South Carolina Board of Pharmacy MINUTES

Board Meeting 9:00 a.m., November 14, 2007 Synergy Business Park, Kingstree Building 110 Centerview Drive Room 108 Columbia, South Carolina

Wednesday, November 14, 2007

Meeting Called to Order

Dock Henry Rose, R.Ph., chairman, of Greer, called the regular meeting to order at 9:06 a.m. Other Board members participating in the meeting included: Davis Hook, R.Ph., vice chairman, of West Columbia; 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 Allen Toole, R.Ph., of Liberty.

Staff members during the meeting: included: Lee Ann Bundrick, R.Ph., Administrator; Marilyn Crouch, Program Assistant; Ron Cook, Investigator; Eddie Durant, Temporary Investigator; Beverly Gould, Administrative Assistant; Diana Harder, Administrative Assistant; Joe Newton, R.Ph. Investigator; and Tom Porter, R.Ph., Pharmacist Inspector. LLR employees participating during the meeting included: Sharon Dantzler, Deputy General Counsel, LLR-Office of General Counsel; Sandra Dickert, Administrative Assistant; Pat Hanks, Attorney, LLR-Office of General Counsel; Shirley Robinson, Hearing Advice Attorney; and Wayne Whitworth, Temporary Investigator.

Members of the public attending the meeting included: Desa Ballard, Esq., Mike Blakely, Carmelo Cinqueonce, Stacy Cook, Esq., James Deween, Kevin Floyd, Miguelina Ford, Stephanie Frazier, Katrina Freeman, Keith Guest, Martha Hanks, Daryl Hendrix, John Lago, P.J. Little, Dan Luce, Reynold McClain, Eugene Matthews, Esq., Paul Neuner, Tracie Paschall, Tom Phillips, Minerva Reyes, Tina Rish, Eric Ridings, Hope Rivers, April Robinson, Debbie Rowell, Cheryl Ruff, Kacy Schuman, Charles Shively, Scotford Smith, Caroline Sojourner, Robert Spires, Ed Voss, Jon Wallace, Esq., Catherine Warner, and Rick Wilson, Esq.

Mr. Rose 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.

Pledge of Allegiance

All present recited the Pledge of Allegiance.

Invocation

Mr. Bradham delivered the invocation.

Chairman's Remarks – Dock H. Rose, R.Ph.

Mr. Rose stated *The Greenville News* carried an article regarding the nice things Communi-Care has been doing for the community. He went on to say the article reflected Blue Cross Blue Shield's \$1,000,000 gift to Communi-Care

Introduction of Board Members and all other persons attending

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

1. Approval of Minutes for the September 19-20, 2007 *MOTION*

Mr. Bradham moved the minutes of the September 19-20, 2007 meeting be accepted as written. Mr. Banks seconded the motion, which carried unanimously.

2. Approval of Reciprocity Candidates for Licensure:

March 15, 2007, June 26, 2007, August 8, 13, 15, 22, 24, 2007, September 4, 7, 12, 13, 14, 21, 24, 26, 2007, October 2, 4, 23, 24, 28, 2007

MOTION

Mr. Hook made a motion, seconded by Mr. Banks and unanimously carried, that the Board approve the reciprocity candidates for licensure as listed above.

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

Mrs. Bundrick introduced Mr. Joe Newton as the new pharmacist inspector. Mr. Newton began working with the Board on October 17, 2007. He has been training with Mrs. Clelia Sanders and is currently performing some retail inspections in the field independently.

The next Board vacancy begins July 1, 2008 and ends June 30, 2014 for the fourth Congressional District. Before December 31, 2007 a candidate interested in running for the vacancy must submit a biography and a petition bearing the signatures of at least 15 pharmacists practicing in the fourth district and be licensed and actively practicing pharmacy in South Carolina. To date we have not received any information regarding potential candidates.

Board staff mailed out the ten percent random continuing education audit letters for the pharmacists selected by the ReLaes system on October 17, 2007. The random continuing education audit letters will be mailed out to the pharmacy technicians in the next couple of weeks.

During the month of October Mrs. Bundrick had a student from the South Carolina College of Pharmacy, USC campus, Ms. Jennifer Mauney.

As of this report the Board has approximately 2,128 state certified pharmacy technicians and 4,173 active registered pharmacy technicians. The Board has 6,043 active licensed pharmacists and 3,328 permitted facilities. The Board now has routing companies.

Mrs. Bundrick stated the South Carolina Society of Health System Pharmacists has offered the Board an opportunity to have an exhibit booth at their upcoming annual convention in March. This would be an excellent opportunity for the Board staff to improve public awareness of the Board and its duties and responsibilities. As a reminder the March 2008 Board meeting will be in Myrtle Beach at the Marriott Grande Dunes and the meeting will be on Tuesday, March 11th instead of the normal Wednesday date.

Mrs. Bundrick and the Board of Pharmacy staff have attended the following meetings since the September Board meeting. Mrs. Cle Sanders attended and provided a continuing education program at the South Carolina Pharmacy Association rally on September 20th in Spartanburg, September 24th in Columbia, September 25th in Aiken, October 8th in Florence, October 9th in Charleston, October 18th in Anderson, and October 22nd in Columbia. Thanks to Mrs. Sanders for an outstanding job.

Mrs. Bundrick attended the rally in Charleston and one of the rallies in Columbia. She met with Dean DiPiro and Dr. Rowen from the South Carolina College of Pharmacy on October 1st regarding licensing issues. Mrs. Cle Sanders and Mrs. Bundrick met with Dan Bushardt on October 8th to review information concerning VAWD. There was a BRS/DLP staff meeting on October 23rd and a telephone IRC meeting on October 30th. There was a Board of Pharmacy Panel Hearing and Citations on October 31st. There was a Board of Pharmacy staff meeting on November 1st. The Board staff held citation hearings on November 1st. Mr. Ron Cook attended the RPP Advisory Committee meeting on November 2nd, along with Mr. Mills Scoggins and Dr. Richardson. Mrs. Sanders made a notebook bi-forms presentation to the agency director and the LLR leadership on September 24th and October 30th. The agency is moving forward with implementing this for all agency inspectors. She commended Mrs. Sanders on all her hard work and dedication to make this possible. The Board of Pharmacy was the pilot project and it was very successful. Mrs. Sanders has compiled a user friendly manual for the notebook bi-forms.

