

President Gene Minton called the meeting to order at 9:00 am with Board Members Gene Minton, L. Stan Haywood, Carol Yates Day, Robert A. Graves, and Andy Bowman present. Also present were Executive Director Jay Campbell, Board Counsel Clint Pinyan, Director of Investigations Josh Kohler, Associate Director of Investigations Krystal Brashears Stefanyk, Director of Operations Kristin Moore, and Director of Licensing Deborah Stump. Present as visitors were: Brent Slaughter, NC Mutual Drug; Tori Mayer, Publix; Joey McLaughlin, Realo Drug; Christine Davis, Cardinal Health; Robert Kustra, GSK; Amy Timberlake, GSK; Bill Cover, NABP; Adam Carrera, UNC/ESOP; Megan Cuomo, UNC/ESOP; Amanda Lo, South University; Crissy Nystrom, Wingate University; Lanae Linard, UNC/ESOP; Ethan Meadows, Campbell Univ.; Jordan Walker, Campbell Univ.; Jenna Grago, Campbell Univ.; Alyssa Morgan, UNC/ESOP; Roya Naim, Campbell Univ.; and Nick Candle, Campbell Univ.

### Ethics Statement & Welcome

President Mixon read the Ethics Statement regarding any conflicts of interest and/or appearance of conflicts of interest of any Board member. No conflicts were noted by Board members.

Mr. Minton requested that the audience members introduce themselves to the Board.

### Minutes of the April 2016 Board Meeting

The members received the May 2016 meeting minutes and May 16, 2016 conference call meeting minutes prior to this meeting for review. It was moved by Mr. Graves, seconded by Mr. Mixon, to accept the minutes as submitted. The motion passed with no dissenting votes.

### Recognition of Board Member – Keith Vance

Mr. Campbell welcomed Keith Vance who was elected to the Northern District board seat, and will take that position when commissioned by the Governor on May 1, 2017.

### Presentation on eProfile and VPP Systems, Bill Cover, NABP Member Relations and Government Affairs Director

Bill Cover, NABP Member Relations and Government Affairs Director, presented an overview of NABP eProfile and VPP programs. The eProfile program tracks and stores continuing education acquired by pharmacists and the VPP program collects and, when requested, conducts inspections of pharmacies. He also reviewed the NAPLEX and MPJE exams, the FGPEE program, and the licensure reciprocity process.

### Discussion of Status of CLIA-Waived “Rapid Diagnostic” Tests by Pharmacists

Board staff has received numerous questions about pharmacies’ ability to perform “rapid diagnostic” and other “Clinical Laboratory Improvement Amendments Act (CLIA) –waived” tests.

Mr. Campbell stated that when FDA approves an in vitro diagnostic device, it may designate the devices as approved “for home use or that, as determined by the Secretary, are simple laboratory

examinations and procedures that have an insignificant risk of an erroneous result, including those that . . . employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or . . . the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.” 42 USC § 263a(d)(3).

If so deemed by the FDA, these tests may be performed in a laboratory that has applied for a waiver of CLIA requirements. Id. § 263(a)(d)(2). CLIA-waived tests don’t require, as a condition of FDA approval, any sort of “prescription” or medical order.

Unlike some states, North Carolina law does not impose a separate layer of regulations on top of CLIA. If a facility meets the criteria to perform CLIA-waived tests, and obtains from the Centers for Medicare and Medicaid Services (CMS) a CLIA waiver, then that facility may perform any CLIA-waived tests. <https://www2.ncdhhs.gov/DHSR/ahc/cli/cliafaq.html>

After discussion it was the consensus of the Board that there is nothing in the law that would prevent a pharmacy that applies for, and obtains, a CLIA waiver from CMS from performing CLIA-waived tests.

### Investigations/Inspections Reports

#### General Report

Joshua Kohler, Director of Investigations and Inspection, presented the June 2016 investigative report.

#### Proposed Policy Concerning Voluntary Surrenders of License Registrations, or Permits

At the request of Board members, Board staff presented a formalized policy concerning requests for a voluntary surrender of a license, registration, or permit.

After discussion, it was the consensus of the Board to approve the policy as presented.

#### Report on Implementation of Team F.O.C.U.S

Josh Kohler, Director of Investigations/Inspections, updated the Board on implementation of Team F.O.C.U.S, a reorganization of the Investigations/Inspections Department approved by the Board at the March 2015 Board meeting. Team F.O.C.U.S reorganized the investigations field staff into five (5) districts with two field staff members per district consisting of one investigator and one inspector. Mr. Kohler stated that inspections have doubled since the implementation of Team F.O.C.U.S without hindering the investigation of complaints.

