COMMONWEALTH OF MASSACHUSETTS

NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE BOARD OF REGISTRATION IN PHARMACY

September 1, 2015 239 Causeway Street ~ Room 417 A&B Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Contact
8:30	I	CALL TO ORDER		P. Gannon
8:35	II	APPROVAL OF AGENDAPharmacy Intern Introductions		
8:40	II	 APPROVAL OF BOARD MINUTES Draft of August 4, 2015 Regular Session Minutes 		
8:45	IV	 APPLICATIONS Medminder Systems, Inc. – New Community Pharmacy The Whittier Pharmacist, Inc – Renovation/Expansion 		
9:15	V	REPORTS Applications approved pursuant to Licensure Policy 13-01	Reports	R. Harris
9:20		 FLEX SESSION Revision to Valor Act Policy Update to License Status Codes on the Check a License website NABP DISTRICT 1& 2 Meeting		V. Berg D. Sencabaugh

9:45	VI	REGULATIONS:	
		 <u>Proposed amendments to 247 CMR 5.00</u>: Orally and Electronically Transmitted Prescriptions and Reporting Requirements to the Prescription Monitoring Program (PMP) <u>Proposed amendments to 247 CMR 9.00</u>: Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments. Proposed amendments will include provisions pertaining to naloxone, as required by M.G.L. c. 94C, § 19C. <u>Proposed new regulation, 247 CMR 17.00</u>: Sterile Compounding. 	V. Berg H. Engman; D. Sencabaugh; K. Barnes; W. Frisch
11:45	VII	 FILE REVIEW PHA-2015-0101, Vashkar Karim, PH22444 SA-INV-7142, Apothecare Pharmacy, DS89820 SA-INV-6655, The Medicine Shoppe, DS2793 SA-INV-6073, Baystate Home Infusion, DS3300 SA-INV-6010, Pentec Health, Inc, DS89913 SA-INV-6071, Freedom Fertility, DS89717 SA-INV-6357 Cape Cod Infusion, DS89832 SA-INV-6647 Boston Home Infusion, DS2623 PHA-2015-0099, CVS Pharmacy #140, DS2729 	
12:30		LUNCH BREAK	

1:30	VIII	 EXECUTIVE SESSION The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, the Board will discuss and evaluate the <u>Good</u> <u>Moral Character</u> as required for registration for pending applicants, petitions for termination of probation, petitions for reinstatement, petition for reconsideration and violation of probation. 	CLOSED SESSION
2:30	IX	M.G.L. c. 112, 65C SESSION	CLOSED SESSION
5:00	х	ADJOURNMENT	

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE REGULARLY SCHEDULED MEETING 239 Causeway Street, Fourth Floor Room 417A Boston Massachusetts, 02114

September 1, 2015

Board Members Present

Board Members Not Present

Timothy Fensky, R.Ph, FACA

Patrick Gannon, R.Ph., MS, President Edmund Taglieri, Jr. R.Ph., President-Elect Richard Tinsley, MBA, M.Ed., Secretary Garrett Cavanaugh, R.Ph. Catherine Basile, Pharm D, R.Ph. Susan Cornacchio, JD, RN. William Cox CPhT Michael Godek, R.Ph. Karen Conley, DNP, RN Andrew Stein, Pharm D, R.Ph. Phillippe Bouvier, R.Ph.

Board Staff Present

David Sencabaugh, R.Ph, Executive Director David Dunn, R.Ph, Associate Executive Director Heather Engman, JD, MPH Board Counsel Kelly Ann Barnes, JD, R.Ph, Director of Pharmacy Quality Assurance William Frisch, R.Ph, Director of Pharmacy Compliance Richard Harris, Program Analyst Monica Vasquez, Compliance Officer Colleen Collins, PharmD, R.Ph. Contract Investigator Christina Mogni, R.Ph. Investigator

TOPIC: I

CALL TO ORDER

<u>DISCUSSION</u>: A quorum of the Board was present. President P. GANNON opened the meeting at 8:31AM, and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. P. GANNON also announced that the Board was recording the meeting.

