

# South Carolina Board of Pharmacy

## MINUTES

Board Meeting

9:00 a.m., November 19 2008

SC Pharmacy Association

1350 Browning Road

Columbia, South Carolina

**Wednesday, November 19, 2008**

### **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 9:00 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; Tom Porter, R.Ph., Pharmacist Investigator; and Clelia Sanders, R.Ph., Pharmacist Investigator. LLR employees participating during the meeting included: Randy Bryant, Assistant Deputy Director; Sharon Dantzler, Deputy General Counsel, Office of General Counsel; Pat Hanks, Attorney, Office of General Counsel; and Bob Selman, LLR Legislative Liaison.

Members of the public attending the meeting included: Victor Arzabe, Mark Boesen, Stephanie Bryant, Carmelo Cinqueonce, Senator Ronnie Cromer, Jon Davidson, Joanne Epley, Kevin Floyd, Wilbur Harling, Ken Hipshfur, Toni Hurdle, Brandi Johnson, Megan Montgomery, Ken Monroe, Carolyn Moore, Joe Mullinax, Christy Pettit, Thomas Phillips, Vimal Porag, Roy Putrino, Eric Ridings, Nasim Roosin, Frank Sheheen, Robert Spires, Rob Stone, and Rick Wilson.

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 and the front entrance of the SC Pharmacy Association.

### **Invocation**

Mr. Bushardt delivered the invocation.

### **Pledge of Allegiance**

All present recited the Pledge of Allegiance.

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

Mr. Hook thanked the SC Pharmacy Association for allowing the Board to meet at their facility and thanked staff for preparing for the meeting.

### **Introduction of Board Members and all others 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 September 17-18, 2008**

Mr. Hook noted one correction on page two. He stated Dr. Atwater should read Mr. Atwater.

#### **MOTION**

Mr. Banks made a motion the Board accept the minutes from the September 17-18, 2008 meeting as amended. Mr. Bushardt seconded the motion, which carried unanimously.

#### **2. Approval of Reciprocity Candidates for Licensure:**

July 9, 13, 25, 28, 2008, August 4, 5, 8, 13, 17, 19, 25, 27, 28, 2008, September 2, 3, 5, 8, 9, 17, 18, 19, 22, 25, 26, 27, 2008, October 2, 3, 2008

#### **MOTION**

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

Mr. Bradham thanked Mr. Mullinax and Mr. Joe Newton for assisting him with the reciprocity interviews.

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

Mrs. Bundrick stated the next Board vacancy begins June 1, 2009 and ends June 30, 2015 for the second congressional district. Before December 1, 2008 a candidate interested in running for the vacancy must submit a biography and a petition bearing signatures of at least fifteen pharmacists practicing in the second district and be licensed and actively practicing pharmacy in South Carolina. To date staff has received information on Mr. Wade Cobb as a candidate.

The Office of Licensure and Compliance will be distributing the ten percent random continuing audit for the pharmacists and the pharmacy technicians within the next couple of weeks as required by law. Ms. Renee Young will be handling the initial licensure of pharmacists and certification of pharmacy interns. Mrs. Sally Green is in the process of training Ms. Young. The expected timeframe of the transfer of duties should be the first week of December; however, Mrs. Green will be available for questions. She is in the renewal section of the Office of Licensure and Compliance. Mrs. Linda Shepherd who has handled the technicians in the past is being trained as a backup for the pharmacists; however, she will be handling the state certification requirements and registration of the technicians.

During the month of October Ms. Brandi Johnson and Ms. Stephanie Bryant were on rotation at the Board office. They are both students from the South Carolina College of Pharmacy – USC Campus. For the month of November staff has Ms. Nasim Roosin, who is also a student at the South Carolina College of Pharmacy – USC Campus. She was pleased to say all three students were present for this meeting. She noted the students have worked very hard on some projects of which one will be discussed later in the meeting.

As of this report there are approximately 2,439 active state certified pharmacy technicians. There are 4,535 active registered pharmacy technicians, 6,215 active licensed pharmacists, 3,476 permitted facilities, and three routing companies.

