

**South Carolina Board of Pharmacy
Board Meeting**

9:00 a.m. June 15, 2016
Synergy Business Park
110 Centerview Drive, Kingstree Building Room 108
Columbia, South Carolina

Wednesday, June 15, 2016

1. Approval of March 16, 2016 Minutes

Mr. Hyatt made a motion to approve the minutes. Mrs. Russell seconded the motion and it carried unanimously.

2. Approval of Reciprocity Candidates for Licensure:

Dates: March 10, April 21, May 13, 2016

Mr. Livingston made a motion to approve the candidates. Mrs. Gillespie seconded the motion and it carried unanimously.

3. Administrator's Report – Lee Ann Bundrick, R.Ph.

Report given.

4. Inspectors' Report

Report given.

5. Report from:

Finance Report – Lee Ann Bundrick, R.Ph.

Report given.

Office of Disciplinary Counsel – Pat Hanks

Report given.

Office of Investigation and Enforcements – Mark Sanders

Report given.

6. IRC Recommendations for dismissals and dismissals with non-disciplinary letters of concern. Review of proposed consent agreements, voluntary surrenders, relinquishments, cease and desist and temporary suspension from the Investigative Review Committee (IRC)

Mr. Livingston made a motion to approve 12 dismissals. Mrs. Russell seconded the motion and it carried unanimously.

Mr. Livingston made a motion to approve 15 formal complaints. Mrs. Russell seconded the motion and it carried unanimously.

Mr. Livingston made a motion to approve 2 letters of caution. Mr. Straus seconded the motion and it carried unanimously.

Mr. Blackmon made a motion to approve 1 relinquishment. Mrs. Gillespie seconded the motion and it carried unanimously.

Mrs. Gillespie made a motion to approve 4 dismissals with letters of concern, under the resolution guidelines. Mr. Livingston seconded the motion and it carried unanimously.

Mr. Livingston made a motion to approve 7 cases for formal complaints. Mrs. Gillespie seconded the motion and it carried unanimously.

Review of Resolution Guidelines

Mr. Livingston made a motion to defer this to the September meeting and ask Mr. Hugh Mobley and Mr. Davis Hook, IRC Co-chairs, to attend. Mr. Blackmon seconded the motion and it carried unanimously.

Consent Agreements

2015-93

Mr. Livingston made a motion to defer the consent agreement for changes. Mr. Morris seconded the motion and it carried unanimously.

2015-150

Mrs. Gillespie made a motion to approve the consent agreement. Mr. Livingston seconded the motion and it carried unanimously.

Voluntary Surrender

2016-32

2016-36

2016-46

2016-60

2016-63

2016-74

2016-78

Mr. Livingston made a motion to approve the voluntary surrenders. Mr. Morris seconded the motion and it carried unanimously.

Agreement to Relinquish

2013-51

2015-90

For information only.

A. In the Matter of CVS, Michele Anders, Citation Appeal Request 2015-121

Mr. Livingston made a motion to go into executive session for legal advice. Mr. Blackmon seconded the motion and it carried unanimously.

Mr. Blackmon made a motion to come out of executive session. Mrs. Russell seconded the motion and it carried unanimously.

Mrs. Gillespie made a motion to overrule the citation due to adequate evidence hasn't been given by the State to indicate there has been a violation of the statute. Mr. Livingston seconded the motion. Mr. Strauss and Mr. Morris opposed the motion. Dr. Richardson abstained from the vote. The motion carried by majority vote.

B. Request Release from Board Order – William Kennedy

This was heard in closed session. Mr. Livingston made a motion to approve the request. Mrs. Russell seconded the motion and it carried unanimously.

C. Request Approval of Pharmacy Technician Registration Online Application – Destanee

Springs

Did not appear. Mr. Livingston made a motion to defer the request until an appearance is made. Mrs. Russell seconded the motion and it carried unanimously.

D. Request Approval of Pharmacy Technician Registration Application – Jessica Perry Goodman

Mr. Livingston made a motion to defer the request until an appearance is made. Mrs. Russell seconded the motion and it carried unanimously.

E. Request Approval of Pharmacy Technician Registration Renewal – Ramiro Gustavo Garcia Duran

Mrs. Gillespie made a motion to deny the request. Mr. Livingston seconded the motion and it carried unanimously.

F. Dispensing, Administration and Delivery of Treatment Medication in South Carolina Narcotic Treat Programs Proposal – Crossroads Treatment Centers, Scott Ray

Mrs. Gillespie made a motion to defer this to the Healthcare Collaborative Committee. Mr. Livingston seconded the motion and it carried unanimously.

