MINUTES OF THE PUBLIC HEALTH COUNCIL

Meeting of November 9, 2016

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, November 9, 2016 - 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 October 20, 2016 Meeting **(Vote)**

2. PRELIMINARY REGULATIONS

a. Informational briefing on proposed regulatory amendments to 105 CMR 141.000: *Licensure of Hospice Programs*

b. Informational briefing on proposed regulatory amendments to 105 CMR 153.000*: Licensure Procedure and Suitability Requirements for Long-Term Care Facilities*

c. Informational briefing on proposed rescission of 105 CMR 151.000: *General Standards of Construction for Long Term Care Facilities in Massachusetts*

d. Informational briefing on proposed regulatory amendments to 105 CMR 150.000: *Licensing of Long-Term Care Facilities*

e. Informational briefing on proposed regulatory amendments to 105 CMR 156.000: *The Training of Nurses' Aides in Long-Term Care Facilities*

f. Informational briefing on proposed regulatory amendments to 105 CMR 157.000: *The Registration and Operation of Temporary Nursing Service Agencies*

g. Informational briefing on proposed regulatory amendments to 105 CMR 720.000: *List of Interchangeable Drug Products*

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, November 9, 2016
Beginning Time: 9:09AM
Ending Time: 11:09AM
Attendance and Summary of Votes:

Board Member	Attended	Record of the Public Health Council October 20, 2016 Meeting (Vote)
Monica Bharel	Yes	Yes
Edward Bernstein	Yes	Yes
Lissette Blondet	Yes	Yes
Derek Brindisi	Yes	Yes
Harold Cox	Yes	Yes
John Cunningham	Yes	Yes
Michele David	Yes	Abstain
Meg Doherty	Yes	Yes
Michael Kneeland	Yes	Yes
Paul Lanzikos	Yes	Yes
Lucilia Prates-Ramos	Yes	Yes
Michael Rigas	Absent	Absent
Alan Woodward	Yes	Yes
Summary	**12 Members Present, 1 Member Absent**	**11 Members Approved, 1 member Absent, 1 Abstained**

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, November 9, 2016 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: Monica Bharel, MD, MPH; Edward Bernstein, MD; Lissette Blondet; Derek Brindisi; Harold Cox; John Cunningham, PhD; Michele David, MD; Meg Doherty; Michael Kneeland, MD; Paul Lanzikos; Lucilia Prates-Ramos; and Alan Woodward, MD.

Absent member(s) were: Michael Rigas

Also in attendance was Margret Cooke, General Counsel at the Massachusetts Department of Public Health.

Commissioner Bharel called the meeting to order at 9:09AM and made opening remarks before reviewing the agenda.

ROUTINE ITEMS

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

Commissioner Bharel began updates by announcing that Ron O'Connor has been promoted to serve as the Director of DPH's Office of Local and Regional Health. Ron has been with the Department for over 28 years and was appointed Interim Director of the Office in February 2015. As Interim Director, Ron has led the Office in establishing a platform for regular communications between the Department and local public health officials, fostering more meaningful relationships and a culture of collaboration. He has also focused on building a local capacity-building framework that is responsive to the ever evolving priorities and needs of our many boards of health and local public health staff. The Commissioner further stated that she believes the efforts of Ron and the Office of Local and Regional Health team will continue to provide a strong foundation for our support of the Special Commission on Local and Regional Health which was established by the legislature this past summer. Commissioner Bharel then congratulated Mr. O'Connor and thanked him for his dedicated service.

Next, Commissioner Bharel noted that this past May, the Department submitted more than 13,000 pages of documentation to the Public Health Accreditation Board (PHAB). The Department is now preparing for a planned site visit conducted by a three person PHAB Site Visit Team – the next important step in DPH achieving national accreditation. The PHAB Site Visit Team will be made up of public health experts from across the country and will meet with us in order to review DPH's submitted documentation. This two-day site visit is planned for mid-December and provides an exciting platform for the Department and Massachusetts to highlight the innovative and ground breaking efforts taking place here to improve our Commonwealth's public health.

