this ambulatory surgery center is what we do really well: efficient, affordable, high quality, and outpatient. That's right up our alley, and we've had a long standing and trusted relationship with UMass Memorial and I think that's why we've been invited to joint venture with them.

Dr. Woodward – So that ambulatory surgical experience is really about a year at the Dedham site.

Mr. Shields – The planning and process dates back several years, but it has been [in operation] about a year and a half.

Dr. Woodward – But it is a joint venture I assume primarily for the capitalization, as well as maybe some expertise.

Dr. Dicson – For us it is the expertise. We visited the site with New England Baptist and were impressed by the efficiencies they brought to that. We are very good at high acuity care and running trauma centers but the lower acuity environment we were going to have to build up our management capabilities in that area, and that's why we chose Shields.

Dr. Woodward – And as far as this proposal and the unwinding condition: it would fall back to UMass. Does that present a problem in this contractual relationship.

Mr. Shields – No, it does not. It was part of the agreement

Dr. Dicson – The intent was not to monetize these operating rooms or to sell shares. This is about the long term ability of us to offer high quality care at a low cost.

At the conclusion of questions from council members, Commissioner Bharel asked for a motion to accept the staff recommendation for approval of the Healthcare Enterprises, LLC determination of need application.

Dr. Wong made a motion to accept the staff recommendation to approve the Healthcare Enterprises, LLC application, which was seconded by Mr. Lanzikos.

All council members present voted in favor, with no abstentions.

Upon conclusion of the determination of need presentation and vote, Drs. Cunningham and Kneeland rejoined the meeting at 10:25AM.

Informational Briefing on Proposed Amendments to 105 CMR 700.000: *Controlled Substances Act* related to use of the Prescription Monitoring Program

Commissioner Bharel welcomed Mr. Sheehan back to the table for an informational briefing on proposed amendments to 105 CMR 700.000: *Controlled Substances Act* related to use of the Prescription Monitoring Program. He was joined by Jonathon Mundy, Director of the Drug Control Program within DPH.

At the conclusion of the presentation, Commissioner Bharel asked the members if they had any questions about these proposed changes for Mr. Sheehan or Mr. Mundy.

Dr. Wong – Thank you for that presentation; some of it was a bit shocking to me. 13 million prescriptions for controlled substances in 1 year – do we know how many individuals those were being provided to? Because we only have 6.5 million people in the state, and I know I'm not getting two prescriptions per year for controlled substances.

Mr. Sheehan – I do not have actual breakdown in front of me, but we can provide that to you at a future meeting.

Commissioner Bharel – Dr. Wong, I think you're comment points to the need to look at this. Nationally, we know there is a high number [of controlled substances prescriptions], and in Massachsuetts it reflects that as well.

Dr. Wong – Is there the ability at least to do zip code tracking to see if there are zip codes with high density?
Mr. Sheehan – In the current Massachusetts Online PMP system, there is the ability to extract and look at that data.

Dr. Wong – That could be incredibly helpful. I know from a physician or provider standpoint, there may be a number of providers who are not engaging with the PMP program the way that it was designed. But if these are data coming from pharmacies, which may be much more useful than the number of prescriptions going out, then there may be ways of targeting in some from the back end.

Mr. Lanzikos – I imagine that a number of these prescriptions are for conditions such as ADD, and it would be interesting to separate out how many are being prescribed for that type of purpose versus others. My recollection is from previous presentations that out of state mail order pharmacies do not contribute data. Is that interpretation correct?

Jon Mundy – No, they do report data to the state.

Mr. Lanzikos – So it is universal. Any prescription received by a Massachusetts resident regardless of the source – that data would be captured.

Mr. Mundy – Yes, that is correct. If [the prescription] is received in Massachusetts, it would be captured.

Dr. Woodward – You talked about some data relative to who is in this program. I think it would be great to get a one page synopsis on data presented because I think we would be surprised by a lot of the data and some of the analysis of the percentage of physicians prescribing [certain medications] in high quantities, and certainly the percentage of patients who represent the 80/20, or maybe 90/10 rule, with this – how we are able to point to areas where we can focus attention on treatment and prevention. I think this is a great step forward as far as the expediency in reporting. I do hope that a big piece of this new RFP is the concept of integrating with existing [electronic health records] so it is easy and simple to use, because that is currently one of the major concerns of physicians and why it maybe isn't optimally used in some instances. Would love to have an update with a breakdown and some analysis of the data that gives us some clues as to the magnitude of the problem and some areas of focus.