The pharmacist inspectors conducted 137 inspections since the last Board meeting. Mrs. Cle Sanders has inspected 33 facilities, primarily compounding. Mr. Tom Porter has inspected 51

facilities. Mr. Joe Newton has inspected 50 facilities, and Mrs. Pam Cain has inspected three facilities. Mr. Randy Bryant will update the Board on the investigation component.

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 will be an excellent opportunity for staff assigned to the Board to improve public awareness of the Board and its duties and responsibilities. It will be held in Myrtle Beach at the Marriott Grande Dunes on Thursday, March 12 through Saturday, March 14, 2009.

Mrs. Bundrick met with the new dean of Presbyterian College School of Pharmacy, Mr. Richard Stull, and discussed pharmacy issues regarding the opening of the new pharmacy school. Mr. Stull would like to meet with the Board prior the school opening to inform the Board where the school is headed. The projected date of opening is 2010.

Mrs. Bundrick attended the MPJE state specific review with Mr. Wilbur Harling of the Bureau of Drug Control on October 8-12, 2008 in Chicago with the National Association of the Boards of Pharmacy. They reviewed approximately 4,000 questions to determine if they were appropriate questions to be in compliance with state and federal laws.

Mrs. Cle Sanders completed the basic national certified investigator/inspector training program offered by the Council on Licensure, Enforcement and Regulation. Mr. Tom Porter is conducting medication administration seminars as a result of the Detention Center Committee. He will be conducting four sessions this week and four sessions next week.

The agency has purchased a new telephone system. The Office of Building and Business Services will be receiving new phones in the near future. Some of the other areas within the agency are already utilizing the new phones.

Mrs. Bundrick and the staff have participated in the following meetings since the September meeting:

Staff participated in the Business Writing Workshop sponsored by the agency.

Mrs. Sanders and Mrs. Bundrick participated in a conference call with MUSC regarding compounding pharmacy on October 3, 2008.

A telephone IRC meeting was held on October 7, 2008.

Mrs. Sanders and Mrs. Bundrick participated in a Defensive Driving Class on October 24, 2008.

A telephone IRC meeting was held on November 4, 2008.

Mrs. Bundrick participated in a meeting at the SC Pharmacy Association regarding immunization legislation on November 6, 2008.

A telephone IRC meeting was held on November 10, 2008.

Mrs. Bundrick met with the University Specialty Clinics in regard to the administration regarding the dispensing options they would have in regard to whether they were physician owned or not physician owned.

The Pharmacy Technology Committee met on November 18, 2008.

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

The Board of Pharmacy continues to serve as a site for pharmacy students on rotations from the South Carolina College of Pharmacy – USC Campus. Staff is hoping to have students from the Charleston Campus in the near future. Staff attended a meeting at the College of Pharmacy on November 18, 2008 during which this matter was discussed.

Staff has received nine applications for the three vacant FTE pharmacist inspector positions. Four candidates met the screening criteria, of which one withdrew the application. Mrs. Bundrick and Mrs. Sanders interviewed the three remaining candidates. Mrs. Bundrick has completed the documentation to hire at least three positions and submitted the documentation to Mr. Bryant on November 6, 2008.

The deadline for the first quarter Board of Pharmacy newsletter to NABP is quickly approaching. Mrs. Bundrick asked the members to contact her if they had suggestions for articles. Staff has submitted the newsletter articles to the Board members for their review and comments prior to sending the articles to NABP. Any member having trouble opening the articles for review should contact Mrs. Bundrick.

Hand outs for the members' review which may be of interest include an updated list of the 2008 election changes, a memo from NABP regarding nominations for annual awards, which NABP must receive no later than December 31, 2008, and budget information.

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

Mr. Banks questioned Mrs. Bundrick regarding how often the pharmacies must be inspected and if staff was on course with the inspections. Mrs. Bundrick stated the pharmacies must be inspected every two years and that staff is doing fairly well with the inspections.

Mr. Bushardt asked Mrs. Bundrick if Mrs. Green would handle the reciprocity candidates. Mrs. Bundrick replied negatively. Mr. Bushardt stated he always asks the reciprocity candidates regarding the process and the candidates always sing praises of Mrs. Green. He asked Mrs. Bundrick if it is possible to keep Mrs. Green in the reciprocity aspect of licensure. Mrs. Bundrick replied that is not her decision. She noted Mrs. Green is now in the Office of Licensure and Compliance and Mr. David Christian is her supervisor.