Mrs. Sanders gave a PowerPoint presentation to the SC College of Pharmacy, MUSC campus first year students on retail inspections with emphasis on possible violations and explanation of the inspection report on September 24th.

Staff attended agency, Board staff, compliance staff and legal counsel meetings.

Mrs. Bundrick stated staff is working on the first quarter newsletter. She went on to say should the Board have any suggestions for articles to let staff know. She further stated the draft newsletter would be e-mailed to the Board members for their review and comments prior to the January 1, 2008 deadline.

Mrs. Bundrick and Mr. Wilbur Harling will be attending the MPJE review in Fort Lauderdale, Florida on January 9-13, 2008.

Mrs. Bundrick has been appointed to NABPs Committee on Law Enforcement and Legislation. The committee will be meeting in Chicago, Illinois on January 24-25, 2008.

Mrs. Sanders and Mr. Mobley attended the Quality Assurance for Compounders course sponsored by PCCA in Houston, Texas on November 2-3, 2007.

There are several handouts for the Board's review that may be of interest. These handouts include an e-mail from Chairman Rose regarding committee assignments, the Board of Pharmacy's response to the draft proposed revisions of Regulation 61-17, Standards for Licensing Nursing Homes, a memo from NABP regarding a Petition for Associate Membership, a memo from DEA regarding the use of a practitioner's NPI number, a memo from NABP regarding 2007/2008 committee and task force appointments, a memo from NABP to RxPads.com requesting they promptly remove the Board of Pharmacy contact information for all states and jurisdictions from their site, and the budget information.

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

Mr. Hook commended Mrs. Bundrick for being appointed to the committee.

4. Compliance and Inspector's Report

IRC Recommendations for dismissals and dismissals with non-disciplinary letters of concern. Review of proposed Consent Orders and Stipulations and Petitions from the Investigative Review Committee (IRC), Pat Hanks, OGC and Charles "C" Turner, R.Ph., IRC Chairman

Proposed Disciplinary Sanctions

Mrs. Bundrick stated this information was presented to the Board during the September 2008 meeting. She went on to say at that time the Board asked that they be allowed to review the information at greater length and that it be placed on the agenda for this meeting. She noted the Board may want to hold off on taking action on the first time diversion for pharmacy technicians. Mr. Rose feels the Board may want to move forward. Mr. Bradham stated staff would be doing unnecessary work if the Board acts on the first time diversion for pharmacy technicians.

MOTION

Mr. Bradham made a motion, seconded by Mr. Toole and unanimously carried, that the Board accept the proposed disciplinary sanctions with the exception of the first time diversion for pharmacy technicians.

Report from October 31, 2007 Citation Hearings

This report included actions on the following citations:

Citation 92 – The panel is recommending Citation 92 be upheld in the amount of \$50.00 and Citation 90 and Citation 91, both in the amount of \$500.00, be dismissed.

Citation 98 – The panel is recommending the citation be upheld in the amount of \$500.00

The other matter is being deferred to the January 2008 Board meeting.

MOTION

Mr. Bradham moved the Board accept the Hearing Panel Report of October 31, 2007. Mr. Bushardt seconded the motion, which carried unanimously.

 Hearing Recommendation Case #: 2007-2

Mr. Hanks stated a transcript is forthcoming on this case and that the Board would hear this case during a later meeting.

Consent Orders
 Case #: 2006-58

<u>MOTION</u>

Mr. Hook made a motion the Board add the stipulation that the consent order be amended at a later time that RPP monitor the screenings and that this consent order be held in abeyance while the Board articulate through the process. Mr. Bradham seconded the motion, which carried unanimously.

Case #: 2007-37

MOTION

Mr. Hook moved the Board accept the consent order in this case. Mr. Banks seconded the motion, which carried unanimously.

• Agreement to Relinquishment

Case #: 2007-53 Case #: 2007-57 Case #: 2007-100 Case #: 2007-115

Mr. Hanks briefed the Board on the Agreement to Relinquishment in the above referenced cases.

MOTION

Mr. Banks made a motion, seconded by Mr. Bushardt and unanimously carried, that the Board accept the Agreements to Relinquish in the above-reference cases.

Temporary Suspension

Case #: 2007-59 Case #: 2007-83 Case #: 2007-89 Case #: 2007-90 Case #: 2007-91 Case #: 2007-99

Mr. Hanks presented the members with cases involving for temporary suspension. He noted these cases were for the Board's information.

 Voluntary Surrender Case #: 2007-03

Mr. Hanks presented this case for the Board's information. He noted that no action by the Board was necessary.

Formal Complaints

Case #: 2007-89 Case #: 2007-91 Case #: 2007-93 Case #: 2007-98 Case #: 2007-99

<u>MOTION</u>

Mr. Hook moved to accept the IRCs recommendation regarding the formal complaints. Mr. Banks seconded the motion, which carried unanimously. Mr. Bushardt recused himself from voting in case # 2007-89.

Dismissal with Letter of Concern

Case #: 2007-12 Case #: 2007-36

<u>MOTION</u>

Mr. Banks made a motion the Board approve the IRCs recommendation regarding the two above-referenced cases for dismissal with letters of concern. The motion was seconded by Mr. Hook and unanimously carried.

Dismissal

Case #: 2006-105

MOTION

Mr. Bradham moved the Board accept the IRCs recommendation in the above referenced case for dismissal. Mr. Hook seconded the motion, which carried unanimously.

Cease & Desist

Case #: 2007-ISM Case #: 2007-CMG

Mr. Hanks briefed the Board on the above cases in which cease and desist orders were issued. He noted these cases were for the Board's information and did not need any action.