Commissioner Bharel – That's a great point, and as you know I have also used the system and definitely for the end user it needs to be improved. As we move forward, one of the primary goals is to make it more useable so more people can use it. Another priority goal is to make sure we have a way to access the data and analyze it in a way that can inform some of these questions you're raising. We can put together some interesting facts that I think the council members will be interested in and bring those to you all next time.

Dr. Bernstein – As an end user in the emergency department, one of my cardinal features is do no harm.
I'm concerned that I have never seen any mention of methadone or suboxone captured in PMP. Maybe my experience with it is limited, but I can see that I could make some mistakes if I didn't know that.

Mundy – The PMP does not track suboxone or methadone if it is prescribed for addiction recovery. We do track methadone if it is prescribed for pain management.

Bernstein: I understand that, and am suggesting that it be considered [for inclusion] in the future. One of our goals is to do no harm and protect our patients from overdose, so I think that information would be very useful.

Ms. Doherty – I would think that the Board of Registration in Medicine and the Board of Registration in Nursing and the Board of Registration for Physician Assistants would be very interested in getting that data, and could there be a reporting mechanism when there is a feeling that certain license holders have been abusing the system in that respect. Is there any interaction?

Mr. Sheehan – Some of the limitations we have in our current Massachusetts Online PMP system we outlined in our scope for the RFR that addresses end user abilities for reporting, access, and user interface [to make the system] more user friendly from the end user

perspective. So those are certainly business requirements we're looking to gather as we move forward with the new platform.

Ms. Doherty – I wanted to ask about ease of reporting for pharmacies. As we talk about underreporting, and other reports required by the state, what is the ease of providing the regulated information to you? Is it hard to submit the information that is required by these pharmacies?

Mr. Mundy – No. Most of the big chains have the ability to do that and have big data warehouses. We don't find that to be difficult at all.

Ms. Doherty – Do the smaller pharmacies find it difficult?

Mr. Mundy – I am not aware of it being an issue for smaller pharmacies either. In this day in age, pharmacies are embracing technology and almost all of them have automated pharmacy management system.

Commissioner – And just to clarify, I think you also had a question about referral to boards, and wanted to confirm that the PMP data is used for referral to respective provider licensure board.

Dr. Woodward – I would be interested, as far as the pharmacist, sometimes the physician is unaware that a patient is getting certain medications from multiple sources and even going out of state to other pharmacies. How many times when pharmacists are reviewing this, or check, or are suspicious are denying prescriptions or going back to check with the provider and providing the additional information about the fact that the patient is also at other pharmacies other places getting prescriptions. Is that coming up, or is there a way for them to interact through this system? Or is their only option to go back to what may be multiple prescribers and inform them?

Mr. Sheehan – From the program's perspective utilizing the current Massachusetts Online PMP system we understand there are some system limitations to being able to query by end users. As I talked a little bit about the scope of the new PMP online system, we've collected a lot of information from end users and stakeholders to address the ability to search and query more easily moving forward.

Mr. Mundy – The pharmacists that are engaging in being proactive when using the PMP do exercise their right to contact the prescribers when they feel it is necessary. I'm a pharmacists and I can tell you from past experience that when you're calling a physician it's usually not to tell them they're doing a great job. Sometimes the calls are fielded with collegiality but sometimes they're not. But for the most part the pharmacists that are dispensing are being proactive in their efforts to bring to the attention of physicians concerns when they see them.

Dr. Woodward – I'm suggesting in certain circumstances those pharmacists are going to have greater data access and from multiple sources through their systems above and beyond maybe

what our PMP is supplying, so I'm hoping there is some way to integrate that information when they have a concern. I'm even wondering if there could be a mechanism through the PMP, whether that would come from an individual prescriber that is now suspicious or a pharmacist who's suspicious, to in essence put a note into the system that's going to be picked up by other prescribers subsequently.