Mr. Bushardt asked if there is a process the Board could move through to have Mrs. Green placed back in the pharmacy licensure area. Mr. Hook stated Mr. Bryant would be giving a presentation to the Board and could possibly answer that question.

#### **Assistant Deputy Director – Randall Bryant**

Mr. Bryant presented the members with a copy of the organizational structure of the Office of Building and Business Services and the POL Division. He stated the director contracted with the Budget and Control Board for that department to analyze the professional and occupational licensing process across all of the boards. Upon completion the Budget and Control Board (OHR) made recommendations and the director chose to develop a POL licensing area. He stated approximately 80% of the licensees renew online. He further stated another recommendation was to move toward biennial licensure. He said the State Office of Human

Resources uncovered several areas which have been addressed, some the agency has not addressed, and some areas the agency cannot address. He stated the agency has only been involved with reorganization for 90 days and the agency feels there has been progress, although problems continue to arise. He noted the agency feels confident every problem will be resolved and the restructuring of the POL division will work.

Mr. Bryant stated he would convey the Board's feelings concerning Mrs. Green to Mr. Christian.

Mr. Bryant stated the pharmacy program is with the Office of Building and Business Services because the permitting of the pharmacies/businesses would remain with the program. He noted the programs within the OBB area conduct approximately 12,000 inspections per year. He also stated the individuals Mrs. Bundrick has interviewed should be offered employment within ten days.

Mr. Hook stated the identification badges being worn by the inspectors reflect the Office of Building and Business Services. Mr. Bryant stated he would have that matter rectified.

Mr. Bushardt stated he feels the pharmacies are in the medical profession, not in the building and business area.

Mr. Banks stated the Board is charged with protecting the citizens of South Carolina, which sounds like a health related issue.

Mr. Mobley stated some of the members attended a meeting with the College of Pharmacy during which the curriculum was reviewed. He noted the college is stressing the five 'Ps' of which one is professionalism. He went on to say the agency's structure is in contradiction of what the college is teaching the students, which should be reflected by the Board.

Mr. Bryant stated there are two sides to the organizational chart, one is the internal organizational chart and one is the organizational chart of the Office of Building and Business Services.

Mr. Bryant stated he agrees the individuals who inspect pharmacies should be pharmacists; however, he does not feel the individuals who investigate the complaints regarding pharmacists and pharmacies should be required to be pharmacists and noted there are a number of reasons he feels that way. He went on to say the overwhelming majority of the complaints received in the pharmacy program are arrests made by the Department of Health and Environmental Control (DHEC), Bureau of Drug Control for diversion of controlled substances or medication errors. He noted since the last Board meeting 20 complaints were received by the Office of Investigations and Enforcement (OIE), of which two were medication errors and 18 complaints were controlled substance diversion. He noted that the unusual cases, which require pharmacy expertise, such as compounding violations, are assigned to the pharmacy inspectors. He went on to say the violations of the controlled substance act fall to the Bureau of Drug Control and that the role of LLR's staff is to follow up with that agency on those cases. He said he has met with Mr. Wilbur Harling and his staff and a process has been established.

Mr. Bryant stated he would speak with the agency director to see if she would be willing to move the pharmacy program to the Office of Medical and Health Related Professions.

Senator Ronnie Cromer stated he has met with Mr. Bryant on several occasions regarding the pharmacy program. He went on to say he has drafted legislation, which he mentioned earlier.

He went on to say South Carolina, like other states, is short on revenue and resources. He said they would not be doing their job if they were not looking at cutting expenses. He continued by saying there are two sets of investigators that come into the pharmacy. He said he is looking at combining the agents from the Bureau of Drug Control and combining those individuals with the Board. He stated some states have the Bureau of Narcotics and Dangerous Drugs under the Board of Pharmacy, some states have the Board of Pharmacy, which performs all of the duties, and some states have an agency similar to LLR which performs the majority of the investigatory functions and the Board deals with just the compliance issues. He went on to say he is meeting with Mr. Harling, Mr. Bryant, Mrs. Bundrick, Mr. Cinqueonce, and Mr. Spires on November 20, 2008. He noted he is not looking to eliminate any jobs, but to consolidate functions. He stated this process could take two to three years.