A. Request to Modify Order – Daryl Hendrix

On September 28, 2006 Daryl Hendrix entered into a consent agreement with the Board after it was found she had dispensed controlled and non-controlled prescriptions to patients in 'questionable combination with other prescriptions and/or in excessive dosage quantities which she should have known to have been beyond the scope of legitimate medical need or legitimate medical practice' while she was employed with Congaree Pharmacy.

On October 11, 2007 the Board received a letter from Desa Ballard, Esquire, with a Motion to Amend Order and Terminate Probation in regard to Ms. Hendrix.

Daryl Hendrix and Desa Ballard, Esquire, appeared before the Board at this time. Ms. Ballard is asking that the Order from September 28, 2006 be amended to delete any mention of the suspension of her license and any sanction of probation.

Mr. Ken Woodington, Esquire, confirmed he is taking no position on the Motion to Amend Order and Terminate Probation in regard to Daryl Hendrix.

Mr. Rose informed Ms. Ballard and Ms. Hendrix that the Board would take this testimony under advisement and would take action later in the meeting.

B. Request Release from Board Order – William McCamy

On August 25, 2006 William McCamy entered into a consent agreement with the Board after he admitted that he unlawfully obtained a Schedule IV controlled substance while he was employed at Wal-Mart in July 2004. Mr. McCamy's consent agreement states that his license would be placed in probationary status for one year contingent upon his compliance with certain terms and conditions.

On October 24, 2007 the Board received a letter from Mr. McCamy stating he has met all of the terms and conditions as stated in the consent agreement and is asking that the Board release him from the consent agreement.

Mr. McCamy appeared before the Board at this time and answered questions from the members.

Mr. Durant stated Mr. McCamy was not required to sign a contract with RPP and follow up drug screens were not required.

Mr. Tom Phillips, CVS District Manager for the Columbia area, spoke on Mr. McCamy's behalf.

Mr. Rose informed Mr. McCamy that the Board would take this testimony under advisement and would take action later in the meeting.

C. Request to Modify Order – Reynold McClain

On September 24, 2004 Reynold McClain entered into a consent agreement with the Board after he admitted to generating fraudulent prescriptions for drugs that he took as well as provided drugs to a friend between 2001 and 2003. He also retained the money from the friend which should have been paid to the pharmacy. The consent agreement in part states that his license be placed in probationary status for five years and that during that time he would not serve as a PIC or permit holder of a pharmacy.

On October 29, 2007 the Board received a letter from Mr. McClain that his consent agreement be amended to allow him to serve as a pharmacist in charge (PIC).

Mr. Banks recused himself from participating in this matter.

Mr. McClain, Tommy Martinez, Latecia Cobbs-Rich, of RPP, and David Banks appeared before the Board and spoke in regard to this matter.

Mrs. Cobbs-Rich stated Mr. McClain is in full compliance with his RPP contract.

Mr. Banks stated Mr. McClain works at the base store in his district. He wishes all of his pharmacists worked as hard as Mr. McClain.

Mr. Rose informed Mr. McClain that the Board would take this testimony under advisement and would take action later in the meeting.

Recess

The Board took a ten minute recess at 9:57 a.m. and returned to public session at 10:15 a.m.

Return to Public Session

5. Old Business

D. Surescripts E-Prescribing Pilot Project – Information Regarding E-Prescribing Activity in South Carolina

On October 31, 2007 the Board received a letter from Mr. Ken Whittemore of Surescripts that contained an update to the e-prescribing pilot project in South Carolina. Mr. Whittemore was unable to appear at the September 2007 meeting and had a conflict with this meeting. He has asked that he be placed on the agenda for the March 11, 2008 meeting. The Board agreed to defer this matter to the March 2008 meeting.

6. New Business

E. Request to Approve Reciprocity Application – Scotford Smith

On July 9, 2007 the Board received a reciprocity pharmacist license application from Scotford Smith. Mr. Smith's application reflects he answered yes to the question asking if his license has been revoked, suspended, restricted, terminated, or subject to disciplinary action in any jurisdiction. He noted on the application that he had been fined \$500.00 by the Kentucky Board of Pharmacy in 2003 for lacking one continuing education unit for 2002. He was also required to complete 0.2 continuing education units to satisfy the deficiency. Since his application contained a yes answer staff notified him by letter that the application could not be handled in a routine manner and that he must appear before the Board to answer any questions the Board members may have.

Scotford Smith appeared before the Board at this time and answered questions from the meeting. The state of Kentucky required 15 hours of continuing education, although it does not contain restrictions such as attending live classes.

Mr. Rose informed Mr. Smith that the Board would take this testimony under advisement and would take action later in the meeting.

F. Request to Approve Intern Hours – April Robinson

On July 20, 2007 the Board received a letter from April Robinson in regard to her intern hours. Ms. Robinson's letter states staff informed her there was a record of her intern hours for 2006, however, staff did not have her Notification of Employment on file for 2006. She has been working the MUSC Children's Hospital for the past 14 months. Ms. Robinson was notified in writing that she was scheduled to appear before the Board to discuss her request.

April Robinson appeared before the Board at this time and offered the following testimony.

When she began working at MUSC she learned the Pharmacy Services Coordinator would file the documentation for the Notification of Employment. She found the paperwork was missing when she contacted staff and sent the documentation via certified mail.

Ms. Harder stated it appears Ms. Robinson mailed the hours of experience as required for the year 2006; however, staff did not receive the Notification of Employment for those hours until July 2007.

Mrs. Dantzler reviewed the form and noted it was dated May 16, 2006.

Mr. Rose informed Ms. Robinson that the Board would take this testimony under advisement and would take action later in the meeting.