The Bureau of Infectious Disease and Laboratory Sciences staff has completed the migration of HIV/AIDS surveillance data into the Massachusetts Virtual Epidemiologic Network or "MAVEN". This successful step marks the full integration of data of the more than 90 infectious diseases or associated agents that we require that local health department, health care providers, and clinical laboratories report to us. This statewide electronic system enables us to join together clinical disease case reports, laboratory reports, and epidemiologic investigations into a common disease surveillance and case management system. MAVEN serves as a central epidemiologic informatics system for all reportable infectious diseases that supports local health departments and state epidemiologists and clinical staff to effectively conduct disease investigations, manage outbreaks, and prevent transmission, all while maintaining the highest levels of security and patient confidentiality. This achievement is the product of ten years of development of MAVEN. Created right here in Massachusetts, MAVEN is now utilized by multiple state and city health departments across the country, as well as a number of international locations. Commissioner Bharel concluded by commending Assistant Commissioner Kevin Cranston, Dr. Alfred DeMaria, and entire BIDLS staff.

On Monday, November 7th, DPH released preliminary 2016 third quarter and updated 2015 data on opioid-related deaths among Massachusetts residents. Some key findings in the latest quarterly report include:

- 1,005 confirmed cases of unintentional opioid overdose deaths for the first nine months of 2016, with an estimated 392 - 470 suspected opioid-related deaths that may be added to that total, a pace that is unfortunately higher than the first nine months of 2015.
- A continued drop in death rates involving heroin, which have decreased at approximately the same rate that fentanyl-related deaths have increased.
- A continued rise in the number of fentanyl-related deaths with 74 percent of deaths in Q3 that had a toxicology screen showing a positive result for fentanyl.
- A third quarter decline in 2016 in the number of prescriptions and patients receiving schedule II & III opioids, when compared to the same three-month period in 2015.
- A steady increase in the number of opioid-related EMS transports, with a parallel increase in the number of transports requiring more than one naloxone administration in an effort to reverse the overdose.

During the same third quarter of 2016, the Administration rolled out several new opioid prevention, intervention, and treatment initiatives including:

- Expanding first-in-the-nation core competencies for safe prescribing of opioids to community health centers, advanced nursing, physician assistant, and dental schools.

- Successfully launching MassPAT, the new online prescription awareness and monitoring tool.

- Approval of new standing orders that allow EMS providers to administer a higher dose of naloxone to counteract overdoses.

- Adding 75 treatment beds in Taunton and Western Massachusetts.

- And the release of an unprecedented report – Chapter 55 – using advanced data to further understand the underlying causes of opioid-related deaths. This first-of-its-kind report can be found at www.mass.gov/opioids.

Commissioner Bharel then stated this report underscores that there are no easy answers in an epidemic; and so, we must continue our efforts to bend the curve of these trends. While we continue to see a decline in the number of deaths involving heroin, the data also serve as a sobering reminder of why the opioid crisis is so complex and a top public health priority. While the data continue to be troubling, the Commonwealth has never before put forth such a focused effort on addressing opioid addiction. She concluded by saying that she is confident that our sustained efforts will pay off in the long run.

Earlier this year, Commissioner Bharel shared information about the launch of the Nursing Home Rapid Response initiative. This effort seeks to ensure greater transparency, quality improvement, support of our long-term care system, and when necessary, proactive accountability when it comes to those who care for our nursing home residents. Commissioner Bharel then invited Eric Sheehan, Director of the Bureau of Health Care Safety and Quality and Kate Fillo, Quality Improvement Manager at the Bureau of Health Care Safety and Quality to give updates on this initiative. Eric Sheehan then proceeded to give an update on Information Transparency, Transfer of Ownership, and State Fines and Civil Monetary Penalties (CMP). Kate Fillo then updated the Council on Quality Improvement, including the Supportive Planning and Operations Team program. Upon the conclusion of their presentation, Commissioner Bharel asked the Council if there were any questions on the given updates.

Dr. Woodward applauded the proactive approach regarding the Nursing Home Rapid Response initiative. He then questioned the charge of $50/day for fines and inquired on whether there was anything to do to change that. He also asked whether it was all of the $3.1 million in federal fines that come to the state for this fund and for this use.

Mr. Sheehan responded saying that $3.1 million from CMS is dedicated to the Commonwealth. They then go through the procurement process to allocate those funds depending on certain initiatives.

Commissioner Bharel then stated that the $50/day is set in the Massachusetts statute.

Dr. Woodward replied that he understands that it is a part of the statute but it doesn't seem to be quite enough. He then asked due to CMS involvement would it be likely that facilities then receive fines from both the state and CMS.