Commissioner Bharel – As we use the system more, we'll all learn how to use it better together. To your other point on the interstate issue: we are working on memoranda of understanding with surrounding states and its really being picked up at a national level, too. We're trying to see how to have these various PMP systems communicate with each other, so that's another piece of information.

Dr. Bernstein – As you go forward with the procurement, I think if they could build in an email system which could notify the physician after a certain number of prescriptions have been issued would be very helpful. As physicians will start to look at this as educational versus punitive system, you will start to have more compliance with it. I have often encountered delays when entering the date of birth and name, because there are multiple addresses so I have to then go back in order to get to the second address. I'm sure there is a more efficient mechanism you're working on, but as you go forward maybe some of these things can be fixed.

Mr. Sheehan – As we put together the proposal for the RFR, we touched on alerts and a lot of the business requirements we gathered were around the technology for alerts and notifications, as well as easier mechanisms for end users to set parameters for the types of alerts they would like to receive. All of that is in the scope of work we did provide and asked potential bidders to help us solve.

Dr. Bernstein – The key number of prescribers and pharmacists that determine the level of an alert should be researched; I'm not sure we really know what those all mean and how to use this properly. For me, I generally have a conversation with my patients about my findings, but I don't really have any guidance and didn't know if there was a way to build something into the system that looks at certain levels and outcomes.

Mr. Lanzikos – Are prescriptions that are dispensed from inpatient pharmacies reported to the system?

Mr. Mundy – No, but if a patient is discharged with a prescription from the outpatient pharmacy then those medications are reported to the system.

Mr. Lanzikos – But those for inpatient use are not captured, only if [the patient] is going home with them.

Mr. Mundy – Correct.

Dr. Wong left the meeting momentarily at 10:40AM and rejoined at 10:48AM.

Informational Briefing on Proposed Rescission of 105 CMR 525.000: *Newburyport Shellfish Treatment Plant*

Commissioner Bharel welcomed Julian Cyr, Director of Policy and Regulatory Affairs, and John Halter, Chief of Regulatory implementation, for the Bureau of Environmental Health for an informational presentation in the proposed rescission of 105 CMR 525.000: *Newburyport Shellfish Treatment Plant.*

At the conclusion of the presentation, Commissioner Bharel asked the members if they had any questions about these proposed changes for Mr. Cyr or Mr. Halter.

Dr. Woodward – Is there any other entity that is impacted by rescission of this regulation?

Mr. Cyr – This regulation only applies to this one facility. The facility is operated by the Division of Marine Fisheries, and does not include other facilities. Other shellfish purification activities would be covered by other existing Department regulations.

Dr. Woodward – When you referred to 105 CMR 133.000: *Fish and Fishery Products,* is that part of the combined food regulations that were updated less than a year ago?

Mr. Cyr – Those regulations were brought before PHC for consolidation. They have not been filed with the Secretary of State, and we are awaiting further guidance on how proceed. But, yes – that regulation was brought before the Council as part of that consolidation.

Dr. Woodward – And approved, is that correct?

Mr. Cyr – I believe that is correct, but I would defer to legal counsel.

Mr. Lanzikos: On a serious note, I'm glad something like this is coming forward because as citizens we take a lot for granted with our food and often don't consider it until something goes amiss and not when things go right every day. I just want to thank you and your staff for your vigilance.

Dr. Woodward – This was really related to restricted areas for clamming. And there really are no other restricted areas where clams are being purged by this process?

Mr. Cyr – Correct. So that would fall under the Division of Marine Fisheries. Clams that are harvested from restricted areas must go through this process, otherwise they remain restricted.

Presentation on Ticks and Tick-borne Disease in Massachusetts

Commissioner Bharel welcomed Dr. Catherine Brown to the table for a presentation on Ticks and Tick-borne Disease in Massachusetts.

Upon the conclusion of the presentation, Commissioner Bharel asked council members if they had any questions about the presentation for Dr. Brown.

Mr. Brindisi – When we think about potential mitigating efforts, I think we need to go back to the source. For Lyme disease, I know local public health is not doing the surveillance. Do health care providers have a role to play in this surveillance.