TOPIC II. APPROVAL OF AGENDA

<u>DISCUSSION</u>: D.DUNN informed the Board that the minute's approval for minutes from August 4, 2015 would be deferred to a later meeting.

<u>ACTION</u>: Motion by E. TAGLIERI, seconded by C. BASILE, and voted unanimously to approve the Agenda with the noted changes.

D. SENCABAUGH introduced C. BENEVIDES as the Board's APPE rotation intern. He attends MCPHS University in Worcester, MA.

H. ENGMAN introduced Melissa Tobin as the Board's Legal rotation intern.

P. GANNON asked for any other interns in the audience to stand up and be recognized.

<u>TOPIC III.</u> **APPROVAL OF BOARD MINUTES** Draft August 4, 2015, Regular Session Minutes <u>DISCUSSION</u>: DEFERRED

TOPIC IV. APPLICATIONS:

TIME: 8:34

TIME: 8:34AM

- 1. Medminder Systems, Inc. New Community Pharmacy, Marlborough, MA
- 2. RECUSAL: P. BOUVIER recused himself and was not present for the discussion or vote on this matter.

<u>DISCUSSION</u>: The application for this pharmacy was on the August agenda, but had to be deferred, since the MOR is Board Member P. BOUVIER. Each of the other Board Members was required to file potential conflict paperwork (through Board Counsel H. ENGMAN) with the State, and did so.

Medminder was represented by Atty. Paul Garbarini, COO Brian Bouvier, and COO Eran Shavel. The business model is focused on housebound, dual eligible, frail patients for whom prescription delivery and compliance / adherence tools would be most useful. Initially they are planning to start off with one pharmacist and one technician, but will soon add another pharmacist, and eventually want any and all technicians to be nationally certified. Garbarini reported that Medminder (Hours=Monday-Saturday 9 – 5 and closed Sunday) was requesting 2 waivers; 1) they want a waiver for signage, since 2) they want to be a "closed pharmacy".

<u>ACTION:</u> Motion by C. BASILE, seconded by M. GODEK, and voted unanimously to approve the Medminder Systems, Inc.'s application to operate a New Community Drug Store, and waivers, pending a successful compliance inspection. P. BOUVIER was recused and out of the room at the time of the vote.

Time: 8:32AM

TOPIC IV. APPLICATIONS:

2. The Whittier Pharmacist, Inc. Renovation Bradford, MA RECUSAL: E. TAGLIERI recused himself and was not present for the discussion or vote on this matter.

DISCUSSION:

P.BOUVIER returned and was present for this discussion and vote. The Whittier Pharmacist was seeking approval to begin renovation in their facility located in Bradford, MA. Renovation plans included upgrades to their administrative area, as well as enhancements to their clean room, used for sterile compounding. Whittier was represented by MOR Ralph Luciano, Director of Pharmacy Karen Cheverie, and owner Michael Arcidi. Mr. Ron Raneri, architect, accompanied them to answer questions specific to construction plans.

Director of Pharmacy Quality Assurance K. BARNES and Director of Pharmacy Compliance W. FRISCH recently reviewed Whittier's project and Whittier answered questions they had during a conference call, while reviewing the blueprints, containment strategy, and continuity of care plans for the time during construction. W. FRISCH stated that both he and K. BARNES were satisfied with the plan put forth by Whittier, which plans to close down the IV room during construction, then retest the entire pharmacy prior to resuming that compounding. Cheverie explained that a "friendly" competitor, Preferred Pharmacy Services would be handling some of the patient needs during this time, if they were unable to do so themselves with commercially available product, They estimated the work would take approximately 4 weeks. After some questioning by Board members about construction in general, and security measures during construction, the Board took action.

<u>ACTION:</u> Motion by K. CONLEY, seconded by P. BOUVIER, and voted unanimously to approve The Whittier Pharmacist's request to move forward with their renovation plan, and to reopen after a successful inspection.

TOPIC V.

REPORTS

Applications Approved Pursuant to Licensure Policy 13-019:03AMDISCUSSION: R HARRIS noted that during the past month there has been Thirty -four (34)Change of Managers, approved by staff action.