Mr. Sheehan replied that that is correct.

Dr. Woodward then asked if most of the institutions we have fined also receive federal fines.

Mr. Sheehan answered that that is possible but it is dependent on the facts during each individual investigation.

Commissioner Bharel then noted that the state fines were our way of incorporating state authority.

Ms. Prates-Ramos asked for clarification on whether Healthcentrics would do capacity building with the nursing homes or whether Livanta is involved in any way.

Ms. Fillo replied that Livanta handles more of the review while Healthcentrics caters to the quality improvement piece, visiting nursing homes, hosting webinars and other informational sessions.

Ms. Prates-Ramos then asked if Healthcentrics then reports quality issues to Livanta the QIO.

Ms. Fillo replied that Healthcentrics is looking at specific quality data.

Ms. Prates-Ramos stated that there is a lot of work to be done with nursing homes and applauds their efforts.

Commissioner Bharel asked if there were any other comments or questions from the Council. Seeing none, she then proceeded with the agenda.

1. ROUTINE ITEMS
c. Record of the Public Health Council October 20, 2016 Meeting (Vote)

Commissioner Bharel asked if any members had any changes to be included in the October 20, 2016 meeting minutes. Seeing none, the Commissioner asked for a motion to approve the minutes.

Dr. Woodward made a motion to approve, and Ms. Blondet seconded the motion. All approved, except Dr. David who abstained from the vote as she was not present at the October 20th meeting.

2. PRELIMINARY REGULATIONS
a. Informational briefing on proposed regulatory amendments to 105 CMR 141.000: Licensure of Hospice Programs

Commissioner Bharel stated that as a part of Executive Order 562, the Department has conducted a comprehensive review of six regulations related to Long Term Care. This thorough review has resulted in proposed amendments that will help ensure high quality care and protections for both for residents in long term care facilities and for patients who require community-based services for daily living, including hospice care. These proposed amendments also ensure state regulations meet current best practices in clinical care, comply with recently enacted state legislation, and align with federal standards and regulations.

With these driving principles in mind, Commissioner Bharel asked Lauren Nelson, Director of Policy and Quality Assurance from the Bureau of Health Care Quality and Safety; Sherman Lohnes, Director of the Division of Health Care Facility Licensure and Certification also from the Bureau of Health Care Safety and Quality; and, Rebecca Rodman, Deputy General Counsel to provide an informational briefing on proposed regulatory amendments to 105 CMR 141.000: Licensure Of Hospice Programs.

Upon the conclusion of the presentation, the Commissioner asked the members if they had any questions or comments.

Dr. Cunningham noted that they are training in order to complete the suitability review within 30 days of the application. He asked what the usual timeline was previously.

Mr. Lohnes replied that in the prior regulations there was no time specified which led to the applicant's confusion. Normally the Department asks applicants to submit 30 days in advance but they did not have the regulatory authority to do so.

2. PRELIMINARY REGULATIONS

a. Informational briefing on proposed regulatory amendments to 105 CMR 153.000: Licensure Procedure and Suitability Requirements for Long-Term Care Facilities

With no further questions regarding the previous presentation, Commissioner Bharel then asked Ms. Nelson, Mr. Lohnes, and Ms. Rodman to remain at the table to present an informational briefing on proposed regulatory amendments to 105 CMR 153.000: Licensure Procedure And Suitability Requirements For Long-Term Care Facilities.

Upon the conclusion of the presentation, the Council was invited to ask questions and give comments.

Mr. Lanzikos asked in regards to two facilities that will be closing shortly in Melrose, whether their licenses will be permanently removed from the system or is there a possibility for reactivation.

Ms. Rodman replied that the license itself cannot be reactivated there's a provision for the beds to be out of service but not entirely gone. Beds can be brought back into service in a newly licensed facility but that is a DoN process first before it comes before licensure.

Mr. Lanzikos asked what set of regulations pertains to out of service beds.

Mr. Lohnes replied that it is this regulation 105 CMR 153.000.

Mr. Lanzikos then asked how many out of service beds are there in the Commonwealth.

Mr. Lohnes that is information that we keep on our database, however, he does not have the number with him today.

Mr. Lanzikos asked what is the value of keeping these beds latent.