G. Request to Approve Non-Resident Wholesale/Distributor/
 Manufacturer Application – H. D. Smith Wholesale Drug Company
 P. J. Little and Stacy Cook

On July 12, 2007 the Board received a Non-Resident Wholesale/Distributor and/or Manufacturer application from H. D. Smith Wholesale Drug Company. The application included yes answers to questions asking if the permit has been denied, refused or revoked for violation of any pharmacy laws, etc., to the question asking if a permit has been charged, convicted, fined or entered in a plea of guilty or nolo contendere, the question asking if any of these charges were for 'any offense involving fraud, dishonesty, or an act of violence, whether or not a sentence was imposed?' and to the question asking if the action(s) were 'For any offense involved the practice of pharmacy, or relating to acts committed within a pharmacy or drug distributor setting or incident to pharmacy practice, whether or not a sentence was imposed?' The application also reflects a yes answer to the question asking, "Have you ever: (b) Had disciplinary action taken against you, or a pharmacy or drug distributor facility you owned, or a pharmacy or drug distributor facility where you were employed, by the Board of Pharmacy (or its equivalent) in South Carolina or any other state or country?' Since the application contained a yes answer staff notified the company that staff could not process the application in a routine manner and that a representative must appear before the Board to answer any questions the Board members may have.

BJ Little, Stacy Cook, Esquire, and Gene Matthews, Esquire, appeared before the Board at this time. Ms. Cook offered testimony in response to the yes answers reflected on the application.

Ms. Cook stated the individuals involved with the company at the time the actions took place are no longer employed there. She further stated the company is a national wholesale drug company licensed in 46 states. She understands the actions relate to an application the company filed with a distribution facility based in New Jersey. She noted the company has been licensed since 1991. The company entered into a consent agreement with the State of Illinois in regard to the purchase of wholesale drugs by an unlicensed company. The company was fined, which was paid. H. D. Smith now has a written policy that the company only purchase directly from manufacturers in the future unless the manufacturer requires the wholesaler to purchase from an authorized wholesale distributor.

Ms. Cook stated the company has eight different distribution facilities throughout the area. She went on to say there are three licensed distribution facilities in South Carolina. One facility is based in Wooddale, Illinois which is VAWD certified, one is based in Kentucky, which is VAWD certified and one is based in New Jersey, which is not VAWD certified. The non-certified plant has not made shipments to the state. None of the company officers named Smith were involved in the charges or disciplinary actions.

Ms. Little, a company representative, stated Henry Dale Smith is the company owner, and the business is family owned and located in Springdale, Illinois.

Mr. Bradham asked that the written policy be faxed to Mrs. Dantzler.

Mr. Rose informed Ms. Little, Ms. Cook and Mr. Matthews that the Board would take this testimony under advisement and would take action later in the meeting.

H. Request to Approve Reciprocity Application – James Deneen On July 23, 2007 the Board received a reciprocity pharmacist application from James Deneen. Mr. Deneen's application reflected a yes answer to the question asking if his license has ever been revoked, suspended, restricted, terminated, or subject to other disciplinary action in any jurisdiction. His explanation on the application states he was reprimanded in July 1997 by the Nevada Board of Pharmacy for a medication error. Since his application contained a yes answer staff notified Mr. Deneen that staff could not handle the application in a routine manner and that he must appear before the Board to answer any questions the Board members may have.

James Deneen appeared before the Board at this time and offered the following testimony.

Mr. Deneen is currently licensed without restriction in Vermont. His primary license was issued in Illinois and he also holds an inactive license in Maryland. He was the only pharmacist in the facility at the time the prescription was filled. The pharmacy was using computer generated codes and ge mistyped a code. He dispensed the medication to the patient with incorrect information on the prescription label; however, he did counsel the patient on the medication. The patient contacted the pharmacy, the district manager, and then the Board.

Mr. Rose informed Mr. Deneen that the Board would take his testimony under advisement and would take action on the matter later in the meeting.

I. Request to Approve Reciprocity Application – Minerva Reyes
On November 6, 2006 the Board received a reciprocity pharmacist application from Minerva
Reyes. Ms. Reyes' application reflects a yes answer to the question asking if her license has
ever been revoked, suspended, restricted, terminated, or subject to other disciplinary action in
any jurisdiction. Her explanation on the application indicates she was disciplined by the Florida
Board of Pharmacy for medication error. Since her application contained a yes answer staff
notified Ms. Reyes that her application could not be handled in a routine manner and that she
must appear before the Board to answer any questions the Board members may have.

Minerva Reyes appeared before the Board at this time and offered the following testimony.

Ms. Reyes is currently licensed and in good standing in Florida. In July or August 2004 CVS Pharmacy acquired Eckerd Pharmacy and her facility was the pilot pharmacy to convert the computer system. The pharmacy hired a couple of extra pharmacists to assist with the conversion. A major wildfire came through in September and the facility was using a generator and a flashlight to operate. A prescription for two individuals with the same last name and similar first names was typed under a different name; however, it was corrected within twenty minutes. The wrong person received the prescription. The error was picked up a week later.

Mr. Rose informed Ms. Reyes that the Board would take this testimony under advisement and would take action later in the meeting.

J. Application for Pharmacist-in-Charge and Permit Holder Change – Apothecare Compounding Pharmacy – Jon Wallace, R.Ph., JD, Charles Shively, R.Ph.

Charles Shively, on behalf of Apothecare Compounding Pharmacy in Greenville, has applied for reinstatement of pharmacy permit #5669. This permit was initially issued on October 10, 2000.

A Cease and Desist Order was issued against the pharmacy on September 14, 2007. Charles Shively has applied to accept the responsibility of permit holder and PIC for this facility. A prelicensing agreement has been drafted by Pat Hanks, Litigating Attorney, in this matter.

Charles Shively and Jon Wallace, Esq., appeared before the Board at this time. The following testimony was offered.

Mr. Wallace stated the request is for Mr. Shively to become the permit holder and pharmacist-incharge for Apothecare Compounding Pharmacy. He asked that Mr. Shively be allowed to inform the Board what he has done to turn the pharmacy around during the past six weeks.

Mr. Shively stated this is a wonderful opportunity to establish a reference for compounding pharmacies in South Carolina. Since his involvement with this particular establishment he has worked to that affect. He is aware of the outlying USP <795> and USP <797> guidelines and has designed a complete operations manual, or current compounding guideline, for the pharmacy. The guidelines include a matrix that shows how the pharmacy's standard operating procedures reference USP Chapters <795> and <797>. The opportunity to be involved in an independent compounding pharmacy is special. The issues with Apothecare Compounding Pharmacy are nothing more than opportunities to put in place a reference for other compounding pharmacies. He would own approximately twenty-five percent of the pharmacist.

