**MINUTES OF THE PUBLIC HEALTH COUNCIL**

**Meeting of December 11, 2019**

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**

**PUBLIC HEALTH COUNCIL**

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**Henry I. Bowditch Public Health Council Room, 2nd Floor**

**250 Washington Street, Boston MA**

**Docket: Wednesday, December 11, 2019 - 10:00 AM**

1. **ROUTINE ITEMS**
	1. Introductions
	2. Updates from Commissioner Monica Bharel, MD, MPH.
		1. Review of Opioid-related Overdose Death Data, 3rd Quarter 2019
	3. Record of the Public Health Council Meetings held October 16, 2019 and October 25, 2019. **(Vote)**
2. **DETERMINATION OF NEED**

a. Request by Partners HealthCare System, Inc. for substantial change in service to add an MRI unit and CT unit. **(Vote)**

1. **FINAL REGULATIONS**

a. Request to rescind emergency regulation 105 CMR 801.000, *Severe Lung Disease Associated with Vaping Products* **(Vote)**

b. Request to approve proposed emergency regulation 105 CMR 665.000, *Minimum Standards for Retail Sale of Tobacco and Electronic Nicotine Delivery Systems* **(Vote)**

The Public Health Council will meet in Executive Session as authorized by M.G.L. c. 30A, s. 21(a)(3) for the purpose of discussing strategy with respect to litigation, specifically:

* Vapor Technology Association v. Charlie Baker, in official capacity and Monica Bharel, in official capacity
* Mass Dynamics et. al. v. Charles Baker, as Governor and Monica Bharel, as Commissioner of Public Health
* Vapor Zone v. DPH et al.
* Vapor Technology Association v. Charlie Baker, in official capacity and Monica Bharel, in official capacity

*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**

Attendance and Summary of Votes:

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

**Date of Meeting:** Wednesday, December 11, 2019

**Start Time:** 10:07am **Ending Time:** 12:21pm

| **Board Member** | **Attended** | **Record of the Public Health Council October 16, 2019 Meeting (Vote)** | **Record of the Public Health Council October 25, 2019 Meeting (Vote)** |
| --- | --- | --- | --- |
| Monica Bharel | Yes | Yes | Yes |
| Edward Bernstein  | Yes | Yes | Yes |
| Lissette Blondet | Yes | Yes | Yes |
| Derek Brindisi | Yes | Yes | Yes |
| Kathleen Carey | Yes | Yes | Yes |
| Elizabeth Chen | Yes | Abstained | Abstained |
| Harold Cox | Yes  | Yes  | Yes |
| John Cunningham | Yes | Yes | Yes |
| Michele David | Absent | Absent | Absent |
| Michael Kneeland | Absent | Absent | Absent |
| Keith Hovan | Yes | Yes | Yes |
| Joanna Lambert | Yes | Abstained | Abstained |
| Lucilia Prates-Ramos | Yes | Yes  | Yes |
| Secretary Francisco Ureña | Yes | Yes  | Yes |
| **Summary** | **12 members present, 2 members absent** | **10 members approved, 2 members absent, 2 members abstained.** | **10 members approved, 2 members absent, 2 members 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 Friday October 25, 2019 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; Derek Brindisi; John Cunningham, PhD; Joanna Lambert, Lissette Blondet, Harold Cox; Secretary Elizabeth Chen; Keith Hovan; Lucilia Prates-Ramos; Secretary Francisco Ureña and Kathleen Carey PhD.

Absent member(s) were: Michael Kneeland, MD and Michele David, MD.

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

Commissioner Bharel called the meeting to order at 10:07 AM and before moving into the public portion of our meeting, Commissioner Bharel requested the Public Health Council meet in Executive Session as authorized by M.G.L. c. 30A, s. 21(a)(3) for the purpose of discussing strategy with respect to litigation, specifically:

* Vapor Technology Association v. Charlie Baker, in official capacity and Monica Bharel, in official capacity
* Mass Dynamics et. al. v. Charles Baker, as Governor and Monica Bharel, as Commissioner of Public Health
* Vapor Zone v. DPH et al.
* Vapor Technology Association v. Charlie Baker, in official capacity and Monica Bharel, in official capacity

Dr. Bernstein made a motion to enter Executive Session, Ms. Prates Ramos seconded it.

