South Carolina Board of Pharmacy

Board Meeting

9:00 a.m., September 17-18, 2008 Synergy Business Park 110 Centerview Drive, Kingstree Building Columbia, South Carolina

Wednesday, September 17, 2008, Room 202-02

Meeting Called to Order

Davis Hook, R.Ph., chairman, of West Columbia, called the regular meeting of the SC Board of Pharmacy to order at 9:04 a.m. Other Board members participating in the meeting included: Allen Toole, R.Ph., vice chairman, of Liberty; David Banks, R.Ph., of Simpsonville; Bobby Bradham, R.Ph., of Charleston; Dan Bushardt, R.Ph., of Lake City; Hugh Mobley, R.Ph., of Lancaster; Leo Richardson, Ph.D., of Columbia; and Dock Henry Rose, R.Ph., of Greer.

Staff members participating during the meeting included: Lee Ann Bundrick, R.Ph., Administrator; Marilyn Crouch, Program Assistant; Eddie Durant, R.Ph., Temporary Investigator; Joe Newton, R.Ph., Pharmacist Investigator; and Tom Porter, R.Ph, Pharmacist Investigator. LLR employees participating during the meeting included: Sharon Dantzler, Deputy General Counsel, LLR-Office of General Counsel Sandra Dickert, Administrative Assistant; Pat Hanks, Attorney, Office of General Counsel; and Bob Selman, Legislative Liaison.

Members of the public attending the meeting included: Shanna Amerson, Michael Ayotte, Ron Bartley, Michael Bazley, Emily Belleban, Mike Blakely, Ashley Burns, Joseph Busuttil, Shannon Davis Carter, Sherrie Chapman, Carmelo Cinqueonce, Ivy Coleman, James Deweese, Nina Ellison, Janelle Hicks, Cathy Kuhn, Tammy McDowell, Megan Montgomery, Amanda Moore, Joe Mullinax, Khyan Patel, Christy Pettit, Tom Phillips, Patti Powell, Rebecca Rabbitt, Laticia Cobb-Rich, Eric Ridings, Carla Redding, Ken Rogers, Solon Symeonidis, Rick Wilson; and Mary Elizabeth Wood.

Mr. Hook announced this meeting was being held in accordance with Section 30-4-80 of the S. C. Freedom of Information Act by notice mailed to The State Newspaper, Associated Press, WIS-TV and all other requesting persons, organizations, or news media. In addition, notice was posted on the bulletin boards at the two main entrances of the Kingstree Building.

Pledge of Allegiance

All present recited the Pledge of Allegiance.

Invocation

Mr. Bushardt delivered the invocation.

Chairman's Remarks – Davis Hook, R.Ph.

Mr. Hook stated he has concerns regarding public safety, improving health care and third party intervention in the health care arena. He went on to say things that require alterations of therapeutic protocols and diagnostic aids are a concern. He said limited product selection and some red tape involvement in dispensing of those medications are also a concern. He further stated the reimbursement for providers which diminishes and affects the quality of care. He does not mean the finances as the quality of care. He feels health care providers should be in charge of public health care. He asked how can we have medications stored in facilities with temperature allowances of typically 59 to 85 degrees, yet we allow mail order prescriptions mailed into South Carolina without any allowance for the temperature they may be coming into

or shipped from. He noted there too is a counseling absence involved in mail order and also the patient/pharmacist relationship. He stated Internet prescriptions concern him as the Board knows from the NABP inspections there may be as much as fifteen percent of the drugs may be counterfeit and the Board is also concerned about the controlled drugs producing diversions that goes throughout the Internet. He asked how this matter can be dealt with and feels it must be dealt with cooperation with other agencies and states and their regulatory agencies. He feels the pharmacists should have more collaborative involvement with practitioners. He feels pharmacists should be more involved with inquiring about patient outcomes. He thinks pharmacists should have programs that involve more medication compliance programs to be shared with patients who are taking medications and what they should be taking or taking incorrectly. He believes pharmacists should have more patient screenings or detection and prevention of disease and believes pharmacists should be administering immunizations.

Mr. Hook stated he has been in contact with Dr. Louis Costa, president of the Board of Medical Examiners, Dr. John Black, president-elect of the Medical Association, and Mr. Todd Atwater, who is Mr. Cinqueonce's counterpart in the medical profession. He further stated they all agree health professionals need to work together on the issues.

Introduction of Board Members and all other persons attending

The Board members, staff, and members of the public attending the meeting introduced themselves.

Approval of Excused Absences

All members were present.

1. Approval of Minutes for the June 18-19, 2008 Meeting <u>MOTION</u>

Mr. Banks made a motion the Board accept the minutes of the June 18-19, 2008 meeting. Mr. Bradham seconded the motion, which carried unanimously.

Approval of Agenda *MOTION*

Mr. Bradham made a motion, seconded by Mr. Bushardt and unanimously carried, the Board approve the agenda.

2. Approval of Reciprocity Interview Candidates for Licensure June 2^{nd} , 10^{th} , 13^{th} , 23^{rd} , 26^{th} , 30^{th} , July 1^{st} , 3^{rd} , 7^{th} , 9^{th} , 11^{th} , 15^{th} , 18^{th} , 2008 *MOTION*

Mr. Banks made a motion the Board approve the reciprocity candidates for licensure as listed. Mr. Rose seconded the motion, which carried unanimously.

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

Mrs. Bundrick is pleased to announce that staff had an exhibit booth at the SC Pharmacy Association Annual Convention, June 19-22, 2008 in Hilton Head, SC. Our staff attended. She would also like to thank Mr. Carmelo Cinqueonce and his staff at the association for working with us and making this possible.

As of this report there are approximately 2,343 active state-certified pharmacy technicians, 4,172 active registered pharmacy technicians, 6,133 active licensed pharmacists, 3,392 permitted facilities, and three routing companies.

Mr. Bryant would like to apologize for not being able to attend this meeting due to prior work related commitments. Mrs. Bundrick and Mr. Bryant had a conference call with the Board leadership yesterday, September 16, 2008 to update them on the recent reorganization of the agency. As always, Mr. Bryant is available by conference call if necessary.

Since the last Board meeting, the agency has consolidated areas in an effort to put the POL Division back together. The Board of Pharmacy is now under the Office of Business and Buildings which consists of business permits under Mr. Bryant's supervision. Mr. Rion Alvey is responsible for the medically related boards.