G. Greenville Health System Permits – Fred Bender

Mr. Livingston made a motion that the Board's opinion is that this is a change of ownership. Mrs. Gillespie seconded the motion and it carried unanimously.

H. Expungement Process – Spencer Morris, PharmD

Mr. Morris will work with 2 other Board members to begin the discussions and bring back to the full Board.

I. Request Approval of Non-Resident Pharmacy Renewal – Wickliffe Pharmaceuticals Inc., Kenneth Ukauwa

Mr. Strauss made a motion to defer the request until an appearance is made. Mr. Livingston seconded the motion and it carried unanimously.

J. Request Approval of Non-Resident Pharmacy Permit Renewal – Anazao Health Corporation, Won Dolegowski

Mr. Livingston made a motion to approve the request, pending a completed application as outsourcing facility with appropriate fees. Mrs. Russell seconded the motion and it carried unanimously.

K. Marijuana Summit – Spencer Morris, PharmD
Report given.

L. Permitting of Reverse Distributors – Rebecca Gillespie, PharmD
A report is to be given at the September board meeting.

M. NABP Annual Meeting Report – Rob Hubbard, R.Ph.
Report given.

N. Delegate for NABP Dist III Meeting August 14-16, 2016, Point Clear, AL

Mr. Livingston made a motion for Mr. Strauss and Mr. Morris be delegates, along with Mrs. Bundrick and one other staff member. Mr. Blackmon and Dr. Richardson serve as alternates.

Mrs. Gillespie seconded the motion and it carried unanimously.

O. Election of 2016-17 Chair and Vice Chair

Dr. Richardson made a motion to nominate Mrs. Russell as Board Chair. Mrs. Gillespie seconded the motion and it carried unanimously.

Mr. Livingston made a motion to nominate Mr. Blackmon as Board Vice-Chair. Dr. Richardson seconded the motion and it carried unanimously.

P. Delegate for MALTAGON October 9-12, 2016

Mr. Livingston made a motion for Mr. Strauss and Mr. Morris be delegates, with Mrs. Gillespie being the alternate delegate and Mrs. Bundrick and one other staff member. Mrs. Russell seconded the motion and it carried unanimously.

Q. Review of Policies and Procedures

Mr. Livingston made a motion to delete Policy & Procedure #138. Mrs. Gillespie seconded the motion and it carried unanimously.

8. Committee Reports

Review of Structure and Guidelines

Discussion only. No votes taken

Maltagon 2017 Planning

Mr. Morris will be the chair of the planning committee.

Pharmacy Technician – Rebecca Gillespie, PharmD

No meeting to report.

Compounding – Carole Russell, R.Ph.

The committee made a motion for the Board's approval of a response to the FDA guidance issued regarding prescription requirements under Section 503A, hospital and health system compounding and facility definition under Section 503B. A motion coming from a committee does not require a second and it passed unanimously.

Mr. Livingston made a motion that the Board give approval for the committee to create legislation regarding the compounding inspection reports. Mr. Morris seconded the motion and it carried unanimously.

Mr. Morris made a motion to refer the sterile inspection form back to the committee for modification needed until the regulation moves forward. The committee will allow the document to be distributed to the interested parties prior to the board meeting, if approved by LLR's Governmental Affairs. Mrs. Gillespie seconded the motion and it carried unanimously.

Legislative – Addison Livingston, PharmD

No meeting to report.

Nuclear Pharmacy – Spencer Morris, PharmD

No meeting to report.

Pharmacy Practice & Technology – Terry Blackmon, R.Ph.

Pharmacist Working Conditions - The committee made a motion to recommend to the Board to develop a policy and procedure for guidance of standards of an overall safety workplace environment for pharmacists and technicians. A motion from a committee does not require a

second and it passed unanimously. Mrs. Gillespie asked that it be sent back to the committee for their determination of whether it should be a policy and procedure or regulation.

Recovering Professional Program – Leo Richardson, PhD
No votes from their meeting to present.

Healthcare Collaborative

Approval of Ketamine Infusion Pilot Project for Roper Hospital

The Board of Nursing and Medical Examiners have already reviewed and approved this as amended pursuant to the Healthcare Collaborative's recommendations. Mr. Livingston made a motion to approve the request. Mrs. Russell seconded the motion and it carried unanimously.

Medication Integrity – Addison Livingston, PharmD
No meeting to report.

Non-Resident Application Review

Request for Reconsideration of Fine - Wesley Pharmacal

Mrs. Gillespie made a motion to deny the request. Mr. Livingston seconded the motion and it carried unanimously.