Following the motion, a roll call of all members was conducted, and the Council moved into Executive Session at 10:14am.

Prior to moving into executive session, Commissioner Bharel asked the Public Health Council and Department staff necessary to attend the session will now exit the Council room to go into executive session.

At the conclusion of the executive session, Public Health Council members will return to the Council room and we will move to the rest of our agenda.

The public portion of the Public Health Council meeting resumed at 10:21am.

**1. ROUTINE ITEMS**

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

*Performance Recognition Awards:*

Commissioner Bharel recognized staff here at the Department for the work they are doing every day on the extensive list of topics and programs that make up DPH. DPH held an annual employee performance recognition awards and formally recognized over 70 employees for their contributions to the Department and Commonwealth over the past year, ranging from our work in environmental health to data sharing to facilities improvements. DPH staff has garnered not one, but two awards to be presented by Governor Baker at his annual performance recognition ceremony. Two DPH teams will receive the Manuel Carballo Governor’s Award for Excellence in Public Service which recognizes the outstanding contributions of state employees who serve the citizens of Massachusetts. The first DPH team was part of the EHS Interagency Emergency Response to the 2019 Southcoast Nursing Home Closures on the South Shore. These 24 DPH staff represent operations, policy, programs, communications and legal. Their work involved extraordinary efforts responding to the community, the families, and the media. As a result of our team efforts, a process that normally takes 120 days was completed in fewer than 30 days and all 300 nursing home residents were safely relocated. This was the most significant mobilization of state agencies to manage such closures in more than a decade.

The second team was the Department’s Title X Protection Team which worked for a year and a half to protect family planning services here in the Commonwealth. Policy changes and funding decisions made by the current federal administration threatened the delivery of these critical services and thanks to our team’s thoughtful work and strategic communication, millions of dollars were allocated by our state to ensure funding and no disruption of services for thousands of low-income individuals. Our efforts showed the nation that Massachusetts fully supports access to women’s reproductive health care and family planning services.

***Governor Health Care Bill:***

Commissioner Bharel stated that Governor Baker filed a comprehensive health care bill that prioritizes behavioral health and access to primary care while seeking to reduce costs.

The bill also:

* Requires payers and providers invest more in behavioral health, setting a target to increase behavioral health expenditures by 30% over three years;
* Requiring payers maintain accurate, up to date behavioral health provider directories;
* Eliminating same-day charges for patients with medical and behavioral health appointments on the same day; and
* Eliminates facility fees and surprise bills for emergency and unplanned service for better access to care and greater patient cost transparency; and

While the legislature is now in recess for the holiday season, the Commissioner indicated she will bring the Council updates on progress in the New Year. For more information on the bill, the Commissioner directed members to mass.gov/improve-health-care-by-investing-in-value.

***Quarterly Opioid Data Report:***

Commissioner Bharel stated that the quarterly opioid overdose report that was released last week. She indicated these reports help guide the Commonwealth’s response to the opioid epidemic, and are snapshots in time that provide the data that state and local communities need to assist us in responding more effectively.

Opioid-related overdose deaths in Massachusetts declined an estimated 6 percent in the first nine months of 2019 compared to the first nine months of 2018, according to the new quarterly opioid report. The newest opioid report is accompanied by two new sections – the first is on opioid or benzodiazepine use in mothers during pregnancy and substance exposure in newborns.

Between 2016 and 2019 in Massachusetts overall, 1.85 percent of mothers used opioids or benzodiazepines during pregnancy and 1.72 percent of infants were exposed to one of these substances in the mother’s womb.

Secretary Urena arrives at 10:25am.

The second section looks at emergency department visits. Between January and September of 2019, the percentages of acute opioid and heroin-related ED visits among men were more than twice those of women. Individuals between 25 and 44 years old experienced the highest number of opioid-related ED visits. The Commissioner noted that while this kind of information continues to inform our response and approach to the opioid crisis, we can’t let down our guard because there are still too many families in the Commonwealth who have been devastated by the loss of a loved one from this preventable and treatable disease. Fentanyl remains a formidable obstacle to our efforts and its presence in these deaths has risen to an all-time high.