Dr. Brown – good question, and a complicated one. We know that Lyme disease is one of the most underreported diseases. Follow up by health care providers and local ehalth (recording). CDC has shown there is high underreporting. Underreporting is always going to be a problem, particularly since there are not immediate systems. We are focused on reporting trends

Mr. Brindisi – When we think about potentially mitigating efforts, I think we have to go back to try to identify the source of the infection. In the presentation, your numbers derive from the place of residence, correct? I know with Lyme disease, local public health does not do the disease surveillance. Do you think that is a gap, and that we're missing something as far as the source of infection? The onus is on the health care provider and the question is, are they doing the proper disease surveillance that local public health would have normally done for other diseases?

Dr. Brown – That is a good question, but also a complicated one. We know that Lyme diseases is one of the diseases that is significantly underreported. And when we transition from having local public health to provider follow up and reporting, we had concerns about our ability to maintain good surveillance data. The work that the Centers for Disease Control has done with four different states shows that in all four of those states, which Massachusetts was not one of, underreporting was a significant problem. They do not use the same case method follow up we do – they use the standard, local public health follow up model. Also, when we transitioned from local health to providers we looked at our data very closely to see if we saw any drop off and the fact is that we didn't. The problem is that Lyme disease of the high burden of disease and because there is no immediate public health intervention, once the person has the disease it's kind of too late. Underreporting is always going to be a problem. I am very confident that our data is accurately tracking trends, which is why I'm comfortable saying that right now, at least for the time being, we've sort of leveled off with Lyme disease. Do I think that's every single person in the state who has Lyme disease? Absolutely not.

Mr. Brindisi – Right, but when we think about disease surveillance, often the question is travel history. I know that local public health asks that question, but are the providers asking that question? Because that will help identify the source of the infection.

Dr. Brown – Because the incubation period for Lyme disease is so long – up to 30 days – there is no way to do accurate exposure identification with tick-borne disease. A couple of years ago, we did some enhanced surveillance where we asked patients diagnosed with Lyme disease if they were willing to fill out some additional information for us. We asked them to track their activities and for the 30 days prior to the onset. And so we asked them were they just in their

own yard, their own neighborhood, or did they spend time further away, and then to document the percentage of time they spent in each of those places. There used to be this feeling that Lyme disease was something that was acquired around your own home. What we learned from this is that different people get it in different places, and I think that's representative of the fact that we have endemic Lyme disease. Where they got it is not as important to me as recognizing that this is something affecting the entire state.

Mr. Lanzikos – Since there is such a strong correlation between age and acquisition of all [tick-borne] diseases, and also since there is a correlation on timing, a couple recommendations in terms of dissemination: working very closely with the Executive Office of Elder Affairs and the local councils on aging. There are 349 councils throughout the Commonwealth. By getting some of this material out to them, especially in the springtime, they can disseminate it at senior centers and in newsletters. The National Council on Aging has an annual conference where you could give a presentation or train some of their instructors. I would recommend to the Department to do some videos and podcasts on this to disseminate locally. Virtually everyone can understand it the way you explain it and then take personal protective measures. I want to commend you for all of your work.

Dr. Brown – I appreciate your ideas. We do have a series of videos that are posted online and are publically available for local boards of health to use, for anyone to use.

Mr. Lanzikos – I encourage you to send those out annually to local cable networks so they are aware of them.

Dr. Brown – We have actually done for the past two years a rather extensive media buy to get those out. There are obviously resource limitations, and it is not showing at every commercial, but we absolutely are working on that. I will also say that going to senior centers and presenting is one of our favorite things to do. In fact, Kevin Cranston [Director for the Bureau of Infectious Disease] gave one yesterday. They are a great audience and an excellent target audience.

Dr. Wong – As an infectious disease specialist, one of the problems we have is that diagnostics for any of these [tick-borne diseases] is not great. It is probably best for Lyme disease, but generally diagnosis takes full blown infection to be present to get positive serologies or indications and that can be a lot of the problem with underreporting. For Babesia and Anaplasma, the diagnostics are terrible and not user friendly. I think as you're doing here and on the website for primary education, if someone comes in and expresses concern that they may have been exposed to Lyme I think we have to try and look at all three versus examining one and forgetting about the others. That awareness is probably not very high in the primary care community and is getting better in the infectious disease community.