### Financial Report

#### General Report

Gail Brantley, Financial and Administrative Services Director, presented the May 2016 financial report to the Board.

Set Dates for Finance Committee Review of Proposed FY 2016-17 Budget

Board staff presented a proposed FY 2016-17 budget process timeline for the the Budget and Finance Committee consisting of Mrs. Day, Mr. Graves, and Dr. Bowman.

After discussion, it was the consensus of the committee to approve the timeline.

Legislative Update

Mr. Campbell updated the Board on several legislative issues.

Set Date and Time to Certify Western District Runoff Election

The Western District Runoff Election between Cathy Huie and Bill Mixon will conclude at midnight on June 24, 2016. After discussion, it was the consensus of the Board to convene by conference call on Monday, June 27, 2016 to certify the election results.

Update on Pharmacist Use of Board-Sponsored Controlled Substance Reporting System Training Continuing Education

At the June 16, 2015 Board meeting, Board members approved funding a Controlled Substance Reporting System on-line continuing education program for pharmacists. The program is a joint effort between the UNC Eshelman School of Pharmacy and the Board and is available to pharmacist at no costs.

Patrick Brown, UNC Eshelman School of Pharmacy, updated the Board on the implementation of the program. He stated that 350 pharmacists have used the online CE program to date. He stated that they are expecting use of the program to grow during pharmacist license renewal time.

Board President Minton Recognized by the UNC ESOP Alumni Association with the 2016 Distinguished Service Award

Mr. Campbell congratulated Mr. Minton, on behalf of the Board members and staff, on being named the 2016 recipient of the UNC Pharmacy Alumni Association Distinguished Service Award.

Further Discussion of Member Retreat Dates/Locations

At the May 2016 Board meeting, it was the consensus of the Board to hold the retreat September 8<sup>th</sup> – 9<sup>th</sup>, 2016. After discussion, it was the consensus of the Board to hold the retreat at Wrightsville Beach. Mr. Minton will work with staff to choose a venue.

Reports to the Board

Wendy Cox, UNC Eshelman School of Pharmacy, updated the Board on enrollment for the coming year.

Bill Mixon updated the Board on the FDA Pharmacy Compounding Advisory Committee meeting.

Patrick Brown, UNC ESOP, and Jenna Huggins, NC Mutual Drug, reported on the new entrepreneurship residency program that has been created at UNC Eshelman School of Pharmacy in collaboration with North Carolina Mutual Drug.

### Consent Agenda

It was moved by Dr. Bowman, seconded by Mr. Mixon with no dissenting votes to approve the consent agenda. The motion carried with no dissenting votes. The following items were approved.

#### **Prehearing Conference**

##### **Staff Issues Letters of Warning**

RPh. Robin Tinney, License #10163; RPh. Alesha Covington, License #20461; and Wal-Mart Pharmacy, Permit #07960 were subjects of a prehearing conference held May 9, 2016, heard by Mr. Bill Mixon, regarding allegations that Doris M. Johnson via civil suit in Guilford County Superior Court on January 5, 2015, alleges that on January 14, 2012, Wal-Mart Pharmacy #07960, Fayetteville, NC, improperly substituted SMZ-TMP 800-160mg in place of the prescribed medication Nitrofurantoin 100mg wherein the allergy to SMZ-TMP was noted on the original prescription. Pharmacy records indicated RPh. Robin Tinney was the pharmacist of record who filled and dispensed the improper medication while under supervision as pharmacist-manager RPh. Covington. Patient Johnson experienced pain and numbness in her hands and feet, and was seen several times at High Point Regional Medical Center and Wake Forest Baptist Hospital for reassessments. Recommendation: Staff Issued **LETTERS OF WARNING** be issued to RPh. Tinney, RPh. Covington and the permit.