DPH will continue to work with our community partners to expand treatment options and opportunities, target resources to areas and populations that have the greatest need, promote best practices, and foster greater opportunities for healing and recovery.

With no questions or comments, the Commissioner proceeded with the docket.

**1. ROUTINE ITEMS**

**c. Record of the Public Health Council October 16, 2019 Meeting and October 25, 2019 Meeting (Vote)**

Commissioner Bharel asked if any members had any changes to be included in the October 16, 2019 meeting minutes. There were no changes.

Commissioner Bharel asked for a motion to accept the minutes. Motion to accept minutes, Dr. Cunningham made the motion and Dr. Carey seconded it. Secretary Chen and Ms. Lambert abstained. All other present members approved.

Commissioner Bharel asked if any members had any changes to be included in the October 25, 2019 meeting minutes. There were no changes.

Commissioner Bharel asked for a motion to accept the minutes. Motion to accept minutes, Dr. Cunningham made the motion and Secretary Urena seconded. Secretary Chen and Ms. Lambert abstained. All other present members approved.

**2. DETERMINATION OF NEED**

**a. Request by Partners HealthCare System, Inc. for substantial change in service to add an MRI unit and CT unit. (Vote)**

Commissioner Bharel invited Margo Michaels, Director of the Determination of Need Program, and Rebecca Rodman, Deputy General Counsel, to review the DoN staff summary for Partners HealthCare’s request to add MRI and CT units at its Foxborough satellite.

Commissioner Bharel stated there is a representative of the Sturdy Memorial Hospital Ten Taxpayer Group that formed related to this application here to speak upon conclusion of Margo’s presentation. Additionally, there are representatives of the applicant here with us today, who are available to respond to questions after Margo’s presentation.

Commissioner Bharel invited Joseph Casey from the Sturdy Memorial Hospital TTG to the table in order to provide some brief remarks regarding the application.

Mr. Casey made a request that Partners should not expand in the Foxborough location. With increasing BH patients are adding to additional cost for security and patient care personnel. There is no Emergency room care to the Partners site which will impact the patients seen at Sturdy in terms of specialty care services. Sturdy sees mostly Medicare and Medicaid patients The DON application pertaining to the imaging expansion was only recently available on the DPH website. EMR interoperability would be required to maintain a Sturdy request that application track and support patients that require a PCP since Partners is stating they are addressing a primary care shortage in the area. Sturdy states there was a lack of contact from Partners regarding this process. Sturdy request the applicant follow the disaggregation policy and to allow for the community to understand the regulations and protocol Partner is following. Community hospitals should be prioritized in these matters. The Community Health Initiatives process is not clearly represented from the applicant.

Upon the conclusion of the presentation, the Commissioner asked the Council if they had any questions.

Dean Cox asked about language in the report regarding excessive concerns around imaging in the Commonwealth, and concern about cost of service and asked if the applicants can address these concerns.

Ms. Michaels stated the HPC has reported that that Massachusetts has excessive use of imaging overall; we asked applicants to address its use of low value imaging through this Condition.

Dean Cox asked about the issue of excessive cost for this project, and who is eligible to receive the service and the panel of patients to receive the service.

Ms. Michaels stated they rely on HPC and CHIA reports on the costs of providers and believe the applicant made a good case that increased efficiencies through the service will not affect patient cost. Part of the annual reporting to the DoN program looks at payer mix which will be tracked in a 5 year reporting period in relation to Partners and others.

Dean Cox asked how the Applicant will respond to Sturdy’s concerns, with the major concern being that the service request by Partners is going to negatively impact Sturdy Hospital.

Dr. Smith stated they share the concern of being sure to best serve the patients for the community and there is a need met both by Sturdy and by Partners for primary care services which requires more specialty services.

Dean Cox asked about including data points that would track those receiving primary care as a result of the new service, and how the CHI funds are deployed.