ACTION: So noted

TOPIC VI. FLEX SESSION

TIME: 9:04

1. Valor Act Changes

Discussion: Chief Board Counsel V. Berg updated the Board on a provision in the FY16 budget that allowed for the waiver of licensure fees for those military professional impacted by service and eligible for the Valor Act.

2. Updates to License Status Codes

Discussion: Chief Board Counsel V. Berg updated the Board on streamline License Status Codes that would be displayed on the Board website under the "check a license" tab. The streamlined codes would be simplified for the public inquiring if the licensee is able to practice. V. BERG noted that the proposed changes would insure consistency in information provided by all DHPL Boards. The was debate among Board members regarding "retired" license status.

The Board members noted the proposed changes.

3. NABP / AACP District 1 / 2 Meeting Delegate

Discussion: D. SENCABAUGH reminded members of the District 1 & 2 NABP to be held in Portsmouth, NH. September 24-26. D. Sencabaugh informed the Board members that it would be necessary to vote on a representative that would vote on the resolutions to be considered and forwarded to annual NABP meeting for discussion by all the NABP Districts.

Nomination for Delegate: M. GODEK nominated T. FENSKY to serve as the Massachusetts delegate to the NABP District 1 / 2 meeting, seconded by K. CONLEY; and voted unanimously by roll call vote; P. GANNON; yes, E. TAGLIERI; yes, M. GODEK; yes, G. CAVANAUGH; yes, C. BASILE; yes, S. CORNACCHIO; yes, K. CONLEY; yes, W. COX; yes, R. TINSLEY; yes, A. STEIN; yes, P. BOUVIER; yes. Nomination for Alternate Delegate: Motion by C. BASILE to nominate M. GODEK as the alternate Massachusetts Delegate to the NABP District 1 / 2 meeting, seconded by E. TAGLIERI and voted unanimously by a roll call vote; P. GANNON; yes, E. TAGLIERI; yes, M. GODEK; yes, G. CAVANAUGH; yes, C. BASILE; yes, S. CORNACCHIO; yes, K. CONLEY; yes, W. COX; yes, R. TINSLEY; yes, A. STEIN; yes, P. BOUVIER; yes.

4. NABP / AACP District 1 / 2 Meeting Resolutions

DISCUSSION: The Board members reviewed two resolutions that it thought worthy of consideration at the NABP District Meeting.

1. White Bagging / Brown Bagging:

DISCUSSION P. GANNON noted that increasing insurance companies where forcing pharmacies in re-dispense medication at hospitals or infusion pharmacies previously dispensed by specialty pharmacies. P. GANNON remarked on concerns of; chain of custody, and proper storage, as key factors that should be considered as part of the resolution so that patient safety is protected with the new health care delivery models.

ACTION: Motion by P. GANNON, seconded by E. TAGLIERI, and voted unanimously to approve the resolution on White Bagging and Brown Bagging and send to the NABP District 1 / 2 meeting for consideration.

2. Naloxone Rescue Kits:

DISCUSSION: K. BARNES presented the resolution for consideration. The proposed resolution would be for NABP to work with the FDA to make naloxone an OTC product to increase its availability. M. GODEK requested the addition of "readily available" of the pharmacist in preventing drug abuse. E. TAGLIERI requested the addition of first responders for access to naloxone rescue kits.

ACTION: Motion by A. STEIN, seconded by C. BASILE and voted unanimously to approve the resolution on Naloxone Rescue Kits and send to the NABP District 1 / 2 meeting for consideration.

TOPIC VII REGULATIONS

TIME: 9:40

1. Draft amendments to 247 CMR Section 5.0; Orally and Electronically Transmitted Prescriptions and Reporting Requirements to the Prescription Monitoring Program (PMP).

Discussion: H. ENGMAN updated the Board on the EO562 Regulatory Review The Board must review regulations that are duplicative. H. ENGMAN noted that She worked with the Departments Deputy Chief Legal Counsel R. RODMAN Identifying regulations in 247 CMR Section 5.00 that were duplicative with 105 CMR 7.01.003 pertaining to electronic prescriptions and the reporting requirements of pharmacies to the Prescription Monitoring Program (PMP). H. ENGAMAN noted that PMP reporting would be moved to a yet to be developed reporting section within 247 CMR and that regulation and the corresponding discipline would be moved to 247 CMR 10.00 Discipline Proceedings.