Mr. Hanks briefed the Board on the pre-licensing agreement for this matter.

Mr. Shively has had pharmacy doors re-keyed and has had five keys made for the doors. He would have one key, his staff pharmacist, Richard Pearson, would have a key, and the remaining keys would be placed in a safe.

Since 2002 Mr. Shively has been mostly working in non-compounding pharmacy, although he had earlier stated he had been working in a compounding pharmacy most of his career.

Mr. Claude Banks, owner of Apothecare Compounding Pharmacy, pharmacist license has been temporarily suspended; however, he has not held himself out to be a pharmacist to Mr. Shively's knowledge. Mr. Wallace has no knowledge of Mr. Banks holding himself out to be a licensed pharmacist.

Mr. Mobley expressed concerns over an article in the October 30 2007 edition of *The Greenville News* which lists 'Claude Banks, R.Ph.'

Mr. Shively gave the Board an overview of the products included veterinary that would be prepared in the pharmacy. He made references about products that they "Manufactured". Mr. Mobley asked questions regarding his statements and expressed concerns about compounding verses manufacturing.

Mr. Banks has an Order to Show Cause from the SC Department of Health and Environmental Control on the controlled drugs aspect prior to opening the pharmacy.

The pharmacy has not been open nor has the pharmacy purchased medications since the Cease and Desist Order was issued in September.

Mr. Shively's resume indicates a lapse of full time employment between June 1992 and March 2000. During this time he taught courses at an Arizona college. From March 1990 to June

1992 he worked part-time with Value Drugs he recovered from an automobile accident in which his first wife was killed. He spent some time in 2006-2007 working with CVS in Hampton, South Carolina following his move from Arizona.

Mr. Rose informed Mr. Wallace and Mr. Shively that the Board would take this testimony under advisement and would take action later in the meeting.

K. Presentation of Workflow Balance – Dan Luce, Walgreens

On November 11, 2007 the Board received a request from Dan Luce of Walgreen's asking he be allowed to make a presentation to the Board in reference to workflow balance.

Dan Luce of Walgreens made a brief presentation of workflow balance which falls under central processing technology.

Mr. Rose informed Mr. Luce that the Board would take this presentation under advisement and would take action later in the meeting. He noted the action may include referring this matter to the Technology Committee.

Dr. Richardson left for a luncheon appointment at this time.

Executive Session

MOTION

Mr. Banks moved the Board enter executive session to seek legal advice on the matters brought before the Board. The motion received a second from Mr. Bradham. The motion carried unanimously.

The Board entered executive session at 12:15 p.m.

Lunch

Following executive session the Board recessed for lunch and resumed public session at 2:20 p.m.

Return to Public Session

MOTION

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

Mr. Rose noted for the record that no motions were offered or made during executive session.

Request to Modify Order – Daryl Hendrix

MOTION

Mr. Hook moved the Board approve Ms. Hendrix's request to modify the order. Mr. Mobley seconded the motion, which carried unanimously.

Request Release from Board Order - William McCamy

MOTION

Mr. Mobley made a motion, seconded by Mr. Banks and unanimously approved, the Board release Mr. McCamy from the Board Order.

Request to Modify Order – Reynold McClain Mr. Banks recused himself from voting in this matter.

MOTION

Mr. Bushardt moved the Board modify Mr. McClain's order to allow him to become a pharmacist-in-charge. The motion received a second from Mr. Bradham. The motion carried unanimously.

Request to Approve Reciprocity Application – Scotford Smith

MOTION

Mr. Banks made a motion, seconded by Mr. Hook and unanimously carried, the Board approve Mr. Smith's reciprocity application.

Request to Approve Reciprocity Hours – April Robinson Mr. Bradham recused himself from voting in this matter.

MOTION

Mr. Mobley moved the Board deny Ms. Robinson's request. Mr. Toole seconded the motion, which carried unanimously.

Request to Approve Non-Resident Wholesale/Distributor/Manufacturer Application – H. D. Smith Wholesale Drug Company

MOTION

Mr. Bradham made a motion, seconded by Mr. Bushardt and unanimously carried, the Board approve the application with two stipulations: 1) the Board is to receive a copy of their written policy to ensure that no infractions will occur as previously cited and fined for and 2) that the company does not ship to a non-VAWD approved facility.

Request to Approve Reciprocity Application – James Deneen

MOTION

Mr. Banks moved the Board accept James Deneen's reciprocity application. Mr. Mobley seconded the motion, which carried unanimously.

Request to Approve Reciprocity Application – Minerva Reves

MOTION

Mr. Toole made a motion, seconded by Mr. Bushardt and unanimously carried, that the Board approve Minerva Reyes' reciprocity application.

Application for Pharmacist-in-Charge and Permit Holder Change – Apothecare Compounding Pharmacy – Jon Wallace, R.Ph., JD, Charles Shively, R.Ph.

MOTION

Mr. Bradham made a motion, seconded by Mr. Hook and unanimously carried, the Board deny the request to change the permit holder and pharmacist-in-charge.

Presentation of Workflow Balance – Dan Luce, Walgreens

MOTION

Mr. Bushardt moved the Board refer this matter to the Technology Committee. Mr. Mobley seconded the motion, which carried unanimously.

New Business (Continued)

L. Request to Approve Reciprocity Application – Paul Neuner

The Board received a reciprocity pharmacist application dated September 9, 2006 from Paul Neuner. Mr. Neuner answered yes to the question asking, "Have you ever been charged or convicted (including 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?" Mr. Neuner's response to this question reflects that he was adjudicated guilty of misdemeanor battery in 1991. The action is a result from a brief fist fight. He was ordered to pay restitution, serve probation (less than one year), attend an anger management class, and complete community service hours.

Mr. Neuner appeared before the Board at this time and offered the following testimony.

In 1991 he was involved in an altercation with another gentleman and he was charged with assault. He failed to provide a current photograph, which is needed for finalization on the Board's decision.

Mr. Rose informed Mr. Neuner the Board would take his testimony under advisement and would render a decision later in the meeting.