Dr. Brown – Maybe you and I could talk afterwards, because I would like to get your thoughts on the testing because our impression is the polymerase chain reaction tests for Babesia and Anaplasma are very good.

Dr. Wong – They are, but trying to get ahold of those in a clinical setting is quite difficult. And most physicians don't think about sending specimens to the state lab and instead go through a different lab.

Dr. Kneeland – I want to publicly thank Dr. Brown. I teach epidemiology at the University of Massachusetts, and she has graciously agreed to give a presentation on surveillance to two classes in the early winter. I was so impressed by your last presentation, and think it will be a huge benefit to first year medical students and nursing students.

Ms. Doherty – I would like to point out that I was at a council on aging meeting this week where there was a wonderful presentation on this. I live in an endemic area, and we are doing a joint project with all of the towns we provide services for as a visiting nurses association, and so my quest today is to find out if there is any money available for public education on tick-borne illness in endemic areas. We did just look at all of the data from the past five years, town by town, and look at the ratio to see what that means to the public. We use the councils on aging to do our presentations, so I would really like to thank you for your recent presentation.

Dr. Woodward – The expertise on this goes way back, and I had Dr. Al DeMaria came and presented to local public health and medical staff at the hospital, which I think can also be beneficial. While there is amplification, but it may be that the diagnosis didn't exist earlier or the pathogen could have been present in other places.

Dr. Brown – I don't think we actually know the answer to that. We do know that some of these pathogens have been identified in mummified remains in the Italian Alps and present problems for Europeans. We're not exactly sure how those may have gotten here. However, I cannot stress enough the effect of amplification.

Dr. Woodward – I think there is quite varied provider awareness of the issue and the concept, for example, of two doses of an antibiotic. If you had a tick that may well have been attached for 36 to 48 hours and is clearly a deer tick, it is remarkably benign [preventive treatment] and seems to be effective. Primary care providers are not doing that, and it is something that should be emphasized. You'd still have to watch for symptoms and may have to do serologies down the line, but it may be an early treatment/prophylaxis approach.

Dr. Brown – I think early recognition and avoiding getting sick altogether with the prophylactic use of antibiotics is something that we are working on. There is still disagreement within the infectious disease community about whether it is better to use prophylaxis or do a symptom watch. But I think at least presenting both of those things as options, so that both health care providers and the public know they are both options, might actually be worthwhile.

Ms. Doherty – My daughter got Lyme disease and lived on Nantucket at the time. Her presentation was a little odd for the time. One of the things they asked was whether she had traveled to Europe, which she had, but the timing was off. The presentation can vary based on

where it is contracted, but we have become a global society. How do we know there are no infected ticks entering via travel? I think it is something to consider.

Dr. Brown – Dogs and cats do not serve as part of the infection cycle, but a tick could possibly bring an infected tick but the chances of that are so small, the real focus is on local risk and amplification.

Commissioner Bharel requested a motion to adjourn.

Dr. Wong made a motion to adjourn. Dr. Bernstein seconded the motion. All present council members approved. The meeting adjourned at 11:33AM.

LIST OF DOCUMENTS PRESENTED TO THE PHC FOR THIS MEETING:

1. Docket of the meeting
2. Minutes of the Public Health Council meeting of July 15, 2015.
3. DoN Pending Projects
4. DoN Memorandum on DoN Project No. 2-4952
5. Copy of the PowerPoint presentation for the Informational Briefing on Proposed Amendments to 105 CMR 153.000 (*Licensure Procedure and Suitability Requirements for Long-Term Care Facilities*), to Establish a Hearing Process for Closures and Changes of Ownership of Long Term Care Facilities
6. Copy of the PowerPoint presentation for the Informational Briefing on Proposed Amendments to 105 CMR 164.000: *Licensure of Substance Abuse Treatment Programs*.
7. Copy of the PowerPoint presentation for the Informational Briefing on Proposed Amendments to 105 CMR 700.000: *Controlled Substances Act* related to use of the Prescription Monitoring Program
8. Copy of the PowerPoint presentation for the Informational Briefing on Proposed Rescission of 105 CMR 525.000: *Newburyport Shellfish Treatment Plant.*
9. Copy of the PowerPoint presentation on Ticks and Tick-borne Disease in Massachusetts

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Commissioner Monica Bharel, Chair