2. Draft proposed amendments to 247 CMR 9.00 Practice Standards:

DISCUSSION: V. BERG informed the Board of proposed changes as required by an outside budget section in the FY 16 budget? The new statute requires that pharmacies located in areas that are considered a high overdose area for opioids shall maintain: a standing order (naloxone), and continuous supply of naloxone rescue kits or other approved opioid antagonist. Board members were concerned about how and who would determine "the high overdose areas". The Boar was also concerned as how this would be updated and maintained. Board members debated merits of all pharmacies being required to stock so that patients would not be confused in attempting to obtain naloxone. Board members inquired as to supply of naloxone should if all would be required to stock naloxone. The Board was also concerned with the training and how this would be handled with MOR changes, and how would the fact that a pharmacy was carrying naloxone should signage be required. Board member P. BOUVIER desired to review the

statutory language for the proposed requirement. After much debate and concern that they had more questions that needed to be answered the decided to defer this matter to a future meeting?

3. Draft new section 247 CMR. 17.00; Sterile Compounding

The Board continued its discussion on the draft of the new Sterile Compounding regulations. Board Counsel H. ENGMAN captured all changes to the draft via track changes on the screen for the Board members and audience to view. K. BARNES and W. FRISCH facilitated the discussion that centered around new sections for ISO Classification, Smoke Studies, General Facility design and Primary and Secondary Engineering controls.

TOPIC VII FILE REVIEW:

1. PHA-2015-0101; Vashkar Karim, PH22444 TIME:10:56 RECUSAL: G. CAVANAUGH and W. COX recused themselves and were not present for the discussion or vote on this matter.

<u>DISCUSSION:</u> C. MOGNI presented and summarized the investigative report pertaining to this matter. Evidence indicates that there were multiple inspectional deficiencies at The Prescription Shoppe Inc. (owned by Vashkar Karim and located in Everett, MA) noted during inspections in February and March of 2015. During this time period, the MOR had been absent from the pharmacy for 7 months, and that was not reported by Karim. Mr. Karim, at the same time, was listed as MOR of Boston Community Pharmacy in Chelsea, which had never opened. The Prescription Shoppe in Everett has since closed and sold their files to Rite Aid in Everett, however Board staff recommended a reprimand for Karim.

<u>ACTION:</u> Motion by R. TINSLEY, seconded by C. BASILE, and voted unanimously to refer the matter to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter with a consent agreement for a REPRIMAND for Karim, and terms to require him to attest to having read and understood 247 CMR, specifically sections 6, 9, and 15.

TOPIC VII. FILE REVIEW:

2. SA-INV-7142; Apothecare Pharmacy, DS89820 TIME: 11:02PM RECUSAL: W. COX and C. BASILE recused themselves and were not present for the discussion or vote on this matter.

<u>DISCUSSION</u>: C. MOGNI presented and summarized the investigation report that pertained to this matter. An allegation (initiated by an anonymous student) by Senior Whole Health Director claimed that the owners of Apothecare Pharmacy instructed interns to identify themselves as pharmacists, conduct medication reviews, and submit false claims to vendor for services not rendered.

Apothecare MOR Geoffrey Peterson denied the allegations, explaining that interns are supervised, but often while at LTC facilities, supervision is with IPADS and Skype. Senior Whole Health could not substantiate the allegations, and the MTM vendor found no irregularities in the submitted claims. Five (5) area Pharmacy schools were called and representatives stated that they were generally unaware that students were supervised in such a manner..

<u>ACTION</u>: Motion by R. TINSLEY, seconded by G. CAVANAUGH, and voted unanimously to defer this matter until Board Staff drafts an ADVISORY LETTER on the intern supervision issue and also Preceptor/Intern ratios, and brings the matter back to the Board for a vote at a future meeting.