#### **4. Compliance and Inspector's Report**

IRC Recommendations for dismissals and dismissals with non-disciplinary letters of concern. Review of proposed Resolution Guideline Recommendations, Agreement to Relinquish, Consent Agreements, Cease and Desist Orders and the Report from the Investigative Review Committee (IRC), Pat Hanks, OGC and Charles "C" Turner, R.Ph., IRC Chairman

- Consent Agreements  
Case #: 2006-90/2007-0023

#### **MOTION**

Mr. Rose made a motion the Board accept the consent agreement. Mr. Bradham seconded the motion, which carried unanimously.

Case #: 2008-0016/2007-105

#### **MOTION**

Mr. Banks made a motion the Board accept the consent agreement. Mr. Rose seconded the motion, which carried unanimously.

Case #: 2008-106

Discussion ensued regarding whether or not the Board could approve the consent agreement since the investigator involved in the case was not a pharmacist.

#### **Executive Session**

#### **MOTION**

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

#### **Public Session**

#### **MOTION**

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

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

#### **MOTION**

Mr. Mobley made a motion the Board accept the consent agreement pending professional review by a pharmacist within the Board of Pharmacy. Mr. Rose seconded the motion, which carried unanimously.

- Agreement to Relinquish  
Case #: 2008-41  
Case #: 2008-82  
Case #: 2008-99  
Case #: 2008-103  
Case #: 2008-108  
Case #: 2008-111

**MOTION**

Mr. Mobley made a motion the Board approve the agreements to relinquish pending professional review by a pharmacist within the Board of Pharmacy, which is to include information to state what action precipitated the agreement. Mr. Rose seconded the motion, which carried unanimously.

**MOTION**

Mr. Bradham made a motion that future consent agreements and agreements to relinquish include information as to what action precipitated the action and that a pharmacist within the Board of Pharmacy review the cases. Mr. Banks seconded the motion, which carried unanimously.

- November 19, 2008 IRC Report

Dismissals

**MOTION**

Mr. Bradham made a motion the Board approve the IRCs recommendations regarding the cases for dismissals. Mr. Bushardt seconded the motion, which carried unanimously.

Formal Complaints

**MOTION**

Mr. Bradham made a motion the Board the IRCs recommendations regarding the cases for formal complaints. Mr. Mobley seconded the motion, which carried unanimously.

- November 19, 2008 Resolution Guidelines Report

Mrs. Bundrick stated the cases listed on this report were handled by staff based on the guidelines approved by the Board. She further stated these cases were presented as information and no action from the Board was necessary.

**A. Request Release from Order – Lucy Cochran**

A final order dated November 25, 2003 notes Lucy Cochran voluntarily surrendered her license to practice pharmacy in South Carolina on February 21, 2003. It was also noted in the order Ms. Cochran has Crohn's Disease and suffers from complications related to the disease. In January 2003 Ms. Cochran unlawfully dispensed a quantity of a Schedule II controlled substance without a prescription from a practitioner. The final order states Ms. Cochran's license would be reinstated on January 31, 2004 on terms and conditions that she be an active participant of the Recovery Professionals Program (RPP) for five years and that she be subject to weekly unannounced drug screenings for one year from the date of license reinstatement and that after the one year of weekly drug screenings Ms. Cochran would be subject to periodic random drug testing to be conducted by RPP. It was also ordered that Ms. Cochran could not serve as a pharmacist in charge (PIC) and/or permit holder and that she comply with all continuing legal education requirements.

On October 13, 2008 the Board received a request from Lucy Cochran to be released from the final order dated November 25, 2003. On October 23, 2008 the Board received a letter from Jon Davidson of RPP stating RPP supports Ms. Cochran's request to be released from her request.

Ms. Cochran stated she is seeking to be released from the Board's order. She has completed six years with RPP.

Mr. Jon Davidson stated RPP is supportive of Ms. Cochran's request.

### **MOTION**

Mr. Banks made a motion the Board grant Ms. Cochran's release from all restrictions contained in the order. Mr. Rose seconded the motion, which carried unanimously.