M. Request to Discuss Physician Signature Stamps in Long Term Care Facilities – Keith Guest, MD

Dr. Keith Guest appeared to discuss Policy and Procedure #066, which was amended during the September 2007 meeting. The amendment clarified that a prescription handed to a patient must have an original signature. He discussed the use of rubber stamped signatures as noted in the regulations. Legal counsel for the South Carolina Medical Association recommended the physicians follow the law.

It was noted in discussion that the regulations referred to in Dr. Guest's remarks fall under the SC Department of Health and Environmental Control.

Dr. Guest asked if the Board could ask for a legal opinion from the Attorney General's Office in regard to this matter. Mrs. Bundrick stated the Board could obtain an opinion from the agency's general counsel; however, the agency could not seek an opinion from the Attorney General's Office without approval from the Governor's Office.

7. Committee Reports

Mr. Rose stated the committees have been divided into two groups. He hopes that each group would be able to hold meetings on the same day.

• Immunization Task Force – Davis Hook, R.Ph., David Banks, R.Ph., Dan Bushardt, R.Ph., Leo Richardson, PhD., Joe Mullinax, R.Ph.

Mr. Hook asked Mr. Cinqueonce, Executive Vice President of the SC Pharmacy Association, to give an update on the immunization bill.

Mr. Cinqueonce stated a hearing on the bill was scheduled for Spring 2007; however, the hearing was postponed. He further stated the association continues to work on advancing the legislation and would pursue further action when the General Assembly reconvenes in January 2008. He also stated he would be speaking with DHEC for assistance in this matter.

Mr. Cinqueonce stated a training seminar was recently held in which 80 pharmacists participated.

 Pharmacy Technician Committee –David Banks, R.Ph., Dan Bushardt, R.Ph., Davis Hook, R.Ph., Leo Richardson, PhD

Mr. Banks stated the committee has not met since the September 2007 Board meeting; however, Hope Rivers was present to update the Board on the technician certification program.

Update of Technician Certification Program – Hope Rivers

Hope Rivers appeared at this time and offered the following presentation.

Following the joint meeting of the Pharmacy Technician Committee and the Legislative Committee in September 2007 she was charged with attempting to develop a statewide program that would meet the needs of South Carolina as it relates to having more certified pharmacy technicians. The SC Technical College System hosted a statewide meeting on October 18, 2007 of pharmacy technicians and technical colleges not currently offering pharmacy technician courses. A subcommittee was formed and met on October 30, 2007 to develop a certificate program. The subcommittee is reviewing a certificate program that would have approximately 22 credit hours and would begin in Autumn 2008. The program could be completed in one semester. The next meeting of the subcommittee is scheduled for January 11, 2008. The subcommittee has also been charged with developing competency examinations for the certificate program.

Ms. Rivers provided the Board members with an outline regarding the Pharmacy Technician Certification and Training Update.

Mr. Bradham stated the system is moving in the direction which the Board has asked.

Mr. Banks stated he hopes to hold committee meetings at 9:00 a.m., Friday, December 7, 2007.

Mr. Cinqueonce stated the Association's Board of Executive Directors instructed him to attempt a resolution regarding the pharmacy technician registration issue. The Board asked him to reach to the chain drug store association and its local chapters. He went on to say a possible resolution was discussed during a previous meeting has been amended slightly. The resolution would establish three tiers of pharmacy technicians: 1) basic technician, with a 2:1 ratio, 2)

technician examined, with a 3:1 ratio, of which one technician must be nationally examined (PTCB) or certified, the other two pharmacy technicians must be registered; and 3) state certified technician, completed academic training program, ratio would be expanded to 4:1, of which two of the pharmacy technicians must have completed the formal academic program. He noted the Association's Board has approved the language and wanted the Board of Pharmacy to know where the association is coming from. The Association would like to pre-file the legislation by December 1, 2007.

Mr. Bushardt asked that the association not pre-file the proposed language until after December 7, 2007.

Mr. Robert Spires stated he recently attended the presidential officer retreat with ASHP. He stated ASHP is beginning a Pharmacy Technician Initiative and will be working with states and societies in pharmacy technician training. He went on to say ASHP is moving forward in formally training pharmacy technicians.

• Recovering Professional Program Committee – Leo Richardson, PhD., Davis Hook, R.Ph., Dan Bushardt, R.Ph., David Banks, R.Ph.

Dr. Richardson stated RPP met on November 2, 2007. He further stated he asked RPP to appear before the Board to discuss pharmacy technician participation in RPP and the optional alcohol exclusion law. He presented the Board members with a copy of the alcohol exclusion law.

Pharmacy Technician Participation in RPP

Mr. Frank Sheheen, Mr. Rick Wilson, and Mr. Ron Cook appeared before the Board at this time.

Mr. Sheheen stated RPP has recently been meeting with all of the health related boards and have two boards yet to meet with. He further stated RPP does feel that the program could handle the pharmacy technicians and would like to have pharmacy technicians on board with RPP. He noted there is room for growth in RPP and he has added staff and two more offices. He asked the Board to assist in bringing the technicians into the RPP program.

Mr. Rick Wilson stated he has spoken with Mr. Parker Boulware of the agency's Administration office, who has stated the money is there to absorb the fee. He noted the participant pays all of the fees, drug screenings, etc. for participation in the program.

A letter dated November 7, 2007 from Kim Keeney, CPhT, Chairman of the Academy of Pharmacy Technicians, states that the Academy held a quarterly meeting on October 21, 2007. At that time the members voted to have a RPP representative present the program's services and costs to the academy during the next quarterly meeting prior to stating a position.

A discussion ensued on fees that would be assessed to the technicians.

MOTION

The committee made a motion that the pharmacy technicians be included in RPP effective December 1, 2007. Since the motion came from committee no second was needed. The motion carried unanimously.

Mr. Sheheen stated he is a member of the South Carolina Faces and Voices of Recovery. He is asking for the Board's support, in writing, of the repeal the alcohol exclusion law. He noted the law was written in 1947 and he briefly explained what the bill states. He presented the members with a copy of House bill H.4059 which would appeal the law.