The Office of Licensure and Compliance under Mr. David Christian will be handling all renewals and initial routine licenses with a compliance component that will monitor board orders. Mrs. Sally Green will be handling pharmacists and Mrs. Linda Sheppard will be handling pharmacy technicians.

The Office of Investigations and Enforcement is now under Mr. Mark Dorman. Mr. Randy Bryant has been working with OIE during the transition. OIE will now have a drug diversion unit specializing in investigations working with DHEC Bureau of Drug Control on all medically related professional diversion cases which include pharmacy, dentistry, nursing, medical and veterinary boards. Mr. Ray Trotter will review these cases and sign off on them. Mr. Eddie Durant will now be performing inspections. Mr. Trotter and Mr. Durant will both be assisting the diversion unit as needed.

Remaining in the program area are board meetings, committee meetings, permitting of facilities, inspections investigation of medication errors and legislative issues. Staff remaining in the program include Mrs. Marilyn Crouch, Ms. Beverly Gould, Ms. Stephanie Calhoun, Mrs. Karen Duval and six full time or part time pharmacists, Mrs. Cle Sanders, Mr. Tom Porter, Mr. Joe Newton, Mr. Eddie Durant, Mr. Ray Trotter and myself.

Mr. Ron Cook, Mr. Mills Scoggins and Mr. Wayne Whitworth have been transferred from the pharmacy program to OIE in the drug diversion unit.

Mr. Randy Bryant met with DHEC Bureau of Drug Control on dual employment of some of their pharmacist investigators to assist with inspections of permitted facilities as well as the new drug diversion unit.

As you are aware, there was a reduction in fees for the pharmacy technicians this year. In 2009, there will be a reduction in fees for the pharmacists and possibly for the permits. We will go to biennial renewals starting in 2009, probably starting with pharmacists and permits then the next year pharmacy technicians.

There have been issues with the telephone system during the reorganization. The agency is purchasing a new telephone system to be implemented in the near future. In the meantime, Ms. Crouch has an updated list of telephone numbers for staff to distribute.

Mr. Bryant will be available to answer any questions upon his return.

My staff and/or I have participated in the following meetings since the June meeting:

Mrs. Sally Green and I attended the LLR Leadership Phase II training on August 12, 2008.

Mr. Al Toole and I attended the NABP/AACP District III annual meeting in Destin, Florida August 17-19, 2008.

The Pharmacy Technician Committee, the Legislative Committee, the Pharmacy Technology Committee, the Compounding Committee, the Nuclear Committee, the RPP Committee, the VAWD Committee, the Medication Errors Committee, and the Pharmacy Practice Committee met on August 26, 2008. Mr. Davis Hook, Mr. Al Toole, Mr. David Banks, Mr. Dan Bushardt, Mr. Bobby Bradham and Dr. Leo Richardson were the Board members who participated in these meetings.

Mrs. Sally Green, Ms. Stephanie Calhoun and Mr. Robbie Boland attended the NABP Program Review and training August 27-29, 2008 in Chicago, Illinois.

A telephone IRC meeting was held on September 2, 2008.

Mrs. Bundrick attended a legislative meeting with Senator Ronnie Cromer, Mr. Carmelo Cinqueonce, Mr. Jim Quackenbush, and chain pharmacy representatives on September 4, 2008.

Mrs. Bundrick was appointed and participated in NABP's Task Force on Standardized Pharmacy Technician Education and Training September 9-10, 2008 in Chicago, Illinois.

Mrs. Cle Sanders, Mr. Joe Newton and Mrs. Bundrick will be participating in the SC Pharmacy Association's Regional Rallies throughout the state. Board staff will be part of a panel discussion with representatives from the SC Pharmacy Association, SC College of Pharmacy, DHHS/Medicaid and DHEC Bureau of Drug Control. Issues of discussion from the Board's perspective include Proviso 65.9, immunizations and compounding issues.

Mrs. Cle Sanders participated in the Regional Rally on September 9, 2008 in Anderson, SC.

Mrs. Bundrick participated in the Regional Rallies on September 11, 2008 and September 16, 2008 in Anderson, SC.

Mr. Joe Newton participated in the Regional Rally on September 15, 2008 in Charleston, SC.

Mr. Joe Newton will be participating in the Regional Rallies in Aiken on September 18, 2008 and in Greenville on September 23, 2008.

Mrs. Bundrick will be participating in the Regional Rally in Florence on September 25, 2008.

In October Mrs. Cle Sanders will be participating in the Regional Rallies in the Myrtle Beach area.

Mrs. Cle Sanders is in Alaska for the National Clear Conference presenting the PC Notebooks-MiForms for the agency. Her presentation is September 25-26, 2008. South Carolina is one of two states making a presentation on this technological advancement.

Mr. Joe Newton will be attending the National Governor's Alliance E-Health Forum on behalf of the Governor's Office in Arlington, Virginia September 25-26, 2008.

Staff has attended agency, board staff, compliance staff and legal counsel meetings.

The Board of Pharmacy has continued to serve as a site for pharmacy students on clinical rotations fro the SC College of Pharmacy – USC Campus. Staff had Ms. Ashley Plott during the month of August. Ms. Megan Montgomery and Ms. Mary Elizabeth Wood started their rotation this month.

To date, Mrs. Bundrick has received four applications for the three vacant FTEs for the pharmacist inspector positions. Mrs. Bundrick is in the process of setting up interviews for the positions.

Mr. Wilbur Harling and Mrs. Bundrick will be participating in the MPJE State Specific Law Review at NABP in Chicago, Illinois October 8-12, 2008.

The deadline for the fourth quarter Board of Pharmacy newsletter to NABP is quickly approaching. Mrs. Bundrick asked the Board to let her know if they have any suggestions for articles. Staff has been sending the articles to the Board members for their review and comments. Mrs. Bundrick asked the Board members to let her know if they are having problems receiving this information.

The Office of Licensure and Compliance will be conducting random continuing education audits for ten percent of the pharmacists and ten percent of the pharmacy technicians in the fall.

Mrs. Bundrick thanked the Board for their support of her and her staff. They always appreciate the encouragement and support the Board gives the staff.

Mr. Mobley asked Mrs. Bundrick about the FTE positions. Mrs. Bundrick replied affirmatively.