Mr. Lohnes responded that it depends on the situation. With a moratorium on beds they have seen situations in Western MA where nursing homes would not be able to increase their capacity and provide service without beds out of service.

Mr. Lanzikos inquired when that exampled occurred.

Mr. Lohnes stated that it occurred 2-3 years ago.

Mr. Lanzikos stated that he does believe this is a matter of policy concern and will raise this issue during the public comment period.

Mr. Brindisi left at 9:49am.

Ms. Doherty arrives at 9:51am.

2. PRELIMINARY REGULATIONS
c. Informational briefing on proposed rescission of 105 CMR 151.000: General Standards of Construction for Long Term Care Facilities in Massachusetts

With no further questions/comments on the previous presentation, Commissioner Bharel asked the group to remain at the table to present proposed rescission of 105 CMR 151.000: General Standards of Construction for Long Term Care Facilities in Massachusetts.

Upon conclusion of the presentation, the Commissioner asked the Council if they had any questions or comments regarding the proposed rescission of 105 CMR 151.000. Seeing, none Commissioner Bharel proceeded with the docket.

2. PRELIMINARY REGULATIONS
a. Informational briefing on proposed regulatory amendments to 105 CMR 150.000: Licensing of Long-Term Care Facilities

Commissioner Bharel again, asked the group to remain at the table to provide an informational briefing on proposed regulatory amendments to information briefing on proposed regulatory amendments to 105 CMR 150.000: Licensing Of Long-Term Care Facilities

Upon the conclusion of the presentation, members were asked if they had any questions.

Ms. Blondet asked how often the review of the regulation, in this manner, occurs.

Ms. Nelson responded that Governor Baker made this a priority in Executive Order 562, in relation to the review of regulations. Some regulations get reviewed more than others depending on the nature of the topic.

Ms. Blondet then asked if the review could be at the discretion of DPH.

Commissioner Bharel replied that it can occur on an as needed basis, for example, if the statute or practice changes. The Executive Order has given the Department the ability to rigorously look at every regulation. The Commissioner then thanked the staff for completing each review in thoughtful way in such a short amount of time. She also thanked the Public Health Council for their help in moving these reviews forward. She concluded by saying it is an opportunity for the Department to streamline and take a close look at many of their policy and procedures and update them to meet standards.

Dr. Woodward noted that this is timely and important. He then commented on the use of emergency medication kits and need for someone on site to be ACLS trained to use the equipment. He then asked what the architectural access board is and inquired whether access refers to access of the facility.

Mr. Lohnes replied that the architectural access board refers to a state board that looks at handicap access versus admission to the facility. He further stated that they work closely in their planned review process to assure those requirements are met.

Dr. Woodward suggested that federal and AIA guidelines should perhaps be included and that building a new facility would possibly need more than access standards.

Mr. Lohnes informed Dr. Woodward that they can certainly make sure that that is clear.

Dr. Cunningham asked if the architectural access board is ADA compliant.

Mr. Lohnes stated that that is correct.

Dr. Cunningham asked for clarification on the requirement of facilities to have policies becoming the requirement of directors to implement policies. He concluded if you no longer have policies it is difficult to implement them and therefore asked the group for clarification on this point.

Mr. Lohnes clarified that there is still a section of the regulation that requires facilities to have policies and procedures and that they wanted to insure that staff are trained and capable to implement those policies.

Dr. Cunningham thanked Mr. Lohnes for his response.

Ms. Doherty stated that on page 15 where "including provision on the use of restraints" is mentioned that the words "physical restraint" should be included to differentiate between chemical restraints.

Mr. Lohnes replied that he believes both are included in the current definition of restraints and acknowledged that it is a very good point. He further stated that they will make sure it is clear.

Dr. Kneeland stated that he agreed with Dr. Woodward's comments. He further explained that if they have a medication kit they should specify a minimum of what it must include.

Ms. Fillo informed Dr. Kneeland and the Council that in sub-regulatory guidance they define the minimum medications that are required in the emergency kit and therefore have the flexibility to add medications as they may become appropriate.

Dr. Woodward stated that rather than specify medications it would perhaps make more sense to refer to the American Heart Association ACLS drugs.

Commissioner Bharel that we are referring to a lower level facility and not ACLS level, therefore it is in regards to medications like aspirin and narcan.