### **5. Old Business**

There was no old business for discussion during this meeting.

### **6. New Business**

#### **B. Request Approval of Non-Resident Wholesale/Distributor and/or Manufacturer Application – Integrated Commercialization Solutions Inc., Rob Stone, Legal Counsel**

On August 22, 2008 the Board received a non-resident wholesale distributor and/or manufacturer application from Integrated Commercialization Solutions Inc. The company answered yes to the questions asking, "Has the applicant(s) ever had a permit disciplined, denied, refused, or revoked for violations of any pharmacy laws, drug laws in South Carolina or any other state?" and "Has the applicant(s) ever been charged, convicted, fined, or entered in a plea of guilty or nolo contendere in any criminal prosecution, felony or misdemeanor, in South Carolina or any other state, or in a United states court and/or 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?"

Integrated Commercialization Solutions, Inc. operates a distribution center located in Reno, Nevada and Brooks, Kentucky. The Kentucky distribution center operates its third party logistics business at the distribution center jointly with its parent corporation, ASD Specialty Healthcare, Inc. and jointly holds a Florida non-resident prescription drug manufacturer permit to operate in that facility. In August 2006 the Florida Department of Health informed the company it should obtain its own out of state prescription drug wholesaler permit for this location. The company filed an application for that permit and now holds its own out of state prescription drug wholesaler permit issued by the State of Florida. In July 2007 the company entered into an agreement with the Florida Department of Health, without admitting any wrongdoing, and paid a fine in settlement of any claims with respect to the status of the company's Florida permits prior to August 2006.

Rob Stone appeared before the Board at this time and offered the following testimony.

The Kentucky distribution center of ASD Specialty Healthcare and its parent company are licensed in South Carolina. The Nevada distribution center is at issue in regard to the application (ASD), which is licensed as a non-resident manufacturer and of which ICS is a subsidiary. He noted the question asking if the applicant has ever been charged, fined, or entered in a plea of guilty or nolo contendere in any criminal prosecution, felony or misdemeanor, in South Carolina or any other state, or in a United states court and/or 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 was answered incorrectly. ICS, its parent company, any affiliates nor employees in Reno have ever been convicted of a crime or any other violation. The question asking if the applicant has ever had a permit disciplined, denied, refused, or revoked for violations of any pharmacy laws, drug laws in South Carolina or any other state was answered correctly. The Nevada center was not affected by the Florida Board of Pharmacy. The Florida Board of Pharmacy issued a Notice of Violation in regard to two matters approximately one year after the issuance of a license to ICS. One of the violations contained in the Notice of Violation was a mistake and the other violation pertained to the facility not being properly licensed. The company agreed to the violation and agreed to pay a \$5,000.00 without admitting liability.

### **MOTION**

Mr. Mobley made a motion the Board approve the application. Mr. Rose seconded the motion, which carried unanimously.

#### **C. Request Approval of Non-Resident Wholesale/Distributor and/or Manufacturer Application – Pharmacorp, Inc., Victor Arzabe**

On May 30, 2008 the Board received a non-resident wholesale/distributor and/or manufacturer application from Pharmacorp, Inc. The applicant answered yes to the question asking, "Has the applicant(s) ever been charged, convicted, fined, or entered in a plea of guilty or nolo contendere in any criminal prosecution, felony or misdemeanor, in South Carolina or any other state, or in a United States court for any offense relating to drug, narcotics, controlled substances, or alcohol, whether or not a sentence was imposed?" Mr. Victor Arzabe, President/CDR of Pharmacorp was arrested and cited for DUWI in Florida on May 6, 2004. He pleaded nolo contendere and completed all of the requirements of the court in order to reinstate his driver's license. He has had two citations since the May 2004 DUWI incident, one in Florida for an illegal turn and one in Georgia for driving with expired insurance. The citation for the illegal turn was dismissed and the citation for driving with expired insurance was also dismissed due to a mix-up with the Division of Motor Vehicles. Pharmacorp was previously issued a non-resident wholesaler distributor and/or manufacturer permit on May 23, 2006. The license expired on June 30, 2007. This permit was issued to Pharmacorp located in North Miami, Florida. By letter dated September 28, 2008 staff notified Mr. Arzabe that he must appear before the Board during this meeting to answer questions from the members regarding the application.