Ms. Rodman responded that regarding primary care, DoN cannot respond to all activities at the location because of the scope of the application. She indicated staff looked very seriously at the application related to need by the Partners patient panel for the services requested, and are tracking Partners patients’ utilization of the service.

Dean Cox stated one of the concerns is looking at the whole system and would look at other parties that are being impacted and a community hospital should be considered.

Ms. Rodman stated that we are looking at the provider organization and the patient panel need for MRI and CT services in a specific location.

Dean Cox asked if the request by Sturdy would not be an appropriate question.

Ms. Rodman stated that is correct.

Dean Cox asked if Sturdy is part of the CHI advisory group and are the concerns of Sturdy Hospital being addressed.

Ms. Rodman stated the advisory group would recognize who are the important players.

Dean Cox stated it seems that Sturdy would be an important player.

Mr. Ben Wood stated that the current community health initiatives guidelines dictate CHI initiatives address social determinants of health for the community instead of a group of patients. The guidelines do require participation by certain sectors, but there is no requirement that an independently community hospital is required to be part of the advisory committee to plan the community health initiative.

Ms. Blondet stated that the component for community engagement is missing in the report and there are significant concerns regarding the lack of representation for the community and the population.

Mr. Wood stated that this is a concern for us as well, and staff requested the Applicant provide a more robust plan which was submitted.

Ms. Blondet asked if we can postpone this approval in order to get a more detailed plan.

Ms. Rodman stated they received a more robust plan and staff determined the project is able to move forward

Mr. Wood stated that additional information included the Applicant’s community engagement plan.

Ms. Rodman stated that the initial plan was not robust and then additional information was received.

Ms. Blondet stated that the community information is not seen in the plan and asked if there is a community element for this plan.

Mr. Wood stated that post approval of PHC, there will be a series of additional community needs meetings in the area, develop a plan and initiate through at ad hoc subcommittee to ensure there are community voices.

Mr. Blondet stated she is concerned about approving projects without having the community plan prior to approval.

Ms. Peterson stated the site at Foxborough has been open for over 10 years and during that time Partners has done a lot of work with the chambers of commerce, work around elder care, offer health education, substance use disorder work and domestic violence awareness in the community.

Kathleen Harrell stated the supplement speaks to additional community engagement including a series of community meetings with representation from the hospital to capture additional needs and give a voice/perspective from the community. There is also the ad hoc subcommittee which would determine social determinants of health needs within the community to move the community health initiative forward.

Ms. Blondet is concerned about the importance of input from residents in the area to contextualize the discussion to create relevant programs during the process for this population.

Ms. Harrell stated that others can be included and ultimately the goal is that the community is represented beyond publicly available data and have local members that will benefit and be involved in decision making during the process.

Dr. Bernstein stated there is a concern about the long term survival and growth of Sturdy Hospital and if there is a commitment to coordinating with Sturdy to provide clarity.

Dr. Smith stated they have a robust relationship with Sturdy and there are other hospitals in the area in terms of thinking about impact. There is a demonstrated need from this community around primary care that is currently not being met. This process is meant to address the need for the community which has a population that is growing and shortage of primary care in the region.

Dr. Bernstein asked what a typical MRI costs for Partners and Sturdy.

Dr. Smith stated that we cannot discuss contracted rates.

Dr. Bernstein asked who pays for it.

Dr. Smith stated that Partners have 90% primary care patients in ACO, which is the highest in the Commonwealth.

Dr. Bernstein asked if there is an incentive to keep cost down.

Dr. Smith stated yes, and the use of imaging can save money if used properly.

Dr. Bernstein stated a concern about unneeded testing.

Ms. Prates Ramos asked why we can’t know the cost of an MRI in the spirit of transparency.

Dr. Smith stated that if a patient had a specific request we can provide that on a case by case basis, but cannot release it publicly.

Ms. Prates Ramos asked if approved, can we request that Sturdy be included in the process for CHI.

Ms. Rodman responded while it is not appropriate as a condition, it is something the PHC could ask Partners to discuss with Sturdy.

Ms. Lambert asked if there is any plan to address the behavioral health needs of community, in particular for primary care panel and integrating services for those patients.