Dr. Woodward went on to say that he would not associate aspirin with and emergency medication kit.

Ms. Fillo informed Dr. Woodward that they are looking at allergic reactions, naloxone, classes of medication but they aren't consistent with ACLS medications that would be traditionally found in an emergency department.

Commissioner Bharel followed up saying that that is to align with the staffing capacities, especially at night where there may not be the same staffing pattern.

Dr. Woodward replied that with the number of arrests that occur in nursing homes it may be beneficial to mandate kits that have more than epi-pens and narcan.

Dr. Bernstein inquired about the possibility to have a code team that can resuscitate people quickly.

Ms. Fillo informed Dr. Bernstein that one of the proposed amendments is to have emergency response policies and procedures to any emergency situation that is identified and that the focus in on the early identification and activation of emergency response services, and basic, high quality CPR.

Mr. Lanzikos stated that given the evolving nature of the patients that are being cared for in the facilities, we are seeing licensed nursing facilities being used for short term younger patients. He noted the importance of anticipating this evolving population. He commented that 105 CMR 151 and 153 reference levels 1, 2, 3 and 4. He inquired on whether this nomenclature is used outside of those regulations.

Mr. Lohnes replied that that is terms we use for licensure. When facilities receive their licenses their beds are designated as level 2 or 3. He then noted that we currently have no level 1 beds. Level 2 and 3 align with beds that are Medicare/Medicaid certified versus those that are Level 3 and Medicaid only beds.

Mr. Lanzikos asked how would the regulations affect a new construction and whether we would anticipate the development of a level 3 unit.

Mr. Lohnes replied that he defers to MassHealth but he believes he believes they require new facilities to be both Medicare and Medicaid certified.

Mr. Lanzikos stated that his understanding is that all beds in a facility should be able to be used for Medicare and non-Medicare recipients.

Mr. Lohnes replied that that may be true for new facilities but there are existing facilities that are Medicaid only due to the requirements when built.

Mr. Lanzikos asked if level 1 facilities exist.

Mr. Lohnes informed Mr. Lanzikos that they can certainly look at that but they would like to have flexibility if changes are necessary.

Ms. Doherty stated that the acuity level of the patients has changed leading to a completely different population.

Commissioner Bharel then asked the members if they had any additional questions or comments. Seeing none, she proceeded with the docket.

2. PRELIMINARY REGULATIONS

e. Informational briefing on proposed regulatory amendments to 105 CMR 156.000: The Training of Nurses' Aides in Long-Term Care Facilities

Commissioner Bharel then announced that this same group will provide an informational briefing on proposed regulatory amendments to 105 CMR 156.000: The Training of Nurses' Aides In Long-Term Care Facilities.

Upon the conclusion of the presentation, members were asked if they had any questions or comments.

Dr. Bernstein asked the group to explain why people aren't required to have an orientation where the training takes place rather than allowing them to work without first completing training. He believes it would be more rational to have an orientation that includes training and would protect patients more than on the job training.

Mr. Lohnes replied that to some degree what they do in this area is highly influenced by federal regulations. There are provisions in the licensure regulations that require staff to be oriented before they go onto the floor. In both DPH and federal regulations before an individual can begin providing care they are required to complete 16 hours of training so that no one is going to floor and providing services without any orientation or training.

Dr. Bernstein asked for clarification regarding the 90 days training.

Mr. Lohnes responded that they have 90 days to complete the nurse aide training. They then need to take the examination by the 4-month point, the 4-month period is required by federal law.

Dr. Bernstein asked if they can be employed prior to that.

Mr. Lohnes informed Dr. Bernstein that they can be employed prior to that but they cannot begin providing services until they have completed the initial training and clinical training that is required.

Commissioner Bharel followed up saying that there is a full requirement for training which is more comprehensive that they have 90 days to complete, however, there is some bare minimum that needs to be completed in order to begin work at the nursing facility.

Dr. Woodward asked whether they are working as an extra body during this time or if they are included in the care team.

Mr. Lohnes replied that he would have to look at the methodology to answer that question.

Ms. Doherty stated that she is concerned because Home Health adds another 75 hours to the original nurse training program. They are also given an orientation to their particular employment but also have to demonstrate competency in order to provide care to patients. Ms. Doherty concluded by saying she is not an expert in Long Term Care but is concerned by the differences in requirements for training. She also asked if there was a language competency in relation to delivering care to patients in LTC.