Victor Arzabe appeared before the Board at this time and offered the following testimony.

Pharmacorp failed to renew its license in Florida in 2007. Pharmacorp did not renew its Florida license because that office was closed down and the business was moved to Georgia. In 2006 Florida passed a law which required all small distributors to pass pedigree back to the manufacturer. The law contained a clause stating the large distributors such as Cardinal, McKesson, Amerisource and H. D. Smith were exempt from the law. Shortly after the law passed they cancelled Pharmacorp's accounts to purchase from them and to distribute their products to the company's customers, which hindered their ability to work and provide customers with medications they needed. Any other distributor that would sell to Pharmacorp would not do so in Florida due to the stringent measures Florida had instated. The company closed its Florida business and moved to Georgia. Pharmacorp sells injectable and oral medications, with the exception of controlled substances, to hospitals. Pharmacorp has chosen not to deal with controlled substances in order not to move through the red tape in dealing with those medications. Pharmacorp also does not compound. Pharmacorp pulls resources together to obtain medications other distributors may not be able to obtain. The company is not

VAWD accredited but is working with the National Coalition of Pharmaceutical Distributors (NCPD) to become accredited with that agency.

Mr. Hook informed Mr. Arzabe that the Board now requires all non-resident companies to be VAWD accredited.

Mr. Arzabe stated the company had determined it would go through NCPD because the company deals with the smaller distributors and meets his company's needs. It is also more economical for Pharmacorp to become accredited through NCPD. He expects to be accredited through NCPD within one week. He noted the website address is [www.NCPD.org](http://www.NCPD.org).

Mr. Arzabe had a DUI arrest and conviction in 2006, which was a personal shortcoming. The repercussions, both personally and professionally have been far greater than he expected. He completed all of the requirements from Florida and his license was reinstated.

Mr. Hook informed Mr. Arzabe the Board would take his testimony under advisement and would discuss the matter in executive session in order to seek legal advice.

**D. Request Approval of Non-Resident Wholesale/Distributor and/or Manufacturer – Apothecary Shop Wholesale, Mark Boesen, Director Pharmacy Operations**

On August 4, 2008 the Board received a non-resident wholesale/distributor and or manufacturer application from Apothecary Shop Wholesale. The applicant answered yes to the question asking, "Has the applicant(s) ever had a permit disciplined, denied, refused, or revoked for violations of any pharmacy laws, drug laws in South Carolina or any other state?" According to a Board Order dated November 6, 2003 the Arizona Board of Pharmacy ordered Apothecary Shop Wholesale to serve six months of probation for not having compounding controls in place. The Arizona permit is now active and in good standing with that Board. By letter dated September 24, 2008 staff notified Mark Boesen Director of Pharmacy Operations for Apothecary Shop Wholesale that he or a representative from the company must appear before the Board to answer questions from the members regarding the application.

Mark Boesen appeared before the Board at this time and offered the following testimony.

The owner owns thirteen retail facilities and one mail order facility in Phoenix, Arizona. One of the retail facilities was disciplined in 2003 as a result of a catastrophic compounding error. A pharmacy technician mislabeled a bottle which caused life threatening illness to four patients.

Mr. Boesen was hired in November 2003 to review and improve quality assurance and to create a safer environment. It is now company policy for a licensed pharmacist to compound some medications and a more strict policy on other medications. Compounding is not done in a wholesale environment. Mobius Therapeutic deals with ophthalmic medications and recently contacted the Apothecary Shop in regard to distributing from their pharmacies. The volume would be too great for their pharmacies since they have a small client population and dispensing would be done by invoice to physicians instead of by prescription. The company is approaching South Carolina to request permission to conduct business within the state to distribute a product which has already been compounded.

Apothecary Shop Wholesale is not VAWD accredited, however, would accept becoming VAWD accredited as a condition of becoming permitted.

Mr. Hook informed Mr. Boesen the Board would take his testimony under advisement and would discuss the matter in executive session in order to seek legal advice.

