South Carolina Board of Pharmacy Board Meeting

9:00 a.m. January 18-19, 2017 Synergy Business Park 110 Centerview Drive, Kingstree Building Room 108 Columbia, South Carolina

Wednesday, January 18, 2017

1. Approval of November 16, 2016 Minutes

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

2. Approval of Reciprocity Candidates

Dates: November 10th, December 8th Mr. Hyatt made a motion to approve the candidates. Mr. Morris seconded the motion and it carried unanimously.

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

Report given.

4. Inspectors' Report

Report given.

5. Reports:

Finance Report –Lee Ann Bundrick, R.Ph.

Report given.

Office of Disciplinary Council- Pat Hanks

Report given.

Office of Investigations and Enforcement– Mark Sanders

Report given.

Appoint Board Members to Review IRC Process and Guidelines

Mr. Hubbard made a motion for Mr. Livingston and Mrs. Gillespie to review the process. Mr. Morris seconded the motion and it carried unanimously.

6. IRC Recommendations for dismissals and dismissals with non-

disciplinary letters of concern. Review of proposed Consent Agreements, Voluntary Surrenders and Temporary Suspensions from the Investigative Review Committee (IRC)

IRC Report – Mark Sanders

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

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

Mr. Livingston made a motion to approve a letter of caution. Mr. Hubbard seconded the motion and it carried unanimously.

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

Resolution Guidelines Report – Mark Sanders

Mrs. Gillespie made a motion to approve a cease and desist. Mr. Strauss seconded the motion and it carried unanimously.

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

Mr. Livingston made a motion to approve dismissals with letters of concern. Mr. Strauss seconded the motion and it carried unanimously.

Consent Agreements

Case #: 2014-91

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

Case #: 2015-93

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

Case #: 2015-105

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

Case #: 2016-34

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

Case #: 2016-37 (Private Agreement)

Mr. Morris made a motion to deny the agreement. Mrs. Gillespie seconded the motion and it carried unanimously. Mr. Morris made a motion to dismiss the case. Mr. Hyatt seconded the motion and it carried unanimously.

Case #: 2016-39

Mr. Livingston made a motion to approve the agreement. Mr. Hyatt seconded the motion. Mr. Morris and Dr. Richardson voted against the agreement. The motion passed.

Case #: 2016-45

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

Case #: 2016-70

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

Voluntary Surrenders

Case #: 2016-154 Case #: 2016-155 For information only.

Relinquishments

Case #: 2014-100 Case #: 2015-16 Case #: 2016-144 For information only.

7. New Business

A. Request Approval of Reciprocity Application – Patricia Williams

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

B. Request Approval of Pharmacy Intern Certificate Application – Felicia Vielbaum

This request was closed to the public. Mr. Livingston made a motion to approve the request. Mr. Hyatt seconded the motion and it carried unanimously.

C. Request Approval of Pharmacy Technician Registration – Travis Hankinson Mrs. Gillespie made a motion to approve the request. Mr. Hyatt seconded the motion and it carried unanimously.

D. Request Approval of Pharmacy Technician Registration – Tyrell Ellis Mr. Morris made a motion to approve the request. Mrs. Gillespie seconded the motion and it carried unanimously.

E. Request Approval of Pharmacy Technician Registration – Mark Davis Mr. Strauss recused himself from voting on this item. Mrs. Gillespie made a motion to approve the request. Mr. Livingston seconded the motion and it carried.

F. Request Approval to be PIC in Two Facilities – Shertech (Nuclear and Compounding), Rusty Prescott

Mr. Livingston made a motion to approve the request. Mr. Hubbard seconded the motion and it carried unanimously.

G. Request Approval for Practitioners to Dispense to Patients in a Teen Center – Steve Ranck Mr. Livingston made a motion to deny this request and encourage Greenville Health System to seek 340B status so they would qualify under Section 40-43-60(I). Mr. Hyatt seconded the motion and it carried unanimously.

H. Request Approval of Non-Resident Pharmacy Permit Application - Akina Pharmacy, Girgis Bassem

Mr. Hubbard made a motion that to deny the request based on using false statement and omission of material fact on application. It is not in the best interest of the public. They cannot reappear before the board for two years. Mr. Hyatt seconded the motion and it carried unanimously.

I. Request Approval of Permits of Talyst in Agape Hospice Facilities – Stuart Williams Mr. Morris made a motion for Mr. Stuart Williams to appear at the next Practice and Technology Committee Meeting on February 23 with detailed policies and procedures on how they intend to utilize the Talyst technology in the Agape Hospice settings with a detailed list of medications they intend to stock in Talyst, pursuant to hospice patient care. Mr. Hyatt seconded the motion and it carried unanimously.

J. Request to Waive Late Renewal Fee – MUSC, Children's Day Treatment Program- Kirk Meekins, MD

This request is deferred to March 15, 2017.

K. FDA Warning Letters and Form FDA-483s – Addison Livingston, PharmD Discussion only.

L. Approval of 2018 Board Meeting Dates: January 17-18th, March 14th, June 13-14th, September 19-20th, November 14th

Mr. Livingston made a motion to approve the 2018 meeting dates. Mr. Hyatt seconded the motion and it carried unanimously.