Committee Deferred to Full Board - Pharamlucence

Mrs. Gillespie made a motion to approve the application with a \$5000 fine. Mr. Livingston seconded the motion and it carried unanimously.

Committee Recommendations for Approval

March 23, 2016 Meeting: The committee made a motion to approve: Acaria Health Pharmacy, ZoSkin Health, Opti Meds Specialty Pharmacy, Ozburn-Hessey Logistics, Remedy Repack, DGN Pharmacy, Paragon Enterprises, CEVA Freight, and Nx Thera, Intermed Distributors. A motion from a committee does not require a second and it carried unanimously.

April 12, 2016 Meeting: The committee made a motion to approve: Vanderbilt Integrated Pharmacy, Getwell Pharmacy, United Pharmacy, El Dorado Pharmacy, Dsquared Pharmaceuticals, Meijer Pharmacy, MD Logistics, Medisuite, US Healthlink, Gideon's Drugs, All-States Pharmacy, Incorporated, Emerald Pharmacy, Prescription Supply, Oculus Innovative Sciences and Cottrill's Pharmacy. A motion from a committee does not require a second and it carried unanimously.

May 11, 2016: The committee made a motion to approve: Premier Compounding Pharmacy, Eli Lilly and Company, Pro Care Pharmacy Care, J Knipper and Company, Care Fusion Solutions, John Hopkins Pharmaquip, Goldtree Rx dba Hillmoor Pharmacy, Grane Supply, Aeromed Sunstar Americans, Southern Anesthesia and Surgical, and Walgreen's # 16405. A motion from a committee does not require a second and it carried unanimously.

Review of Conditional Approvals

March 23, 2016: The committee made a motion to approve with conditions: Releana - recommend approval pending submission and approval of an operational inspection by the Georgia Board of Pharmacy or a board-approved third party; Healthcare Specialty Transaction Services - recommended approval pending submission and approval of an operational inspection by the Georgia Board of Pharmacy or a board-approved third party and all pharmacy services must be provided by a South Carolina permitted facility; Keystone Choice Pharmacy-

recommend approval pending submission and approval of an operational inspection by the Pennsylvania Board of Pharmacy or a board-approved third party, statement that the pharmacy will comply with South Carolina technician to pharmacist ratio and pharmacy is restricted from compounding; Highland Specialty Pharmacy- recommend approval pending submission and approval of a recent inspection by the Mississippi Board of Pharmacy; Genesee Pharmacy - recommend approval pending submission and approval of a recent inspection by the New York Board of Pharmacy; GPS Pharmacy - recommended approval pending submission and approval of non-sterile compounding requirements, compounding training documentation for pharmacists and technicians and an operational inspection by the North Carolina Board of Pharmacy; Park Compounding recommend approval pending submission and approval of documentation of current training for all pharmacists, technicians and interns involved in compounding and a copy of the label for the final product; Opus RX - recommend approval pending submission and approval of PCAB certificate, updated SOPs and a current operational inspection, current documentation of compounding training for all employees involved in compounding. A motion from a committee does not require a second and it carried unanimously.

April 12, 2016: The committee made a motion to approve with conditions: Unyter Enterprises recommend approval pending submission and approval of temperature and humidity monitoring logs and operational inspection by the Georgia Board of Pharmacy, explanation of "yes" answer to the application discipline question number 2, policies and procedures for inspection of outgoing shipments and procedure for emergency situations as noted on the Georgia Board of Pharmacy opening inspection. Sentrix Pharmacy and Discount recommend approval pending submission and approval of label with all components of compounded products listed, evidence of salt to base conversions, one month of cleaning logs, equipment validation logs and temperature humidity monitoring logs, evidence of compounding training for pharmacists and technicians; Acro Pharmaceutical Services recommend approval pending submission and approval of an operational inspection by the Tennessee Board of Pharmacy or other board approved entity; Laboratory Supply recommend approval pending payment of \$5,000 fine for shipping legend products into South Carolina without a permit; USRC Pharmacy recommend approval pending submission and approval of a current operational inspection by the Tennessee Board of Pharmacy, patient specific medications must be mailed directly to the patient's home and not to the dialysis clinic; Mammoth Medical recommend approval pending payment of \$5,000 fine for shipping legend product into South Carolina without a permit; Volcano Corporation recommend approval pending payment of \$5,000 fine for shipping legend product into South Carolina without a permit; Benzer Pharmacy recommend approval pending submission and approval of a successful non-sterile compounding inspection by the North Carolina Board of Pharmacy, label properly showing all components of the compounded prescription, standards of practice for storing, handling compounding, dispensing and disposal of hazards, documentation of the installation and use of a powder containment hood and other containment measures, documentation of ongoing training in the art and science of compounding. A motion from a committee does not require a second and it carried unanimously.