<u>TOPIC IX</u> FILE REVIEW

3. SA-INV-6655 The Medicine Shop DS2793 TIME: 11:17PM

DISCUSSION: C. MOGNI presented and summarized the investigation report that pertained to these matters, on behalf of Investigator C. LATHUM, who was not present at the meeting. Mogni reported that several inspectional deficiencies were identified during a November 2014 inspection, including paperwork-related issues, refrigerator log problems, inventories, outdated compounding chemicals, other expired drugs, and general clutter. W. FRISCH pointed out that it was more clutter than dirt, and that an extensive Plan of Correction (POC) was submitted and implemented by Medicine Shop. He was satisfied with the response, and a subsequent inspection found no deficiencies.

ACTION: Motion by R. TINSLEY, seconded by C. BASILE, and voted unanimously to close the staff assignment with no discipline warranted since remediation was complete.

4. SA-INV-6073	Baystate Home Infusion	DS3300
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<u>DISCUSSION:</u> M. VASQUEZ presented and summarized the investigation report that pertained to these matters. On May 12, 2014, during a <797> audit, OPP Senior Investigators S. PENTA and L. McKENNA learned that an initial result of viable air had yielded abnormal results. As corrective action, removed all cardboard from pharmacy stock and operation area adjacent to the anteroom, Redirected the common entrance to the anteroom to the rear door entrance, and Implement a checking function area by a pharmacist outside the anteroom.

ACTION: Motion by M. GODEK, seconded by E. TAGLIERY, and voted unanimously to close the staff assignment with no violation.

<u>TOPIC VII</u> FILE REVIEW

5. SA-INV-6010, Pentec Health, Inc, DS89913, Mansfield

DISCUSSION: C COLLINS presented and summarized the investigational report that pertained to this matter. The evidence indicates that Pentec Health reported a preliminary count of 4 cfu/m³ of possible coagulase positive *Staphylococcus* from the ISO 8 area on May 2, 2014. The registrant indicated that they did not compound as of May 9, 2014 and completed a full cleaning. Pentec performed a deep cleaning of the area. The POC include the removal of a hand dryer and utilization of only lint free wipes. A final follow up testing yielded no actionable results per USP <797>.

ACTION: Motion by P. BOUVIER, seconded by A. STEIN, and voted unanimously to close the staff assignment with no violation.

FILE REVIEW

6. SA-INV-6071, Freedom Fertility, DS89717, Byfield Time: 11:22 AM

DISCUSSION: C COLLINS presented and summarized the investigational report that pertained to this matter. Freedom Fertility reported and abnormal result of 1 cfu mold from testing conducted on June 2, 2014 as part of its scheduled annual certification. Their vendor, AST, performed room sterilization and complete room certification on June 14-16, 2014 and a RCA investigation ensued. The pharmacy indicated that it ceased compounding June 10, resumed in a limited capacity on June 18 and fully resumed on July 7 subsequent to follow up results within USP <797> action levels. >.

ACTION: Motion by C. BASILE, seconded by G. CAVANAUGH, and voted unanimously to close the staff assignment with no violation.

FILE REVIEW

7. SA-INV-6357; Cape Cod Home Infusion, DS89832, North Falmouth, Time: 11:24 AM

DISCUSSION: C COLLINS presented and summarized the investigational report that pertained to this matter. Cape Cod Infusion reported 1 cfu/m3 fungus identified in a sample taken on July 30, 2014. The registrant ceased compounding, implemented a continuity of care plan, triple cleaned the area and re-sampled. The registrant reported that compounding resumed on August 18, 2014 subsequent to follow up testing that indicated no fungal growth.

ACTION: Motion by C. BASILE, seconded by P. BOUVIER, and voted unanimously to close the staff assignment with no violation

FILE REVIEW

8. SA-INV-6357 Boston Home Infusion, DS2623, Time: 11:25AM

DISCUSSION: C COLLINS presented and summarized the investigational report that pertained to this matter. On May 13, 2014 the registrant timely reported an abnormal result of 5 cfu's of gram negative rods in the ISO 8 classified space. A root cause analysis revealed the cause to be a failed HEPA filter. Compounding was ceased, the filter was replaced and the room was recertified under dynamic conditions. POC included that garbing practices were reviewed with staff and that the frequency of cleaning was increased. A June 18, 2015 inspection was satisfactory.