MOTION

The committee made a motion that the Board support, in writing, the repeal of the alcohol exclusion law. Since the motion came from committee no second was needed. The motion carried unanimously.

Mr. Bradham asked that the committees in group two meet on Tuesday, January 8, 2008.

The matter of the Charles Nettles was heard at this time.

N. Memorandum of Agreement – Charles Nettles, Case # 2007-89 This proceeding was recorded by a court reporter in order to produce a verbatim transcript if requested in accordance with the law.

Mr. Bushardt recused himself from participating and voting in this matter.

MOTION

Mr. Bradham moved the Board enter executive session to seek legal advice in this matter. Mr. Mobley seconded the motion, which carried unanimously.

MOTION

Mr. Hook made a motion, seconded by Mr. Bradham and unanimously carried, that the Board return to public session.

Mr. Rose noted for the record that no motions were offered or made during executive session.

MOTION

Mr. Mobley moved Mr. Nettles pay a \$500 fine, that he take the MPJE prior to reinstatement, that his license be placed on five years probation during which time he not be allowed to serve as a permit holder or pharmacist-in-charge. Mr. Bradham seconded the motion, which carried unanimously. **NOTE:** Mr. Bushardt had recused himself from voting in this matter at the beginning of the hearing.

Request to Approve Reciprocity Application – Paul Neuner

MOTION

Mr. Bradham made a motion, seconded by Mr. Hook and unanimously carried, that the Board approve Mr. Neuner's request for licensure by reciprocity upon receipt of an updated photograph.

 Pharmacy Technology Committee – Al Toole, R.Ph., Hugh Mobley, R.Ph., Bobby Bradham, R.Ph., Dock H. Rose, R.Ph., Joe Mullinax, R.Ph.

This committee had no report. This committee will meet on December 7, 2007.

 Compounding Task Force – Hugh Mobley, R.Ph., Al Toole, R.Ph., Bobby Bradham, R.Ph., Dock H. Rose, R.Ph., Sara Braga, PharmD, James Greene, R.Ph.

Mr. Mobley stated the committee has received a letter from Gene Reeder in regard to the FDA stance on restricting compounding. He presented the members with letters addressed to Administrator Weems and Commissioner von Eschenbach that in part state:

The South Carolina Board of Pharmacy has trained inspectors who are pharmacists to inspect all facilities that offer compounding options. The S. C. Board considers USP 795 and USP 797 as the standard of practice for general or sterile compounding. The S. C. Board is committed to the enforcement of the good compounding practices and public safety as it relates to compounding. This can be accomplished at the state level by well trained pharmacist inspectors who are knowledgeable about pharmacy practice and regulations. The FDA has proposed that a new drug application be filed for any compounded preparation which completely ignores the rationale of timely treatments to secure positive outcomes. Hospitals, clinics, health centers, and pharmacies are constantly called upon for patient specific therapies which are not commercially available but necessary for treatments. Public safety is the focus and issue for the Boards of Pharmacy and the FDA proposal would seriously jeopardize treatment options, patient compliance, increase patient health risks, and impede recovery due to restrictions of therapy.

It is the request of the South Carolina Board of Pharmacy that the State Boards of Pharmacy continue to be the responsible agency for public safety and the regulation of compounding as it relates to patient specific compounding.

The committee made a motion the Board approve sending the letter to the FDA. Since the motion came from committee no second was needed. The motion carried unanimously.

❖ Education of Pharmacists Regarding USP 795 and USP 797 – Hugh Mobley, R.Ph.

Mr. Mobley stated he and Mrs. Sanders attended a quality assurance symposium at PCCA November 1-2, 2007. He further stated they received an overview of USP 795 and 797 policies and procedures in regard to facilities, environmental standards, testing, in-product validation, inproduct testing for stability and potency. He went on to say they did stop gap analysis. He also said Mrs. Sanders was able to see what compounding pharmacists go through. He stated the Board had earlier indicated that pharmacies should be compliant by the next permitting period. This would cause a lot of growth and adjustment for the pharmacies. He doesn't think the Board would want to be punitive until the pharmacies are educated in where they need to be. He and Mrs. Sanders discussed having a four hour continuing education courses for compounding pharmacists in the state on quality assurance and he has spoken with Mr. Cinqueonce in reference to sponsoring the course. He said one or two individuals would assist in the course and that the course would include a segment on the Board's inspection and expectations in regard to what the inspectors would be looking for in compounding pharmacies. After that continuing education course, the compounding pharmacies that are still not compliant would have the opportunity to work towards compliance and at that point the Board would look at them differently. He said if the committee meets in January 2008 an agenda could be formalized and some dates chosen.

Mrs. Sanders stated she was glad she was able to attend the symposium and it substantiates that she and PCCA are on the same page.

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

This committee had not report. This committee will possibly meet on January 8, 2008.

• Legislative Committee – Bobby Bradham, R.Ph., Hugh Mobley, R.Ph., Al Toole, R.Ph., Dock H. Rose, R.Ph.

This committee had not report. This committee will possibly meet on January 8, 2008.

Proposed Central Fill Legislation

Mrs. Bundrick stated the central fill legislation was approved through the agency approximately two years ago, however, no sponsor was found for the legislation. She further stated the Board needs to determine to approve the legislation and attempt to locate a sponsor at this time or see if the Association would submit the legislation.

Mr. Rose stated he has spoken with Senator Cromer and Representative Spires who are willing to sponsor the legislation in the Senate and the House of Representative respectively.

Mrs. Bundrick stated the Board cannot introduce the legislation without having prior agency approval.

Mr. Cinqueonce stated the Association would sponsor the legislation.

❖ Federal Legislation – Clelia Sanders, R.Ph.

Mrs. Sanders briefed the Board on the legislative issues which were discussed during the legislative conference in Virginia. She went on to say she had emailed the information to the Board members.

 Medication Errors – David Banks, R.Ph., Dan Bushardt, R.Ph., Davis Hook, R.Ph., Leo Richardson, PhD

This committee has not met, but will be meeting on December 7, 2007.