**E. Request Approval of Non-Resident Pharmacy – Basic Home Infusion, Roy Putrino**

Roy Putrino appeared before the Board by conference call during the September 17, 2008 meeting regarding the permit application for Basic Home Infusion. The application included a cease and desist order and an attachment addressing violations and fines totaling \$7,650.00 from the New Jersey Board of Pharmacy. During that meeting Mr. Mobley questioned Mr. Putrino regarding compounding issues, the company's policies and procedures, and USP<797>. Also during that meeting the Board voted to deny the application until such time Mr. Putrino could document current compliance with the current USP <797> guidelines.

Roy Putrino appeared before the Board at this time and offered the following testimony.

Basic Home Infusion is a joint commission accredited specialty infusion pharmacy which provides only one therapy. The pharmacy was deficient in two areas according to the joint commission's guidelines: the pressure gauge and fingertip testing. The pressure gauge has now been purchased and installed. He presented information regarding the fingertip testing.

Basic Home Infusion runs tests independently with Western Slope on off label pain medications. The company does selective testing on drugs containing combinations on which the company is not familiar. The company is taking the lab test results to determine 90 % potency to establish the day time line to determine the beyond use date. All products are patient specific but shipped to a registered nurse. Everything is billed to the patient's insurance.

Mrs. Sanders stated she had reviewed the documentation Mr. Putrino had mailed to the Board. She noted the policies and procedures address several procedures she did not think the facility was doing and address several matters happening in hospitals.

Mr. Putrino stated he addressed other issues in the policies and procedures to establish a policy should the pharmacy address those issues. He is heavily involved with hospital since the therapies are not available in the hospital. All employees, including pharmacy technicians, are required to take continuing education training.

Mr. Hook informed Mr. Putrino the Board would take his testimony under advisement and would discuss the matter in executive session to seek legal advice.

**F. SC DHEC MOA – Joanne Epley, R.Ph.**

Joanne Epley, of DHEC, appeared before the Board at this time to discuss the Memorandum of Agreement regarding a declared disaster by the Governor.

**MOTION**

Mr. Rose made a motion the Board approve the MOA. Mr. Banks seconded the motion, which carried unanimously.

**G. Pharmacists Dispensing on Public Health Orders – Joanne Epley, R.Ph.**

Joanne Epley, of DHEC, appeared before the Board at this time to discuss pharmacists dispensing on public health orders. The US Department of Health and Human Services, part of

Homeland Security, is stating the United States is at risk for an anthrax attack and is pushing the states to plan for such an attack.

The Board determined it would table this matter to another meeting.

**H. Pharmacists' Lunch Break – Davis Hook, R.Ph., Clelia Sanders, R.Ph.**  
Mr. Hook stated the Board had received a request from Eckerd Drug Stores in 1999 for the pharmacists to have a 30 minute lunch break and included the process on how the store would handle the lunch break. The Board approved the request at that time. He noted other stores have subsequently made similar requests which the Board has approved with the condition the pharmacist remain on the premises and that the practice act would not be violated.

Mrs. Sanders stated she has found many different questions when she has conducted facility inspections. The questions include:

1. Does the pharmacy have to close if the pharmacist is in the building?

Mr. Hook stated if the pharmacist stays in the building a sign would be placed in a prominent place stating the pharmacist is not on duty; however, if the pharmacist leaves the building a sign stating the pharmacy is closed.

Discussion on this matter ensued. The Board reviewed the previously approved requests from Eckerd Drugs and CVS Pharmacy. The approved CVS Pharmacy request stated that a prescription may be sold while the pharmacist was on lunch break if the pharmacist had verified the prescription prior to going on lunch break, that a pharmacy technician must sign that the prescription was sold during the time the pharmacist was out to lunch and that the pharmacy make at least three attempts to contact the patient within 24 hours. The offer to counsel was not offered on approved request.

Mr. Hook read into record a document from Mr. Quackenbush which states the following pharmacies have policies regarding lunch breaks.

Wal-Mart/Sam's Club – in pharmacies where two pharmacists are on duty the pharmacists lunches are staggered. In pharmacies where only one pharmacist is on duty the pharmacy is closed from 1:30 p.m. to 2:00 p.m. During that time nobody is allowed to remain in the pharmacy

BiLo has the pharmacist eat lunch in direct site of the pharmacy technicians. If the pharmacist leaves the pharmacy the pharmacy closes.