Mr. Mobley questioned Mrs. Bundrick about the reorganization. He asked if there have been issues as far as staffing being able to create the support Mrs. Bundrick needs to make all of the changes. Mrs. Bundrick stated that as of this point in time Mrs. Sally Green and Mrs. Linda Sheppard have been moved to the Office of Licensure and Compliance and they have a new supervisor. She went on to say she is coordinating and working with that office on issues that she has to handle from an administrator's point of view. She noted these issues include 'yes' answers on applications. Mr. Mobley asked if they are located on a different floor. Mrs. Bundrick replied affirmatively.

Mr. Hook stated he and Mr. Toole had a conference call with Mr. Bryant and Mrs. Bundrick on Tuesday, September 16, 2008. He further stated they asked questions regarding licensing issues. He noted Mr. Bryant has instructed the staff to take the Board members' calls personally instead of moving through the Office of Licensure and Compliance.

Mr. Mobley stated the issue is if there is a question they have to traverse barriers to another part of the building to obtain an answer when there is supervision or pharmacist involvement.

Mr. Hook stated during the call they asked if the reorganization was to create improvement to which he replied affirmatively. He does not see how the changes could produce improvement when it is diverse.

Mrs. Bundrick stated the Office of Licensure and Compliance is divided into three sections. The licensure portion of the office is divided into initial applications and renewal applications. She

noted the renewal section handles only renewal applications which are staggered throughout the year. She went on to say the facility applications have remained with the program.

Mr. Mobley questioned Mrs. Bundrick in regard to online address changes. Mrs. Bundrick stated the agency is working on these changes and she was informed the entire agency must be at that point prior to implementing these changes.

Mr. Mobley questioned Mrs. Bundrick regarding the phone system issues. He noted a chain pharmacy supervisor who had applied for a new permit in June 2008 or July 2008 and they have not heard from staff in regard to the permit. He further stated the efficiency of the new process is bogged down. He indicated he gave the individual Mr. Bryant's phone number in an attempt to get the matter resolved. He does not see how making this process diverse is creating efficiency.

Mr. Mobley asked why Pharmacy is under the Office of Building and Business when the other health related boards are under the Medical and Health Related Office. Mrs. Bundrick stated that pharmacy staff permits facilities and her understanding is that is why pharmacy is under the Office of Building and Business.

Mr. Bradham stated he has received a number of calls from his constituents since the reorganization. He kept lists of individuals who had passed the MPJE and the NAPLEX four weeks ago, five weeks ago, and six weeks ago. He called the office and acted like he was an applicant checking on his license. He spoke with three individuals prior to being connected with Mrs. Green with whom he shared the concerns of his constituents. He then contacted Mrs. Youmans' office and Mr. Bryant's office and received calls from both Mr. Bryant and Mrs. Youmans' assistant within one and one-half hours. He stated staff could not tell him when a license was postmarked. He stated there are problems with the phone system and with the mail room. He further stated the reorganization is at the bottom of the customer service poll.

Mr. Mobley questioned Mrs. Bundrick regarding the compliance aspect of the Office of Licensing and Compliance. Mrs. Bundrick stated drug diversion cases are being handled by the Office of Investigations and Enforcement. She went on to say Mr. Ray Trotter will be reviewing the diversion cases and he and Mr. Durant are available to that unit as needed to assist in those cases.

The Board asked Mrs. Bundrick if an agency representative could speak with the Board during Thursday's meeting.

Mr. Hook stated the association's assistance in allowing the Board to have a booth at the conference is important to getting exposure to the profession. He asked the Board to send a thank you note to the association. He asked Mr. Cinqueonce if he would inform his Board the Board of Pharmacy appreciates the use of their facility. He thanked Mrs. Bundrick on being selected and serving on a task force for NABP.

4. Compliance and Inspectors Report

RC Recommendations for dismissals and dismissals with non-disciplinary letters of concern, Proposed Agreement to Relinquish, Consent Agreements and Cease and Desist Orders

Agreement to Relinquish
 Case #: 2007-47
 Case #: 2008-41

Case #: 2008-63 Case #: 2008-81 Case #: 2008-91

MOTION

Mr. Bradham made a motion, seconded by Mr. Banks and unanimously carried, the Board accept the agreements to relinquish in the above cases.

• Consent Agreements

Case #: 2007-94

MOTION

Mr. Bradham made a motion the Board accept the consent agreement in case #2007-04. Mr. Mobley seconded the motion, which carried unanimously.

Case #: 2008-15

MOTION

Mr. Banks made a motion, seconded by Mr. Toole and unanimously carried, the Board accept the consent agreement in case #2008-15.

Case #: 2008-93

MOTION

Mr. Rose made a motion, seconded by Mr. Banks and unanimously carried, the Board accept the consent agreement in case #2008-93.

Case #: 2007-108

Mr. Banks recused himself from voting in this matter.

MOTION

Mr. Rose made a motion, seconded by Mr. Toole and unanimously carried, the Board accept the consent agreement in the above case.

The Board was presented with cease and desist orders issued to non-licensed facilities. These cease and desist orders were presented for the Board's information. Mr. Rose recused himself from participating in discussion on the cease and desist orders.

IRC Report

Cases for Dismissal

MOTION

Mr. Bradham made a motion, seconded by Mr. Banks and unanimously carried, the Board approve the IRCs recommendation in the four cases for dismissals.

2008-53 2008-68 2008-76 2008-84

Cases for Formal Complaints

MOTION

Mr. Bradham made a motion, seconded by Mr. Bushardt and unanimously carried, the Board accept the IRCs recommendation in the cases for formal complaints.

2006-90	2007-45	2008-30	2008-49	2008-52	2008-54
2008-58	2008-60	2008-69	2008-72	2008-77	

Mrs. Bundrick presented the members with the recommendations regarding cases in accordance with the Board's resolution guidelines.

Consent Agreement

MOTION

Mr. Bradham made a motion, seconded by Mr. Toole and unanimously carried, the Board approve the recommendation regarding the consent agreement

2008-67

Dismissals

MOTION

Mr. Banks made a motion, seconded by Mr. Bradham and unanimously carried, the Board approve the recommendations regarding the dismissals.

2007-120 2007-128 2008-5 2008-75

<u>Dismissals with Letters of Concerns</u>

MOTION

Mr. Banks made a motion the Board approve the recommendation regarding the cases involving dismissal with letters of concern. Mr. Bradham seconded the motion, which carried unanimously.