M. Elect Delegate, Alternate Delegate and Staff for NABP's 113th Meeting in Orlando, FL, May 20-23, 2017

Mr. Hubbard made a motion for Mr. Morris, Dr. Richardson, Mrs. Bundrick and one other staff member to attend the meeting. Mr. Livingston seconded the motion and it carried unanimously.

N. Approval of Non-Resident Non-Dispensing Pharmacy Application

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

O. Technician Ratio Discussion Discussion only.

P. Discussion of Questions and Proposal Regarding the Provision of Naloxone to Patients Receiving Services in a DAODAS Treatment Center Pursuant to the Joint Naloxone Protocol Approved by the South Carolina Board of Medical Examiners and State Board of Pharmacy in November 2016.

Mr. Livingston made a motion to view the protocol presented by DAODAS and DHEC as being in compliance with the South Carolina Pharmacy Practice Act and the Naloxone protocol that the Medical and Nursing boards adopted. Mr. Hyatt seconded the motion and it carried unanimously.

8. Committee Reports

- Pharmacy Technician Rebecca Gillespie, PharmD, R.Ph. No meeting to report.
- Compounding Addison Livingston, R.Ph. No meeting to report.
- Legislative Addison Livingston, PharmD, R.Ph.
 Compounding Regulation, Comment Letter from NACDS Information only.
- Nuclear Pharmacy Spencer Morris, PharmD, R.Ph.
- The committee voted to ask the board for approval to forward a letter to the FDA asking: 1) ask the FDA how this will affect the hospital based nuclear practice and 2) change "Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities, Guidance for Industry", page 2, line 40: change from "Production of positron emission tomography (PET) drugs" TO "Production of cyclotron produced positron emission tomography drugs". A motion from a committee does not require a second. It passed unanimously.
- Pharmacy Practice & Technology Terry Blackmon, R.Ph. No meeting to report.
- Recovering Professional Program Leo Richardson, PhD Dr. Richardson gave a report for information only.
- Healthcare Collaborative Committee Carole Russell, R.Ph. No meeting to report.
- Non-Resident Application Review Committee Recommendations

December 7, 2016 Meeting

The committee recommended approval: Masters Pharmaceuticals Cardinal Health 200, LLC (Solon, Ohio); VistaPharm, Inc. Cardinal Health 200, LLC (Grand Prairie, TX); Exel, Inc; Cardinal Health 110, LLC; Aero-Med, Ltd. Advanced Accelerator Applications USA Inc.;

Kuehne + Nagel, Inc.; Fagron Sterile Services (Outsourcing Facility permit); Covidien Sales, LLC; Fagron Sterile Services (Wholesale/Distributor/Mfg permit); Realo Discount Drugs Kenco Logistic Services, LLC (Chattanooga, TN); Stockman's Supply, LLC Butler Animal Health Supply, LLC; Remedi SeniorCare of Virginia, LLC

A motion from a committee does not require a second. It passed unanimously.

The committee recommended conditional approvals:

CCN America, LP pending submission of recent VPP certification/inspection and continued compliance with SC pharmacist to technician ratio.

RxTPL pending completion of controlled-substance vault/cage and submission of current Ohio Board of Pharmacy inspection.

P.I.M.D. International pending completion of controlled-substance vault/cage and issuance of DEA registration.

BrooksideRx pending submission of operational inspection report.

Apothecary by Design pending continued compliance with South Carolina pharmacist to technician ratio.

Kenco Logistic Services, LLC (Southaven, MS) pending payment of \$1,000 fine for shipping into South Carolina without a permit.

Nanobots Healthcare, LLC pending receipt of letter from Texas Board of Pharmacy regarding resolution of inspection deficiencies.

Loudoun Pharmacy Corp. pending submission of operational inspection.

A motion from a committee does not require a second. It passed unanimously.

The committee recommended to defer:

Specialty Chemist Corporation –until submission of label with toll-free number; a copy of PCAB inspection; worksheets from November 6-12, 2016 to reflect accurate BUDs and salt-to-base conversions; an example of multi-dose packaging; thorough policy and procedure regarding shipping; documentation of training in compounding for all compounding personnel to include 6 initial hours of CE and 4 hours of CE annually.

SMA Group, Inc. –pending resubmission of application and all required documents to reflect testimony that applicant performs compounding

A motion from a committee does not require a second. It passed unanimously.

Mr. Livingston made a motion to adjourn. Mr. Strauss seconded the motion and it carried unanimously.

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9:00 a.m. January 18-19, 2017 Synergy Business Park 110 Centerview Drive, Kingstree Building Room 204 Columbia, South Carolina

Thursday, January 19, 2017

Lifestar Emergency Medical Services

Mrs. Gillespie made a motion to revoke the permit. Mr. Hyatt seconded the motion and it carried unanimously.

Consent Agreement 2014-104

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

Ashley Pilgrim

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

Stephanie Snipes

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

Wells Pharmacy Network, LLC - Memorandum of Agreement

Mr. Morris made a motion to lift the sterile compounding restrictions currently imposed and approve their permit contingent upon submission and approval of a pending NABP inspection contingent upon it being approved by the chair of our Non-Resident Application Review Committee and the board administrator. Mrs. Gillespie seconded the motion and it carried unanimously.

Mrs. Gillespie made a motion to accept the MOA with a letter of caution. Mr. Strauss seconded the motion and it carried unanimously.

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