Mr. Lohnes addressed the differences in LTC and Home Health training by saying that in the nursing home there will be supervisors and nurses who are going to physically be there rather than home health where an individual could be conceivably on their own. In regards to aides, in DPH regulations as well as CMS requirements staff is required to be able to respond to the needs of the residents.

Ms. Doherty asked for more clarity on the 90 day period and inquired whether they are certified as a nurse's aide before they go into the nursing home then they develop skill or are they hired and within a 90 day period they then take a course to demonstrate competency.

Mr. Lohnes expounded on the Commissioner's previous statement by informing Ms. Doherty that no one goes onto the floor without having orientation and that the 90 days is the time required to complete the training. The testing for nursing homes is different than the testing for home health as it is conducted by DPH.

Ms. Doherty explained that she understands and asked what are the skills that are expected for a potential or certified nurse's assistant as they are hired by the LTC facility. She then asked whether they have to be certified first or can they be hired prior to being certified and then gain the experience in knowledge, within the facility, during the 90 day timeline.

Mr. Lohnes stated that under Massachusetts and federal law, a nursing home can hire an individual as a nurse aide without being certified, however, before they provide services they have to do a minimum of training and orientation on key skills.

Dr. Woodward stated that he believes they are expressing is the desire for them to be support staff rather than primary providers while they are learning key skills.

Mr. Lohnes stated that there is a requirement of 16 hours of training and they work under the supervision of a nurse.

Ms. Rodman explained that she believes there is confusion because the minimum hour requirements fall under CMS, DPH has more authority of training itself.

Commissioner Bharel stated that another way of saying that is that the requirements are set at the federal level that they comply with and the quality and content of training, the Department has some supervisory control over.

Ms. Rodman confirmed that that is true and we also oversee problems.

Ms. Doherty asked for confirmation on whether there are annual competency continuing ed hours that must be met set forth by DPH.

Mr. Lohnes confirmed that is true and is required for all aides.

Ms. Prates Ramos asked how many hours is required

Mr. Lohnes replied that under federal regulations that is 12 hours in addition under the state regulation there is an additional 4 hours of dementia training required.

Ms. Prates Ramos asked if a nursing aide is hired for a LTC facility they do not need to be a CNA.

Ms. Nelson replied that is correct.

Ms. Prates Ramos then asked for confirmation that they then have 90 days to get that certification and another 30 days to take the competency test.

Ms. Nelson said that is correct per federal guidelines.

Ms. Prates Ramos asked if that certification is done at the place of employment.

Ms. Nelson said that the training can be done a variety of ways, either through community colleges, a private company, and can be arranged in house and done elsewhere.

Ms. Prates Ramos stated that she agrees with the language competency piece and suggests that there be ongoing training for that, if necessary.

Dr. Bernstein said that the wording makes it seem as though incompetent individuals are providing care.

Ms. Rodman suggested sending the Council the CMS regulations to help understand how the two interact. She stated much like an internship there needs to be time to have hands on experience while training. She then noted it can take less than 90 days if they complete the training first.

Dr. Cunningham leaves at 10:27am.

Ms. Prates Ramos stated there is ambiguity with the 90 days and the 4 months to complete.

Ms. Nelson informed her that that those are federal requirements.

Ms. Doherty stated that the determination of need and the requirements of Home Health agencies in the Commonwealth need to be looked at.

Dr. David suggested refraining from discussing it as an internship because internship implies a lot of supervision.

With no further questions, Commissioner Bharel asked the group to remain to present the present an informational briefing on proposed regulatory amendments to 105 CMR 157.000: The Registration And Operation Of Temporary Nursing Service Agencies

2. PRELIMINARY REGULATIONS
f. Informational briefing on proposed regulatory amendments to 105 CMR 157.000: The Registration and Operation of Temporary Nursing Service Agencies

Upon the conclusion of the presentation, members were asked if they had any questions or comments.

Ms. Doherty noted she doesn't see anything on demonstrating competency. She noted that there has to be something that says the temporary nurse demonstrates specific competencies for the specific area they are hire for. She then noted home health was left out and needs to be added.

Ms. Rodman replied that the temporary nurse agencies do provide nurses other than LTC facilities and that is reflected in the regulation.

Ms. Doherty requested that that be made clear.