- Pharmacy Benefit Management (PBM) –Davis Hook, R.Ph., David Banks, R.Ph., Dan Bushardt, R.Ph., Leo Richardson, PhD., Joe Mullinax, R.Ph.
 - Carmelo Cinqueonce

Mr. Cinqueonce stated the Association filed a bill to regulate PBMs. He went to say the bill has approximately 12 objectives. He noted it is hard for the legislators to understand what the bill is attempting to accomplish. He further stated the Association has discussed with its Legislative Committee the possibility of submitting a re-draft of the bill for the upcoming legislative session. He said Senator Cromer, the bill's sponsor, is willing to work with the Association in the re-draft. He went on to say they have looked at the following states that have successfully passed legislation to regulate PBMs: Tennessee, Maine, Georgia, and Washington, DC.

Mr. Cinqueonce stated the first part of the bill would require the PBM to confidentially disclose the relationship and arrangements it has with pharmaceutical manufacturers and others to the covered entity. He further stated there is also oversight and requires both the Board of Pharmacy and the Department of Insurance to issue a Certificate of Authority and a Certificate of Compliance to regulate the PBM.

 Federally Qualified Health Clinics – Bobby Bradham, R.Ph., Al Toole, R.Ph., Hugh Mobley, R.Ph., Dock H. Rose, R.Ph.

This committee has not met but will possibly meet on January 8, 2008.

Mr. Bradham stated there are a number of federal legislative issues. He further stated Mr. Cinqueonce had presented issues during the Charleston Rally and during the Board of Advisors meeting at the College of Pharmacy.

Mr. Cinqueonce stated Bill 971 would allow independent pharmacies to negotiate contracts with third party payers was referred favorably out of committee. He noted there were a couple of amendments attached as it moved out of committee. He said one of the amendments was a market share restriction because of concerns that independent pharmacies in too large of a geographical area could have an impact on the market. He continued by saying there is also a sunset provision that states after five years it would be reviewed to see what kind of impact it has had.

Mr. Cinqueonce stated the bill dealing with tamper resistant prescription pads has been delayed; however, it is still out there.

Mr. Cinqueonce stated there is legislation that would seek to limit the requirement on Schedule II medications only. He said there is still some effort behind the bill.

Mr. Cinqueonce stated there is a bill dealing with the A & P issue in an attempt to change the reimbursement cap that was established on generic reimbursement.

Mr. Cinqueonce stated the FDA held an open comments period today to possibly consider a third class of drugs. He went on to say the SC Pharmacy Association's President Elect Kelly Jones is attending this session testifying on behalf of the SC Association and the national association.

 VAWD Committee – Dan Bushardt, R.Ph., David Hook, R.Ph., David Banks, R.Ph., Leo Richardson, PhD

Mr. Bushardt stated he met with Mrs. Bundrick and Mrs. Sanders on October 8, 2007 to discuss the wholesale arena. He went on to say since that meeting President Bush signed into law Bill H.R.3580 that deals with setting standards and identifying technologies in regard to expired drugs and counterfeit drugs.

• Methadone Committee – Dock H Rose, R.Ph., Al Toole, R.Ph., Hugh Mobley, R.Ph., Bobby Bradham, R.Ph.

This committee will meet on January 8, 2008.

 Practice Act Revisions Task Force – Dock H. Rose, R.Ph., Bobby Bradham, R.Ph., Hugh Mobley, R.Ph., Al Toole, R.Ph.

Mr. Rose stated he renamed this committee to the Pharmacy Practice Committee. He further stated Mrs. Youmans has asked that this committee be responsible for answering questions brought to the Board office. He also stated she would like for the questions and answers to appear on the Board's web site. He said the questions and answers must be in writing. Mrs. Youmans would also like for all phone calls to be referred to the website.

 Inspection Report Committee – Dan Bushardt, R. Ph., David Hook, R.Ph., David Banks, R.Ph., Leo Richardson, PhD

This committee had no report, but will meet in January 2008.

MOTION

Dr. Richardson moved the Board approve the first time diversion sanction in regard to pharmacy technicians with their participation in RPP after the technician has been out of practice for six months. Mr. Hook seconded the motion, which carried unanimously.

<u>MOTION</u>

Mr. Banks made a motion, seconded by Mr. Hook and unanimously carried, that the Board amend the motion in regard to the consent order on case # 2006-58 to allow RPP to monitor the drug screenings.

<u>MOTION</u>

Mr. Banks moved the Board change the \$750 fine to \$500 in regard to the failure to notify the Board of PIC. Mr. Hook seconded the motion, which carried unanimously.

MOTION

Mr. Hook made a motion, seconded by Mr. Mobley and unanimously carried, the Board send a commendation and appreciation for Mr. Hyatt's time and service to the Board and that staff order and deliver a plaque for Mr. Hyatt.

Public Comments

Mr. Hook stated he received a call from a pharmacy asking about the requirement for a non-dispensing drug permit. He went on to say if he understands correctly if the facility is physician owned and stocks legend drugs for administration the facility does not need a non-dispensing drug permit. However, if the facility is incorporated and is a separate entity, then the facility would need a non-dispensing drug permit.

Mrs. Sanders stated because some of facilities bring in anesthesiologists and subgroups they actually want to obtain the permit so a consultant pharmacist could be in the facility.

Mr. Hook stated Communi-Care is under a pilot project to deliver pharmaceuticals in-state and that a representative had appeared before the Board during the September 2007 meeting seeking privileges ship pharmaceuticals to Texas. He said he knows they have changed the requirements as a central fill pharmacy and thought the Board may need to check into the project.

Mrs. Bundrick stated Communi-Care has sent her a letter and she is currently drafting a response with Mrs. Dantzler's assistance. She further stated they are asking for approval as a mail order pharmacy.

Adjournment *MOTION*

There being no further business to be brought before the Board at this time, Mr. Bushardt moved the meeting be adjourned. Mr. Banks seconded the motion, which carried unanimously.

The November 14, 2007 meeting of the SC Board of Pharmacy adjourned at 5:02 p.m.