##### **Staff Issues Letters of Warning**

RPh. Lance Wheeler, License #13619; and Medicap Pharmacy, Permit #07696, were subjects of a prehearing conference held May 9, 2016, heard by Mr. Bill Mixon, regarding allegations that On October 20, 2014, a sixty-one (61) year old female patient was dispensed Glyburide 5mg instead of the prescribed medication Lisinopril/HCTZ 20/25mg. The patient ingested an unknown amount of the incorrect medication that resulted in hospitalization. Pharmacy records indicated RPh. Lance Wheeler was the pharmacist of record and dispensed a partial fill of six (6) tablets of Glyburide 5mg to the patient, who was discovered unresponsive in a car and suffering from hypoglycemia. Additional evidence indicated a high volume of prescriptions were dispensed on October 20, 2014, there was a pharmacist/technician ratio violation, and records regarding the partial dispensing of the

medication were neither created nor maintained. Recommendation: Staff Issues **LETTERS OF WARNING** be issued to RPh. Wheeler and the permit.

### **Staff Issues Letters of Warning and No Action**

Technician Rebecca Bostock, Registration #15747; RPh. Nastacia McArthur, License #19700; and RPh. Travis Gilliard, License #10073, were subjects of a prehearing conference held May 9, 2016, heard by Mr. Bill Mixon, regarding allegations that On January 28, 2016, patient Frances Bass was incorrectly dispensed Oxycodone 10/325mg instead of the prescribed medication Hydrocodone 10/325mg dated November 19, 2015. Pharmacy records indicated Technician Rebecca Bostock erroneously entered Oxycodone 10/325mg instead of Hydrocodone 10/325mg, and RPh. McArthur was the pharmacist of record that dispensed the medication to patient Bass. RPh. Gilliard was pharmacist manager. Recommendation: Technician Bostock and RPh. Gilliard receive **LETTERS OF WARNING**, and RPh. McArthur receive a **LETTER OF NO ACTION**.

### **Consent Orders**

Apex Family Pharmacy Inc. d/b/a Blue Ridge Pharmacy, permit #09471, was subject of a prehearing conference held June 20, 2016 regarding a consent order between the parties presented to Mrs. Day regarding permit shipping products into Arizona without a permit using MatchRx.com. Recommendation accepted by permit: **Consent Order of Reprimand**.

Duggins Holdings LLC d/b/a Prevo Drug, permit #11751, was subject of a prehearing conference held June 20, 2016 regarding a consent order between the parties presented to Mrs. Day regarding permit shipping products into Arizona without a permit using MatchRx.com. Recommendation accepted by permit: **Consent Order of Reprimand**.

HealthFirst Pharmacy of Wake Forest, LLC, Permit #08879, was subject of a prehearing conference held June 20, 2016 regarding a consent order between the parties presented to Mrs. Day regarding permit shipping products into Arizona without a permit using MatchRx.com. Recommendation accepted by permit: **Consent Order of Reprimand**.

Beach Pharmacy II, LTD, Permit #04503, was subject of a prehearing conference held June 20, 2016 regarding a consent order between the parties presented to Mrs. Day regarding permit shipping products into Arizona without a permit using MatchRx.com. Recommendation accepted by permit: **Consent Order of Reprimand**.

**Increase in Pharmacists to Technician Ratio**

1. Peak Pharmacy #10461, Nicholas Conley/Pharmacist Manager, Kernersville NC
2. Walgreens #12299, Michael Chester/Pharmacist Manager, Burlington NC
3. Walgreens #12261, Jessica Bass/Pharmacist Manager, Clinton NC
4. Walgreens #12311, Nichole Wilson/Pharmacist Manager, Dunn NC
5. Walgreens #12405, Amanda Woolard/Pharmacist Manager, Fuquay-Varina NC
6. Walgreens #12230, Christopher Oravetz/Pharmacist Manager, Holly Springs, NC
7. Walgreens #12272, Shelley Robinson/Pharmacist Manager, Jacksonville NC
8. Walgreens #12348, David Grove/Pharmacist Manager, Mount Airy, NC
9. Walgreens #12239, Christina Bryant/Pharmacist Manager, Roanoke Rapids NC
10. Walgreens #12238, Marcie J. Quinn/Pharmacist Manager, Wallace NC
11. Walgreens #12294, Kevin Bloom/Pharmacist Manager, Wilmington NC
12. Walmart #12068, Toluope Alokolaro/Pharmacist Manager, Dallas NC
13. Walmart #07959, David Glenn Mintz/Pharmacist Manager, Erwin NC
14. Walmart #12070, Badr Ibrahim/Pharmacist Manager, Greenville NC
15. Walmart #12677, Kristin H. Aumann/Pharmacist Manager, Jacksonville NC
16. Walmart #12524, Ron Proffitt/Pharmacist Manager, Morganton NC