2007-44 2007-97 2007-122 2008-39

A. Request for Reinstatement – Solon Symeonidis

During an approximate time period of February 2007 to April 2007 Mr. Symeonidis failed to verify the status of several controlled substance prescriptions. Consequently a quantity of a Schedule II controlled substance was unlawfully dispensed from a pharmacy in Dillon, South Carolina. Mr. Symeonidis' license was temporarily suspended by the Board on August 9, 2007 and he appeared in a hearing before the Board on January 17, 2008. Following the hearing the Board issued a Final Order in which Mr. Symeonidis' license was suspended for one year, retroactive to August 9, 2007. He was also ordered to pay a \$500 fine within one year, but no later than the date of any petition by him for reinstatement of his pharmacy license, ordered to take a Board approved course on medication errors and was ordered to take, and successfully pass, the MPJE. The Board Order also stated he must appear before the Board prior to reinstatement of his license. Mr. Symeonidis passed the MPJE exam on April 9, 2008. Staff received payment of the \$500 fine on May 28, 2008. Mr. Symeonidis took a Board approved course on medication errors on May 9, 2008 and is now petitioning the Board for the reinstatement of his license.

Solon Symeonidis appeared before the Board at this time. Mr. Symeonidis is requesting the Board reinstate his license.

MOTION

Mr. Banks made a motion the Board approve Mr. Symeonidis' reinstatement. Mr. Toole seconded the motion, which carried unanimously.

B. Request for Reinstatement – James M. Deweese

James M. Deweese admitted to diverting a quantity of Albuterol, Ultram and APAP #3 over a three to four year period and distributed these medications to a personal friend without the

authorization of a practitioner. He was admitted to a treatment center for a twenty day period in November 2002 followed by another treatment program between December 2002 and January 2003. A Memorandum of Agreement and Stipulations, dated May 22, 2003 states Mr. Deweese surrendered his license on October 1, 2002. He enrolled in the Recovering Professionals Program (RPP) on October 29, 2002. A July 16, 2003 Board Order modified his original order to allow Mr. Deweese to serve as a pharmacist in charge (PIC) during the remaining period of his probation. In a letter dated June 15, 2008 Mr. Deweese asked that he be released from his order. The Board received an email from Latecia C. Rich of RPP supporting Mr. Deweese's request for release from his order.

James Deweese and Latecia C. Rich of RPP appeared before the Board at this time and gave the following testimony.

Mr. Deweese stated he has been with RPP for five years and has completed all of the terms and conditions of his consent agreement. He is seeking the Board's approval to reinstate his license without probation.

Mrs. Cobb-Rich stated Mr. Deweese is in full compliance with the conditions of his RPP contract and she would support his reinstatement.

Mr. Deweese plans to continue his recovery with RPP and has become a sponsor for another client. His goal is to continue to help other individuals. He is now working in retail and plans to continue working. He has had no problems in his return to the retail environment.

MOTION

Mr. Banks made a motion the Board approve Mr. Deweese's request for reinstatement. Mr. Mobley seconded the motion, which carried unanimously.

C. Request for Release from Order – Shannon Davis Carter

During a routine inspection of the Medicine Shoppe on September 14, 2006 Shannon Davis Carter was observed performing the duties of a pharmacy technician, such as filling prescriptions, counting tablets and working on a computer. She was not registered as a pharmacy technician at the time nor was a technician registration conspicuously displayed in the store. Ms. Carter entered into a consent agreement, dated February 14, 2007, which states her pharmacy technician registration would be placed on a one year probation contingent upon compliance with terms and conditions of the agreement, which included payment of a \$50 fine. Ms. Carter is now requesting her probation be terminated in accordance with the consent agreement.

Shannon Davis Carter appeared before the Board as this time and gave the following testimony.

Ms. Carter stated she has met all of the terms and conditions of her order and is requesting the Board release her from the order.

MOTION

Mr. Mobley made a motion the Board release Ms. Carter from her order. Mr. Banks seconded the motion, which carried unanimously.

5. Old Business

D. MOA with Medical University of South Carolina

Mr. Hook presented the Board with the final MOA with the Medical University of South Carolina. He noted this final MOA was for the Board's information and that no action was needed since the MOA had already been approved.

Mrs. Bundrick stated UMA has begun submitting applications and staff is now conducting inspections on those facilities.

E. Joint Statement on Pain Management

A draft joint statement on pain management was presented to the Board for its review. The statement says health care professionals should work together effectively to address the dimensions of pain and to provide maximum pain relief with minimal side effects. The statement lists 12 items health care professionals should do to effectively assist patients in the management of pain.

Mrs. Bundrick stated the Board had directed Mrs. Sanders and Mr. Hook to meet with the Board of Nursing and the Medical Board in an attempt to draft a joint statement on pain management to approve for South Carolina. She further stated the Board of Nursing drafted the statement by committee and it was approved by the full Board. She also stated was approved by the Medical Board during its meeting held earlier this week. She said the Board now needs to approve the statement if it comfortable with the statement.

Mr. Mobley asked Mrs. Dantzler if changes have been made in the Medical Board or the Board of Nursing statutes or regulations addressing pain medication prescriptions. Mrs. Dantzler stated there have been complete statute rewrites for the Board of Nursing and the Medical Board licensing act within the past three years. She does not think these rewrites concern pain management.

The Board determined it would vote on this matter later in the meeting.

6. New Business

F. Request Approval of Reciprocity Application – Michael Bazley

On April 24, 2008 the Board received a pharmacist reciprocity application from Michael Bazley. Mr. Bazley answered 'yes' to the question asking, "Have you ever been charged or convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than minor traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned from any such offense?" On April 28, 2005 Mr. Bazley was charged by the University of Florida police with an open alcohol container violation. Mr. Bazley filed a petition to enter a nolo contendere plea with the County of Alachua on October 5, 2005, which was accepted on November 23, 2005. A deferred prosecution document reflects prosecution in the violation would be deferred for three months provided Mr. Bazley agreed to terms and conditions, which included payment of a \$110 fine. Mr. Bazley is currently licensed in North Carolina. He passed the MPJE on July 10, 2008. Staff notified Mr. Bazley by letter dated July 18, 2008 that the Board would be reviewing his application during this meeting and asked that he be present to answer questions from the members.

Michael Bazley appeared before the Board and gave the following testimony.