Dr. David leaves the room at 10:41am and returns at 10:44am.

With no further questions, Commissioner Bharel proceeded with the docket.

2. PRELIMINARY REGULATIONS
g. Informational briefing on proposed regulatory amendments to 105 CMR 720.000: List of Interchangeable Drug Products

Commissioner Bharel asked Ms. Nelson and Ms. Rodman to stay at the table and be joined by Eric Sheehan, Director of the Bureau of Health Care Safety and Quality to present an informational briefing on proposed regulatory amendments to 105 CMR 720.000: List Of Interchangeable Drug Products. The presentation began with an introduction from Mr. Sheehan, followed by Ms. Nelson presenting an overview on the proposed amendments.

Upon the conclusion of the presentation, the Council was invited to ask questions and comment.

Dr. Woodward asked if there was a way to report to DPH physicians who repeatedly write in no substitutions when there is a clear abuse/inhibitory equivalent.

Ms. Nelson replied that there may be in the future. She is not certain if that is something that was included in the regulation but it is something that they can discuss in guidance and noted that the regulation does have to comeback before the Council.

Dr. Woodward noted that we currently have a mechanism that allows pharmacies to report each controlled substance and that it seems like it would be interesting to see if it's the actual medication that has been dispensed, which would mean no-substitution has been written, or if there's a pattern.

Commissioner Bharel informed Dr. Woodward that the PMP tool has great capacity to look at data in aggregate, and although not a part of the regulation, it would allow us to look at aggregate data in a new and improved way.

Dr. Woodward suggested adding it to the regulation potentially.

Mr. Sheehan stated that we are currently collecting Schedule II through V prescriptions through our new PMP clearinghouse. We can certainly look at how we can go back look at our data dictionary that the pharmacies use. There are certainly avenues that we can look at to increase how our data is being reported and analyzed.

Commissioner Bharel informed Mr. Sheehan that she believes Dr. Woodward is commenting on in terms of reporting it doesn't need to be in the regulation due to with PMP it already being in the system.

Dr. Woodward asked does the pharmacist report what was prescribed or what was dispensed. He is interested in looking at any discrepancies between the two.

Mr. Sheehan responded that what is reported into PMP is what is dispensed because that is the information that is collected at the point of sale.

Mr. Lanzikos requested that when the public hearings are set that a list of the dates be sent to the Council.

Dr. David asked how we would educate providers on this opportunity so that is set in their awareness as they are prescribing.

Mr. Sheehan informed Dr. David that they will be providing guidance and working closely with professional boards on training and information.

Dr. Bernstein suggested that there be a website for the information.

Mr. Sheehan replied that there is a currently a website and that they can send the link that has all of this information.

Dr. Bernstein stated that perhaps the board of medical registration can crosslink with that site to assure information is widespread.

Ms. Doherty asked if the formulary would be recommended to hospice and palliative care patients. She then commended the Commission's work.

Ms. Nelson replied that a long term pain management physician was on the Commission and quite often discussed that, hospice patients will definitely be considered. The prescriber who has a relationship with the patient, has the ability to prescribe how they want but do it in a thoughtful way.

Dr. Woodward stated there is always a diversion issue and if it truly equivalent we should be using them consistently across all populations.

Commissioner Bharel informed Dr. Woodward that that is an excellent point and the Commission worked to assure that that is an underlining core principle.

Dr. Bernstein raised the concern of incorporating a way of returning medicines patients don't use.

Mr. Sheehan informed Dr. Bernstein that under the S.T.E.P. law there is a statutory requirement for a Drug Stewardship Program in the Commonwealth.

Commissioner Bharel informed Dr. Bernstein that they are moving in the right direction with police stations and pharmacies and other facilities that have the drug take-back program.

Ms. Doherty informed the group that the federal government changed the stewardship rules that posed big problem in hospice in regards to who “owns” the medication. The nurse is required to turn over those medications to the family once the patient has expired.

Commissioner Bharel thanked Ms. Doherty for her comment and thanked the group for their presentation. Shen then asked if there were any additional questions from the Council, seeing none, she reminded the group that the next meeting is scheduled for December 14, 2016 at 9am. She then called for a motion to adjourn.

Dr. Bernstein made the motion and Mr. Lanzikos seconded it. All approved.

The meeting adjourned at 11:09AM.