**CPP Candidates**

- Lori Brown, PharmD #15581, Mission Health Partners, Asheville NC
- Andres W. Bundeff, PharmD #22776, Pharmacy Care Clinic at WFU, Winston Salem NC
- Candace M. Dixon, PharmD #24004, Pharmacy Care Clinic at WFU, Winston Salem NC
- Erika Lambert, PharmD #25158, Family Medicine Center Chapel Hill NC
- Tacorya D. Morrison, PharmD #24539, Pharmacy Care Clinic at WFU, Winston Salem NC
- Elizabeth C. Oldham, PharmD #11010, Pharmacy Care Clinic at WFU, Winston Salem NC
- Danielle W. Raymer, PharmD #13565, Pharmacy Care Clinic at WFU, Winston Salem NC
- Virginia G. Yoder, PharmD #18262, Pharmacy Care Clinic at WFU, Winston Salem NC

**Reciprocity Candidates**

<b>Candidates License by Reciprocity 5/11/2016 – 6/21/2016</b>					
<b>FNAME</b>	<b>MNAME</b>	<b>LNAME</b>	<b>SUFFIX</b>	<b>RCPSTATE</b>	<b>DTREGIST</b>
Fiona	Monique	Cole		WV	5/11/2016
Abdul		Kader		MD	5/11/2016
Susan	Marie	Brown		SC	5/18/2016
Lindsay	Beth	Goldenberg		ME	5/18/2016
Diliarom	Ulukakhunova	Hill		OH	5/18/2016
Brent	Andrew	Sabacek		TX	5/18/2016
Kristin	Elizabeth	Weaver		NY	5/18/2016
Ryan	L.	Lu		NJ	5/25/2016
Tomasz		Zola		UT	5/25/2016

<b>Candidates License by Reciprocity 5/11/2016 – 6/21/2016</b>					
<b>FNAME</b>	<b>MNAME</b>	<b>LNAME</b>	<b>SUFFIX</b>	<b>RCPSTATE</b>	<b>DTREGIST</b>
Amy	Hatfield	Seung		WA	5/25/2016
Anil	K.	Vinjamuri		VT	5/25/2016
Lakshmi	Deepika	Neeli		MI	5/25/2016
Robert	Anthony	Wallace		AZ	6/1/2016
Jordan	Andrew	Miller		OR	6/1/2016
Heather	Marie	Ryan		MA	6/1/2016
Emily	Ann	Perriello		CT	6/1/2016
Wesley	David	Kufel		NY	6/1/2016
Mina		Gold		NY	6/1/2016
Debra	Stevens	Nicholas		TN	6/1/2016
Zachary	Andrew	Shumoski		PA	6/1/2016
Kimberly	Ann	Brandt		WV	6/8/2016
Madhulatha	Reddy	Malireddy		VT	6/8/2016
Sahar	Naim	Abed		MA	6/8/2016
Ama	Owusu	Marfo		NY	6/8/2016
Austen	Mark	Junior		GA	6/8/2016
Victor		Bakhoun		NJ	6/8/2016
Brooke		Ade		VA	6/15/2016
Shelton	Baker	Hunt		SC	6/15/2016
Mansi	V.	Patel		FL	6/15/2016
Kathryn	Rose	Derrig		CT	6/15/2016
Alice	Chingan	Pan		KY	6/15/2016
Ryan	Blake	Tewell		IN	6/15/2016
Claire	Marie	Reuter		LA	6/15/2016
Jeanne	Brackin	Forrester		SC	6/15/2016
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A copy of the consent orders can be found elsewhere in the Minutes and are incorporated by reference herein.

### **Closed Session**

On a motion from Mr. Graves, seconded by Dr. Bowman with no dissenting votes, the Board moved into closed session to discuss a possible summary suspension and a possible litigation matter.

Open session resumed on a motion from Mr. Haywood, seconded by Mr. Graves with no dissenting votes. Mr. Minton stated that the Board summary suspended RPh. Steven Register, license #13132; and RPh. Benjamin Van Pelt, license #24777.

On a motion from Mr. Haywood, seconded by Mr. Graves with no dissenting votes, the Board moved into open session.

The Board adjourned the meeting at 12:01pm.

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Gene Minton, President

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L. Stan Haywood, Vice-President

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Dr. Andrew Bowman

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William A. Mixon

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Carol Yates Day

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Robert A. Graves