Mr. Bazley stated while studying at the University of Florida he was charged with an open container violation approximately two days prior to graduation.

MOTION

Mr. Bradham made a motion the Board grant Mr. Bazley's reciprocity application. Mr. Rose seconded the motion, which carried unanimously.

G. Request Approval of Reciprocity Application – Joseph Busuttil

The Board received a pharmacist reciprocity application dated May 9, 2008 from Joseph Busuttil. Mr. Busuttil answered yes to the question asking, "Has your pharmacist license in any jurisdiction ever been revoked, suspended, restricted, terminated, or otherwise been subject to disciplinary action (public or private) by any board of pharmacy or other state authority?" On March 20, 1990 the Office of Professional Discipline NYS Education Department fined Mr. Busuttil \$500.00 for a prescription misfill for filling a prescription with a higher dosage of medication than was prescribed. Results from blood tests revealed the blood levels were fine and no harm was done to the patient. Mr. Busuttil is currently licensed in New York and Delaware. He is seeking reciprocity from New York. He passed the MPJE on June 10, 2008. Staff notified Mr. Busuttil by letter dated June 12, 2008 that the Board would be reviewing his application during this meeting and asked that he be present to answer questions from the members.

Joseph Busuttil appeared before the Board and gave the following testimony.

Mr. Busuttil stated he had been working for fourteen straight days when the misfill occurred. He further stated disciplinary action was taken because the Office of Professional Discipline had been contacted. He noted the patient's blood levels were checked and the results were fine.

MOTION

Mr. Banks made a motion the Board accept Mr. Busuttil's application. Mr. Rose seconded the motion, which carried unanimously.

H. Request Approval of Non-Resident Pharmacy Permit Application – Basic Home Infusion, Inc., Roy Putrino, R.Ph.

The Board received a nonresident pharmacy permit application dated June 30, 2008 from Basic Home Infusion, Inc. Included with the permit application was a cease and desist document for engaging in alleged conduct and an attachment addressing violations and fines totaling \$7,650.00 from the New Jersey Board of Pharmacy. The application also included a letter from Basic Home Infusion to the New Jersey Board of Pharmacy addressing issues from the attachment.

Roy Putrino appeared before the Board via conference call and gave the following testimony.

Mr. Mobley questioned Mr. Putrino regarding compounding issues. Mr. Putrino stated New Jersey does not enforce the pressure monitoring He asked Mr. Putrino if the facility monitors temperature and humidity on a daily basis. Mr. Putrino answered affirmatively. Mr. Mobley asked Mr. Putrino to tell him abut surface sampling or measuring for particle counts in the facility's clean and ante rooms. Mr. Putrino stated the facility uses an independent lab for particle counts and in addition the facility conducts a test for the fluid. The facility runs them through a medium and incubates it to see if anything grows from that. Mr. Mobley asked Mr. Putrino how often the facility cleans the clean room and ante room. Mr. Putrino stated the cleaning room is cleaned every day and the hoods are wiped after each compounding. Mr. Mobley asked Mr. Putrino if the facility does any testing for microbial pyrogens using agro plates or surface. Mr. Putrino replied affirmatively and stated testing is conducted twice a month. He also noted logs are also kept on the cleaning.

Mr. Mobley stated he had seen the joint commission's accreditation survey which appears to have been completed in 2006. Mr. Putrino stated the next survey is due in April 2009. Mr. Mobley stated the last time Mr. Putrino's facility was surveyed was conducted under the old USP <797>. He noted several revisions have been made in USP <797> which would change his survey scheduled to be conducted in April 2009. He went on to say it appears South Carolina moving toward the new USP <797> guidelines and part of that has to do with surface sampling, pressure monitoring and cleaning. Mr. Mobley asked Mr. Putrino what kind of training is involved for his personnel. Mr. Putrino stated all personnel are licensed or registered. He further stated the NHIA has eight modules the personnel complete. He went on to say his personnel also goes through a skills checklist twice a year.

Mr. Mobley asked Mr. Putrino what he does for personnel validation as far as periodic testing to assess their ability to compound. Mr. Putrino stated the assessment is done through the skills checklist performed twice a year. He further stated he only has to certify individuals twice a year. Mr. Mobley asked Mr. Putrino if any of his personnel use any soy casien in non-sterile compounding area and then transfer to a sterile compounding area. Mr. Putrino asked Mr. Mobley to repeat the question. Mr. Mobley asked Mr. Putrino if he has a way to use a non-sterile soy casien or reconstituted powder that is mixed and moved to sterile area for incubation? Mr. Putrino replied affirmatively and noted he is doing some high risk compounding. Mr. Putrino stated once personnel runs it through the syringe personnel accounts for the loss of fluid. Personnel then inserts the medium in the cup and incubate themselves. He stated it would have a lot number, a MR number and the date it was put in.

Mr. Mobley stated he was asking about the process by which he takes a non-active growth medium, compound it and perform sterilization. Mr. Putrino stated all of his stuff is sent to an independent lab to test for concentration. Mr. Mobley asked Mr. Putrino, as part of his personnel validation, if he gets a soy casien powder, mix it with non-sterile water or purified water in a non-sterile area, i.e., a general compounding area where individuals are moving around, then take the compound into an ISO controlled area, draw it into a syringe, filter the mixture into several different sterile vials and then take some into non-sterile vials and mark as controlled, incubate both sets of vials for comparison for different growth. Mr. Putrino stated he does not have a batching process like the one Mr. Mobley described. He noted each drug is made specifically for each patient. Mr. Mobley stated this would not be for patient use but for personnel validation only. Mr. Putrino stated he does not perform the process Mr. Mobley described.

Mr. Mobley asked Mr. Putrino about his policies and procedures. He asked if the joint commission required policies and procedures. Mr. Putrino stated personnel follows e required policies and procedures.

Mr. Mobley stated Mr. Putrino indicated he does not have pressure gauges. He asked Mr. Putrino if he uses the same cleaning agents or if he rotates cleaning agents. Mr. Putrino replied the facility rotates cleaning agents and he named different cleaning agents the facility uses. He does use cleaning solutions for the floors are premixed on a daily basis.

Mr. Mobley stated South Carolina requires all new permitted facilities to be in compliance with the current USP <797> guidelines.