May 11, 2016: The committee made a motion to approve with conditions: ProCare Pharmacare recommend approval pending payment of \$1,000 fine for dispensing to patients in South Carolina without a permit; Anutra Medical recommend approval pending a payment of \$2,500 fine for shipping legend products into South Carolina without a permit; HDK Enterprises, doing business as Southside Pharmacy Number 3, recommend approval pending submission and approval of an updated inspection by the Texas Board of Pharmacy; Walgreens Number 16298 recommend approval pending submission and approval of a label with a toll free phone number;

HVO Incorporated recommend approval pending a payment of \$3,500 fine for shipping legend products into South Carolina without a permit; Golden State Medical Supply recommend approval pending submission and approval of a recent California Board of Pharmacy inspection and a notarized statement regarding compliance with NABP VAWD standards; Hall's Warehouse Corporation recommend approval pending submission of new third-party logistics provider application; RXQ Compounding, an outsourcing Facility, recommend approval pending submission and approval of documentation of environmental testing and certification of compounding area and hoods, temperature and humidity monitoring logs for compounding area and updated photos of the compounding area and facility; RXQ Compounding, a non-resident wholesale distributor application, recommend approval pending submission and approval of policies and procedures for shipping refrigerated products and a notarized statement regarding compliance with NABP VAWD standards. A motion from a committee does not require a second and it carried unanimously.

Recommended for Denial

March 23, 2016: The committee made a motion to deny Pharmakon Pharmaceuticals, based on 40-43-83H. They may reapply after one year. A motion from a committee does not require a second and it carried unanimously.

Joint Pharmacist Administered Vaccines Committee – Terry Blackmon, R.Ph.
No meeting to report.

Adjournment

Mrs. Russell made a motion to adjourn. Mrs. Gillespie seconded the motion and it carried Unanimously.

**South Carolina Board of Pharmacy
Board Meeting**

9:00 a.m. June 16, 2016
Synergy Business Park
110 Centerview Drive, Kingstree Building Room 204
Columbia, South Carolina

Thursday, June 16, 2016

1. In the Matter of, Peter Rodruguez

Mr. Strauss recused himself from voting on this matter. Mr. Livingston made a motion to revoke the registration. Mr. Blackmon seconded the motion and it carried.

2. In the Matter of, Aneshca White

Mr. Livingston made a motion to revoke the registration. Mrs. Gillespie seconded the motion and it carried unanimously.

3. Request Approval of MOA – Joseph Masneri

Mr. Blackmon made a motion to issue a public reprimand, continuous suspension until January 1, 2017. At that time reinstate his license with indefinite suspension, immediately stayed with practice restrictions of no dispensing and no access to controlled substances and to continue with RPP for ten years and then reappear before the Board for release from the board order. Mr. Morris seconded the motion and it carried unanimously.

4. Request Approval of Relinquishment – Frank Woodruff

Mrs. Gillespie made a motion to accept an agreement to relinquish the license, in lieu of further proceedings. Mr. Livingston seconded the motion and it carried unanimously.

7. Request Approval of MOA – Katina Ellison

Did not appear. Mr. Livingston made a motion to defer until an appearance is made. Mr. Blackmon seconded the motion and it carried unanimously.

8. Request Approval of MOA – Virginia Mitchell

Did not appear. Mr. Livingston made a motion to defer until an appearance is made. Mr. Blackmon seconded the motion and it carried unanimously.

9. Request Approval of MOA- Kisha Wright

Mrs. Gillespie made a motion to indefinitely suspend her license with an immediate stay, that she remains monitored by RPP for five years, suffer a \$500 fine and cannot be PIC or permit holder for 5 years and a public reprimand. Mrs. Russell seconded the motion and it carried unanimously.

10. Request Approval of MOA – US Compounding

Mrs. Gillespie made a motion to deny the MOA and dismiss with a letter of caution. Mr. Livingston seconded the motion and it carried unanimously.

Mrs. Gillespie made a motion to waive their requirement to come back before the Non-Resident Review Committee and issue a \$500 fine for shipping into this state prior to an approved application for the change of ownership and that permit be issued after review and approval at the staff level of their application. Mr. Blackmon seconded the motion and it was carried unanimously.

11. Request Approval of MOA - Parker Medical Equipment

Dr. Richardson made a motion to assess a \$250 fine with 1 year probation. Mr. Morris seconded the motion and it carried unanimously.

Mrs. Gillespie made a motion to adjourn. Mr. Morris seconded the motion and it carried unanimously.