Ms. Michelle Keenan stated we would involve people within EHS and DPH that would help to incorporate the needs of this area and committed to addressing those needs at a community advisory ad hoc sub

Ms. Lambert asked if there are behavioral health services on site.

Ms. Peterson indicated these services are embedded and are growing.

Mr. Hovan asked how many full time equivalent (FTEs) providers you anticipate having in Foxborough.

Ms. Peterson indicated there will be 25 FTEs between Primary Care and mid-level by the end of 2023

Mr. Hovan asked if they take all patients regardless of ability to pay.

Ms. Peterson stated yes

Mr. Hovan asked DPH staff if the payer mix is reflective of the service area.

Ms. Rodman stated that these details go beyond the scope of this DON.

Ms. Michaels stated they did not look at payer mix by service area.

Dr. Carey asked about patient flow and capacity issues and if it will change if sufficient capacity isn’t available as a result of these new services, and in particular how community hospitals such as Sturdy would be affected.

Mr. Martin stated that the goal would be to provide same day service without having to commute outside their travel area and at times patients are sent to Newton/Wellesley. Patients are offered to been seen outside our system if they do not want to wait but there is no access to check availability of other systems.

Dr. Smith stated that Partners is moving towards all imaging are being read by specialist and the quality of the readings will improve to keep MRIs within the same system.

Dr. Cunningham asked how big the barrier is information to get to different systems in terms of differing EMRs.

Dr. Smith stated currently there are limits to what is available but it should improve for Epic users but ability to work across other systems is still a challenge.

Dr. Cunningham asked about the cost compared to other options.

Mr. Martin stated the goal is to get them seen same day but ultimately they can go where they choose.

Dr. Smith stated that a patient with a complex issue would be able to get care locally.

Mr. Brindisi stated there will be a need for further capacity due to increase in FTEs in the future and asked should be discussed today in order to avoid a capacity issues in 3-5 years. He asked if Sturdy requested community benefits funds from Partners to Sturdy.

Mr. Wood stated that some of the CHI dollars are going to the service area Sturdy hospital.

Mr. Brindisi asked if there was some type of negotiation or lack of response that led Sturdy to register as an opponent to the application.

Ms. Rodman stated she cannot answer this question.

Mr. Casey stated that was a small piece of his concern for opposing the DON.

Secretary Urena asked if there are time delays for referrals for results of imaging.

Dr. Smith stated it will reduce wait time for imaging and provide same day imaging. Currently the wait time is 2-3 weeks out.

Mr. Turner currently the wait time is 2-3 weeks out and planning to be strategic in order to accommodate same day imaging as much as possible depending priority.

Secretary Urena asked if following passage of the VA Mission Act Partners is seeing more referrals to its system and whether that was one area where additional access is needed.

Dr. Smith stated no.

With no further questions, Commissioner Bharel asked for a motion to accept the staff recommendation to approve Partners HealthCare’s request for MRI and CT units.

Secretary Urena made the motion, and Ms. Lambert seconded it.

Ms. Prates Ramos asked if we can include Sturdy Hospital in the process.

Ms. Rodman stated to formally asked Partners to include that in the process.

Dr. Smith stated yes.

Dr. Bernstein made a motion to withdraw the vote, Dr. Bernstein seconded, all approved.

Ms. Blondet stated that the process is not given the attention that it deserves and would like to hear more once they process includes community health portion.

Ms. Rodman stated the applicant has abided by the CHI required guidelines and there will be a report in 4 months on the community engagement investment which can be brought to the PHC members.

Ms. Blondet stated the guideline calls for robust local investment and she was not seeing that.

Mr. Brindisi asked why the condition for community is being asked after the request.

Ms. Michaels stated this Condition was placed in response to the TTG’s concerns: if more people from Partners Patient Panel will be getting their imaging at the new site or whether imaging orders would be driven from outside the Partners Patient Panel. The condition will provide more information on patient panel need.

Mr. Brindisi asked if the data to support this expansion of the imaging increase request.

Ms. Michaels stated yes.