Mr. Hook asked Mr. Putrino how the facility addresses the counseling issue for patients. Mr. Putrino stated the facility has a 24 hour monitoring center staffed with pharmacists and nurses. He further stated the facility is a national company and when the patient contacts the monitoring

center staff can address the issues. He went on to say the system allows physicians to access it through a portal so they can see the patient's prelim tries and see the medication orders, and the nursing notes. Mr. Mobley asked Mr. Putrino if most of the compounded products go to the physician or the patient. Mr. Putrino stated his compounded products go to the patient and he is able to discuss the therapy with the patient. He went on to say everything is posted in the progress notes.

Mr. Mobley asked Mr. Putrino if he does any other kind of test for personnel validation, such as fingertip testing. Mr. Putrino replied negatively. Mr. Mobley asked Mr. Putrino if his facility uses a single agent or multiple agents in cleaning each day. Mr. Putrino replied he uses a single agent each day.

Mr. Hook asked Mr. Putrino if the prescriptions are patient specific. Mr. Putrino replied affirmatively and stated the facility does not send anything to a physician's office. Mr. Hook stated the information contained in Mr. Putrino's application indicated most all of the therapies are administered by pump. Mr. Hook asked Mr. Putrino if these types of products are patient specific. Mr. Putrino stated it goes to the patient via a nurse who is the intermediary. He further stated none of the products are delivered to a physician's office. Mr. Hook asked Mr. Putrino if the nurse is under his employment. Mr. Putrino answered affirmatively. Mr. Hook asked Mr. Putrino if the nurses are licensed in South Carolina to administer medications. Mr. Putrino replied affirmatively.

Mr. Putrino stated he wants to comply with South Carolina's requirements. He asked that if there are any problems that he be given the opportunity to rectify the matter.

Executive Session *MOTION*

Mr. Banks made a motion the Board enter executive session to seek legal advice. Mr. Rose seconded the motion, which carried unanimously.

Public Session MOTION

Mr. Banks made a motion seconded by Mr. Rose and unanimously carried, the Board return to public session.

Mr. Hook noted no official action was taken during executive session.

Non-Resident Pharmacy Permit Application – Basic Home Infusion, Inc., Roy Putrino, R.Ph.

MOTION

Mr. Mobley made a motion the Board deny the application until such time Mr. Putrino can document current compliance with the current USP <797> guidelines. Mr. Banks seconded the motion, which carried unanimously.

Joint Statement on Pain Management

MOTION

Mr. Rose made a motion, seconded by Mr. Banks and unanimously carried, the Board approve the Joint Statement on Pain Management.

LUNCH

The Board recessed for lunch at 12:03 p.m. and returned to public session at 2:00 p.m.

New Business (Continued)

I. <u>Minute Clinic Group – CVS, Caremark Corp. – Michael J. Ayotte, R.Ph., Director of Government Affairs</u>

Michael J. Ayotte, R.Ph., Thomas Phillips, R.Ph. and Nina Ellison, of CVS, Caremark Group, made an informational presentation regarding the minute clinic group. A copy of this presentation is herewith attached to the permanent record of this meeting located at the Board's office.

7. Committee Reports

• Pharmacy Technician – David Banks, R.Ph., Al Toole, R.Ph., Dan Bushardt, R.Ph., Davis Hook, R.Ph.

Mr. Banks stated the committee met on August 26, 2008 and attempted to establish committee members for the year.

The committee discussed at length certification of pharmacy technicians. ICPT is a testing service similar to PTCB and would be an alternative testing service to PTCB. The examination is \$95 and the pass rate is seventy-five percent.

Rebecca Rabbitt, of ICPT, appeared before the Board at this time. She stated there are approximately ten testing sites in South Carolina. She further stated the test is given most every day of the week, with the exception of Sunday. She said results are provided almost immediately.

Mr. Bradham asked Ms. Rabbitt if the test is psychometrically equivalent to the PTCB. Ms. Rabbitt answered affirmatively. She stated they are accredited by the National Commission of Certifying Agencies. Mr. Bradham stated he does not see where ICPT is psychometrically equivalent and asked if there is a reason why the documentation has not been sent to NABP at their request. Ms. Rabbitt stated NABP has information ICPT can share publicly with them. She further stated NABP is a stakeholder in PTCB and for competitive reasons that information cannot be shared with them. She went on to say NABP did reassure them in a memo that recognizes ICPT is NCCA accredited and an appropriate mechanism for boards of pharmacy to use in assessing pharmacy technician tests and they recognize that both testing agencies are NCCA approved. Mr. Bradham understands the accreditation and asked if the test is psychometrically equivalent to the PTCB. Ms. Rabbitt stated ICPT has conducted a practice analysis as to PTCB which is a means to determine what actually needs to be on the test. Ms. Rabbitt did not know that was a requirement for the Board.

MOTION

The committee made a motion to present ICPT as an alternative testing service to the full Board for approval. Since the motion came from committee no second was needed. The motion carried with a majority vote. Mr. Bradham, Mr. Rose, and Dr. Richardson voted nay.

A presentation was made to the Board regarding a comparison of technician duties and ratios.

MOTION

The committee made a motion the Board grant individuals who have passed the requirements as they were given by the technical colleges that have a collaborative agreement with Midlands Technical College of an ASHP accredited program be allowed state certification. All collaborative schools must be in compliance with ASHP accreditation prior to the next school year. Since the motion came from committee no second was needed.

Mrs. Bundrick stated it was brought to the committee's attention during the meeting that some students who graduated from Northeastern were actually denied state certification and some students who graduated at the same time were granted state certification. She further stated staff pulled those registration files and found that the students who were granted state certification had the Midlands Tech certificate at that point in time. She said Linda Sheppard researched the ASHP website and found that Tri County Tech is on the list of accredited schools. She noted approximately 20 students became state certified because of Tri County Tech being the list of ASHP accredited schools. She noted there were approximately 20 students involved.

A collaborative agreement was completed in 2001. Twenty-five students completed the program. A change in the requirements that the school or the students did not know about is when they were being denied. The students who were being denied were the ones that did not have the Midlands Tech name on the certificate. It seems as though there was a change in how the students were being evaluated. There is a hope that the students who complete the program through 2008 under the contract would be granted a window of time to complete the exam under the same set of guidelines as those who were granted state certification.

Mr. Banks stated the committee voted unanimously to honor the request to allow the students to be treated as though they attended Midlands Tech or an ASHP accredited school.

The motion carried with a majority vote. Mr. Bradham abstained from voting on this matter.