ACTION: Motion by P. BOUVIER, seconded by C. BASILE, and voted unanimously to close the staff assignment with no violation

FILE REVIEW

9. PHA-2015-0099; CVS #140, DS2729, Winthrop Time: 11:12 AM

DISCUSSION: M VASQUEZ presented and summarized the investigational report that pertained to this matter. On October 23, 2014 and April 5, 2015, Pharmacy Investigators observed repeat inspectional deficiencies regarding expired ophthalmic and topical medications on the shelves in violation of 247 CMR 9.01(10), during a retail pharmacy compliance inspection. I was indicated that the same MOR was responsible for the facility for all inspections.

On the POC's former MOR indicated that ancillary staff would be assigned each pharmacy a different section of the pharmacy to regularly inspect for expired medications and sign an inspection record. It was reported that a routine compliance inspection performed on June 18, 2015 inspection was satisfactory.

ACTION: Motion by C. BASILE, seconded by K. CONLEY, and voted unanimously to dismiss the complaint with remediation complete conditioned that the Pharmacy submit policy and procedures related to inventory review and that all pharmacy staff members attest to review of the inventory policies and procedures.

TOPIC VIII.

Executive Session:

DISCUSSION: P. GANNON called the session to order. ACTION: At 11:29AM motion by A. STEIN seconded by R. TINSLEY to enter into M.G.L. c. 112 65 SESSION. ACTION: At 12:36 PM motion by R. TINSLEY, seconded by W. COX to suspend M.G.L. 65C. ACTION: At 3:06PM motion by R. TINSLEY, seconded by A. STEIN to re-enter M.G.L. 65C.

TOPIC XI. ADJOURNMENT

DISCUSSION: None

<u>ACTION:</u> At 4:03PM Motion by R. TINSLEY, seconded by C.BASILE, and voted unanimously to adjourn the meeting.

LIST OF EXHIBITS USED DURING THE MEETING

- 1. Draft Agenda for the September 1, 2015 Regularly Scheduled Meeting
- 2. Application to Manage and Operate a New Community Pharmacy, MedMinder Systems, Inc.
- 3. Application for Renovation / Expansion Request for the Board, The Whittier Pharmacist, Inc.
- 4. Application approved pursuant to Licensure Policy 13-01, September 1, 2015
- 5. Division of Health Professions Licensure, Division Policy 14-01, Valor Act Implementation,
- 6. Memo, Division of Health Professions Licensure, RE: License Status Codes
- 7. Memo, Division of Health Professions Licensure, RE: Regulatory Review and recommendations relating to 247 CMR 4.00, 5.00, 6.00, 9.00, 18.00
- 8. 247 CMR 5.00; Orally And Electronically Transmitted Prescriptions; Prescription Monitoring Program (PMP) Reporting Requirements
- 9. 105 CMR 701.000: Regulations Adopted Jointly by the Department of Public Health and The Board of Registration in Pharmacy For The Implementation of M.G.L. c.94C.
- Draft proposed amendments to 247 CMR 9.00: Code of Professional; Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Department. Proposed amendments will include provisions pertaining to naloxone, as required by M.G.L. c. 94C § 19C.
- 11. Draft proposed new regulation, 247 CMR 17.00: Sterile Compounding.
- 12. Investigation Report in the matter of Vashkar Karim, PHA-2015-0101
- 13. Investigation Report in the matter of Apothecare Pharmacy, SA-INV 7142
- 14. Investigation Report in matter of Medicine Shoppe, DS 2793, SA-INV-6655

- 15. Investigation Report in the matter of Baystate Home Infusion, DS3300, SA-INV-6073
- 16. Investigation Report in the matter of, Pentec Health, Inc., DS89913, SA-INV-89913
- 17. Investigation Report in the matter of, Freedom Fertility, DS89717, SA-INV-6071
- 18. Investigation Report in the matter of, Cape Cod Infusion, DS89832, SA-INV-6357.
- 19. Investigation Report in the matter of, Boston Home Infusion, DS2623, SA-INV-6647.
- 20. Investigation Report in the matter of, CVS Pharmacy #140, DS2729, PHA-2015-0099.

Respectfully submitted by:

Richard Tinsley, MBA, M.Ed., Secretary