Commissioner Bharel stated with no further questions, I would now like to ask if there is a motion to accept the staff recommendation to approve Partners HealthCare’s request for MRI and CT units.

Ms. Prates Ramos made the motion, Secretary Urena seconded, Dean Cox and Ms. Blondet opposed, Dr. Cunningham and Dr. Bernstein abstained. All other present members approved.

**3. FINAL REGULATIONS**

a. Request to rescind emergency regulation 105 CMR 801.000, *Severe Lung Disease Associated with Vaping Products* **(Vote)**

b. Request to approve proposed emergency regulation 105 CMR 665.000, *Minimum Standards for Retail Sale of Tobacco and Electronic Nicotine Delivery Systems* **(Vote)**

Commissioner Bharel stated on November 27, Governor Baker signed legislation placing new restrictions on the sale of e-cigarette and nicotine vaping products and flavored tobacco products, with several Council members there in person as we made history together. The new law includes a number of restrictions on the sale of tobacco products, including limiting the sale of flavored nicotine vaping products to smoking bars where they may only be vaped on-site. The legislation also grants DPH new authority to regulate the sale of nicotine vaping products, to ensure the public is informed about the potential dangers of vaping and to implement other provisions of the law in order to protect the public health.

Commissioner Bharel stated there are two votes presented to the Council: first is to rescind 105 CMR 801.000, in order to promulgate new regulation 105 CMR 665.000.

Commissioner Bharel invited Ruth Blodgett, Director of the Bureau of Community Health and Prevention; Lea Susan Ojamaa, Deputy Director for the Bureau; Ben Kingston, Director of Policy for the Bureau; and Lynn Squillace, Deputy General Counsel for the Department, to the table to present on both regulations we are discussing today.

Upon the conclusion of the first portion of the presentation regarding a request to rescind 105 CMR 801.000, the Commissioner asked the Council if they had any questions.

Commissioner Bharel asked the Council for a motion to rescind 105 CMR 801.000 on an emergency basis.

Dr. Bernstein made the motion, Ms. Blondet seconded, all other present members approved.

Staff then presented an overview of proposed emergency regulation, 105 CMR 665.000. Upon the conclusion of the presentation, the Commissioner asked the Council if they had any questions.

Mr. Brindisi asked staff to explain the menthol portion.

Ms. Ojamaa stated that mint and menthol are part of the characterizing flavor and menthol is considered a flavor.

Mr. Brindisi stated this regulation is a great starting point and would suggest continuing to evolve and prevent further use of tobacco products getting in to the hand of youth.

Dr. Cunningham asked if the grid from the presentation provided could be clarified.

Mr. Kingston stated this would be clarified on the chart.

Ms. Lambert asked when the signage will be effective and if retailers have access.

Ms. Ojamaa signage is effective immediately and available immediately for retailers either by downloading or through local boards of health for delivery.

Ms. Blondet asked if it will be available in various languages.

Ms. Ojamaa stated yes it will be available in various languages based on community needs.

Dean Cox asked about local level policies and state policies and impacts of each policy.

Ms. Ojamaa stated there are currently municipalities that restrict flavors and those local provisions will stay in place. In June the state policy restricting sale of all flavored tobacco products will be put into place.

Ms. Squillace stated that the statute recognizes the local regulations.

Dr. Bernstein asked about concerns of consumers and advocates that this is in the best interest of public health.

Ms. Ojamaa stated there are local programs and Boards of Health collaboration and youth groups supporting this regulation with the intention of putting the education first.

Secretary Urena asked about cessation services for constituents.

Ms. Ojamaa stated there is an increase in helpline calls and DPH will track results and collect data.

Commissioner Bharel asked the Council vote to approve 105 CMR 665.000 on an emergency basis.

Mr. Brindisi made the motion, Dr. Cunningham seconded, all present members approved.

Commissioner Bharel stated that this concludes our final agenda item for the day. A friendly reminder, our next meeting is scheduled for Wednesday, January 15, 2020, at 9AM.

Commissioner Bharel asked for a motion to adjourn. Dr. Bernstein made the motion, Ms. Prates Ramose seconded it. All present members approved.

The meeting adjourned at 12:21 PM.