• Compounding – Hugh Mobley, R.Ph., Bobby Bradham, R.Ph., Davis Hook, R.Ph.

The committee met on August 26, 2008.

Mrs. Bundrick stated the committee made a motion the Board clarify OTC compounding and that an article be placed in the next newsletter and in the *Small Doses* publication regarding OTC compounding.

Policy and Procedure #133 states:

The minimum guidelines for pharmacists who are doing over-the-counter (OTC) compounding are:

- 1. Component products used in OTC compounding should be available to the public
- 2. Compounded product should be made on a patient-specific need.
- 3. Compounded product labels should include: active ingredients; strength; dosage; directions for use; expiration date; and one of the following: a) lot number, b) batch number, c) control number, or d) identification number; as well as, appropriate auxiliary labels.
- 4. Patients should receive detailed written or verbal information and counseling with all compounded products.

Discussion ensued regarding Policy and Procedure #133. Mr. Mobley noted during the discussion that North Carolina no longer compounds OTC products.

MOTION

Mr. Banks made a motion to honor Policy and Procedure #133. Mr. Toole seconded the motion. Mr. Mobley amended the motion to add a statement to Policy and Procedure #133 stating in order to maintain the safety of the patient that it is recommended patients have prescription order for an OTC compound. Mr. Banks amended the motion to include Mr. Mobley's recommendation. Mr. Toole seconded the amendment. The motion carried with a majority vote. Dr. Richardson voted nay.

Mr. Mobley stated changes were made to the application on the sterile and non-sterile pharmacies; however the nonresident pharmacies applications did not include that statement.

MOTION

Mr. Mobley made a motion, seconded by Mr. Banks and unanimously carried, that the Board mirror the out of state permit initial and renewal applications to include the question included on sterile and non-sterile compounding.

Mrs. Bundrick presented the members with a letter from the Department of Health and Human Services.

• <u>Legislative – Al Toole, R.Ph., Bobby Bradham, R.Ph., Dr. Richardson, Hugh Mobley, R.Ph.</u>

Mr. Toole stated the committee met on August 26, 2008. He went on to say last legislative session was disappointing. Mrs. Bundrick stated Mrs. Dantzler is drafting regulations for central fill.

Mr. Cinqueonce briefed the Board on federal legislation. He stated federal legislation included physician payment bill HR-6331 which included provisions that are pharmacy friendly. He noted A & P fixed bills remain in Congress

• <u>Medication Errors – Dan Bushardt, R.Ph., Davis Hook, R.Ph., Dr.</u> Richardson

Mr. Bushardt stated the committee met on August 26, 2008 and briefly discussed quality control to assist in the prevention of medication errors. He noted PBM will require quality control. The next standard of pharmacy is PQC which is pharmacy quality commitment.

Mr. Cinqueonce stated the president at the end of 2007 signed federal legislation which establishes patient safety organizations. Any organization which has met certain requirements can file for such recognition.

• Nuclear Pharmacy – Dock H. Rose, R.Ph., Bobby Bradham, R.Ph. Hugh Mobley, R.Ph.

Mr. Bradham stated the committee met on August 26, 2008 during which Mrs. Sanders discussed inspections on nuclear pharmacies. Discussion also ensued in regard to sending a letter to the Board of Nursing, the Nursing Association and nursing schools to include an article in their newsletters on administering compounded medication using aseptic techniques and wearing gloves. Allen Madden was asked to draft a letter for the Board's approval.

Mrs. Bundrick stated Mr. Madden contacted her since the committee meeting was held and stated he did not think this was the avenue to take. The Board did not pursue action since a letter was not drafted.

Pharmacy Practice – Dock H. Rose, R.Ph., David Banks, R.Ph., Hugh Mobley, R.Ph.

The committee met on August 26, 2008. The committee made a motion the Board ask the SC Pharmacy Association to insert the Physicians Assistant policy statement in their publication, *Small Doses*, in order to educate the pharmacy profession. No action needed on motion as the article had already been inserted in the publication.

<u>Pharmacy Technology – Bobby Bradham, R.Ph., Dan Bushardt,</u> R.Ph., David Banks, R.Ph.

Mr. Bradham stated the committee met on August 26, 2008. The Share-to-Care presentation was deferred to the next meeting. Mark Steltz presented his information regarding remote order entry and pharmacy order verifications. A motion was made to submit the request to the full Board for review and consideration. The committee asked that Mr. Steltz submit error rate information, however, the information has not yet been received.

❖ Pilot Project – Wal-Mart

The committee questioned Mrs. Bundrick regarding the Wal-Mart and Walgreens' pilot projects. Mrs. Bundrick stated the stores are to submit to the Board a list of store locations which will be participating in the project. The Board will then forward the Board approved guidelines for the pilot projects.

Mr. Bradham stated he believes permission was given to conduct across the state for seven to eight days during the hurricane; however, now that the hurricane has passed only the approved stores are participating in the pilot projects. A list of stores participating in the pilot projects was included with the committee minutes presented to the members.

Mr. Bradham stated an issue was discussed during the June 2007 meeting regarding a presentation by Judiann Myers. Ms. Myers' presentation concerned emergency boxes in nursing homes requiring replacements. Nursing homes now want to enforce their own interpretations regarding emergency box placements.

MOTION

Mr. Rose made a motion that only a licensed health professional can have access to the stat or emergency box pursuant to the proviso order, the pharmacy servicing the nursing home help facilitate the replacement of the product and that a policy and procedure be in place. Mr. Banks seconded the motion, which carried unanimously.

• Recovering Professional Program - Dr. Richardson, Davis Hook, R.Ph.

Dr. Richardson stated he met with RPP on August 15, 2008. He stated he had asked Mr. Sheheen to brief the Board on the meeting; however, nothing specific needed the Board's vote. He further stated there are approximately 15 pharmacy technicians now enrolled with RPP.

Mrs. Bundrick stated the RPP committee met on August 26, 2008 during which time she discussed General Counsel's determination that clients do not have to stay with RPP for one year if here is a 'no diagnosis' after evaluation. RPP was wanting clients with 'no diagnosis' to be tested for one year.

VAWD – Dan Bushardt, R.Ph., Al Toole, R.Ph.

Mr. Bushardt stated Ken Couch of Smith Drug HDMA gave their position on VAWD legislation. During Mr. Couch's presentation he noted they are not opposed to wholesale distributor legislation but are opposed to having outside individuals regulate and would prefer state inspectors regulate. During his presentation Mr. Couch proposed a fee increase, surety bonds, a designated representative, a criminal records check, increase criminal and civil fines to wholesalers, and reciprocate between states. He went on to say it looks as though pedigree will not go into effect in 2010.

8. Discussion Topics

> Pharmacist On-line Continuing Education - Davis Hook, R.Ph.

Mrs. Bundrick stated Mr. Hook felt it would be good for the agency to have a program for the pharmacists and/or technicians to enter and track their continuing education credits online, which would mean it would not be necessary to conduct continuing education audits since information would be online. She noted Florida already has such a program. She further stated she could check on the possibility of having such a program.

The Board asked staff to present this information to the agency.

Public Comments

Mr. Banks stated he wasn't made aware of some of the changes made in the agency. He further stated he would like to know the current chain of command and where everything is going. He also stated if the continuing education audit would be completed by another part of the agency instead of staff assigned to the Board he would like to know a supervisor's name in case a licensee has an issue and would like to know the supervisor's name if a pharmacist's license is going to be renewed by another department. He would like to see an agency flow chart or an organizational chart.

The Board asked that the newsletter include an article on staff contact numbers.

Adjournment

MOTION

Mr. Banks made a motion the meeting be adjourned. Mr. Bradham seconded the motion, which carried unanimously.

The September 17, 2008 meeting of the SC Board of Pharmacy adjourned at 4:16 p.m.

South Carolina Board of Pharmacy

Board Meeting

9:00 a.m., September 18, 2008
Synergy Business Park
110 Centerview Drive, Kingstree Building
Columbia, South Carolina

Thursday, September 18, 2008 Room 108

Meeting Called to Order

Davis Hook, R.Ph., chairman, of West Columbia, called the regular meeting of the SC Board of Pharmacy to order at 9:23 a.m. Other Board members participating in the meeting included: Allen Toole, R.Ph., vice chairman, of Liberty; David Banks, R.Ph., of Simpsonville; Bobby Bradham, R.Ph., of Charleston; Dan Bushardt, R.Ph., of Lake City; Hugh Mobley, R.Ph., of Lancaster; Leo Richardson, Ph.D., of Columbia; and Dock Henry Rose, R.Ph., of Greer.

Staff members participating during the meeting included: Lee Ann Bundrick, R.Ph., Administrator; Marilyn Crouch, Program Assistant; Eddie Durant, R.Ph., Temporary Investigator; Joe Newton, R.Ph., Investigator; and Tom Porter, R.Ph, Pharmacist Investigator. LLR employees participating during the meeting included: Sharon Dantzler, Deputy General Counsel, LLR-Office of General Counsel and Sandra Dickert, Administrative Assistant.

Members of the public attending the meeting included: Paulette Bentley, Dr. Ray Gaskins, Larry Griffin, Kitty Lindler, Megan Montgomery, Joe Mullinax, John Owens, Christopher Smith, James Wilson, Rick Wilson, and Mary Elizabeth Wood

Mr. Hook announced that this meeting was being held in accordance with Section 30-4-80 of the S.C. Freedom of Information Act by notice mailed to The State Newspaper, Associated Press, WIS-TV and all other requesting persons, organizations, or news media. In addition, notice was posted on the bulletin boards at the two main entrances of the Kingstree Building.

Invocation

Dr. Richardson delivered the invocation.

Pledge of Allegiance

All present recited the Pledge of Allegiance.

Chairman's Remarks - Davis Hook, R.Ph.

Mr. Hook showed the members a proposed newly designed special order license plate.

Mrs. Bundrick stated staff has not yet received the information in regard to ordering license plates for 2009. She further stated staff would forward the information as soon as it is available.

Mr. Hook stated Costco Pharmacy sent the Board a petition signed by three pharmacists and approximately ten other parties asking the Board to consider reviewing the regulatory definition of certified pharmacy technicians. He further stated they think a certified pharmacy technician should be someone who has passed the PTCB exam.

MOTION

Mr. Mobley made a motion the Board send a letter to Costco as a courtesy to let them know the letter was received and to make them aware there is federal legislation which, if passed in its

present form, will increase the requirements beyond what South Carolina requires. Mr. Bradham seconded the motion, which carried unanimously.

Hearings

Memorandum of Agreement - Terry Lewis

This matter was continued to a later date.

Request Reinstatement of License – James Wilson

This proceeding was recorded by a court reporter in order to produce a verbatim transcript should a transcript be requested in accordance with the law.

Executive Session

Mr. Mobley made a motion, seconded by Mr. Bushardt and unanimously carried, the Board enter executive session to seek legal advice in this matter.

Public Session *MOTION*

Mr. Rose made a motion the Board return to public session. Mr. Banks seconded the motion, which carried unanimously.

Mr. Hook noted no official action was taken during executive session.

MOTION

Mr. Bushardt made a motion the Board reinstate Mr. Wilson's license with immediate suspension contingent upon these requirements: 1,500 hours under the supervision of a registered pharmacist in this state in which the Board will issue an intern certificate, pass the MPJE, 60 hours of continuing education, with 30 hours live, five additional years of RPP, the license will be suspended until such time he has received his Georgia license, and when these conditions are met he must reappear before the Board for any modifications. Mr. Banks seconded the motion, which carried with a majority vote. Mr. Bushardt, Mr. Banks, Mr. Toole, and Dr. Richardson voted in favor of the motion. Mr. Bradham, Mr. Mobley and Mr. Rose voted nay.

MOTION

Mr. Bradham made a motion, seconded by Mr. Rose and unanimously carried, the Board enter executive session.

Public Session MOTION

Mr. Mobley made a motion, seconded by Mr. Rose and unanimously carried, the Board return to public session.

Mr. Hook noted that no official action was taken during executive session.

MOTION

Mr. Rose made a motion the November 19, 2008 Board meeting be held at the SC Pharmacy Association office. Mr. Bushardt seconded the motion, which carried unanimously.

Mr. Hook noted Dr. Richardson was excused from voting in the above motion.

Adjournment *MOTION*

There being no further business to be discussed at this time, Mr. Bradham made a motion the meeting be adjourned. Mr. Rose seconded the motion, which carried unanimously.

The September 18, 2008 meeting of the SC Board of Pharmacy adjourned at 12:48 p.m.