Walgreens – if there is a single pharmacist he/she eats lunch in the pharmacy. If there are two pharmacists, lunch is staggered.

Mr. Kevin Floyd stated when this matter arose in 1999 one of the issues involved work load and the quality of life. He further stated the pharmacist could take a break and the work flow could continue. He went on to say the problem was if everyone was forced to leave the pharmacy work stopped and the pharmacist didn't receive that well because once he/she came back he/she was buried in work. He believes the reason the Board worked with the companies on this matter was so the disruption in the work flow wasn't so dramatic.

Mr. Hook stated this issue may need to be deferred to the Pharmacy Practice Committee. He asked that Mr. Floyd, Mr. Ridings and Ms. Christy Pettit of Target to serve on the committee regarding this matter. Mr. Cinqueonce asked that he or a representative from the association be allowed to serve on the committee regarding this issue. Mr. Hook agreed to Mr. Cinqueonce's request. Mr. Hook asked Mr. Porter to also serve on the committee

**I. Immunization Policy and Procedure #138 – Tom Porter, R.Ph.**

Mr. Porter stated approximately three weeks ago he received a call from an individual asking if it were permissible for a pharmacist to administer immunizations in South Carolina and referred her to Policy & Procedure #138. He further stated her impression was that a pharmacist in South Carolina could administer an immunization without a physician's order. He went on to say he informed her that was not the case and referred her to the relevant statute. He said she asked him if he was aware South Carolina is on a registry that states pharmacists may administer immunizations without a prescriber's order. He asked that a statement be included in Policy & Procedure #138 reflecting it would include an order from a South Carolina prescriber.

Mr. Cinqueonce stated he believes the policy and procedure states the training program must be CDC approved, which is not technically correct as CDC does not approve training programs. He recommended this part of the policy be modified to say the CDC reviews training programs.

**MOTION**

Mr. Mobley made a motion the Board amend Policy and Procedure #138 as follows. Mr. Toole seconded the motion, which carried unanimously.

2. Administering pharmacists shall have completed an immunization training program, reviewed by CDC, and resulting in certification as an immunizing pharmacist.
4. An additional requirement an order or protocol from a licensed practitioner

**J. Request Approval of Non-Resident Wholesale/Distributor and/or Manufacturer – CT International, Curtis Vandewally**

On July 23, 2007 the Board received a non-resident wholesale/distributor and/or manufacturer application from CT International. The applicant answered yes to the question asking, "Has the applicant(s) ever had a permit disciplined, denied, refused, or revoked for violations of any pharmacy laws, drug laws in South Carolina or any other state?" The applicant also answered yes to the question asking, "Have you ever 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?" The company entered a California Board of Pharmacy Stipulated Settlement and Disciplinary Order dated December 5, 2006. By letter dated August 17, 2007 staff notified the company that a representative must be present during the November 14, 2007 meeting to answer questions from the members regarding the application. The company did not appear during the November 2007 meeting. The company paid the required registration fees on April 16, 2008.

This matter was deferred to the January 21, 2009 meeting.

**K. Request Approval of Reciprocity Application – Domenic Mellett**

On June 17, 2008 the Board received a pharmacist reciprocity application from Domenic Mellett. Mr. Mellett 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?" In 2004 Mr. Mellett was arrested because he fit the description of an individual who broke into an automobile. The prosecution has failed to provide discovery evidence to his attorney.

Domenic Mellett appeared before the Board at this time and offered the following testimony.

Mr. Mellett was arrested and charged with being an accessory to theft of an automobile stereo. The police and prosecution failed to present his attorney with evidence of the crime and the charges were subsequently withdrawn. He presented the Board with a copy of computer records from the Municipal Court of Philadelphia County, which shows each of the charges were withdrawn on September 9, 2004. A second set of documents indicates the same except that the withdrawal was on behalf of the prosecution. If approved for licensure he would be living in Greenwood.

Mr. Hook informed Mr. Mellett the Board would take his testimony under advisement and would discuss the matter in executive session to seek legal advice.

**L. March 12, 2009 Board Meeting Date – Lee Ann Bundrick, R.Ph.**

Mrs. Bundrick stated as she had reported in her earlier remarks the Society of Health System Pharmacists has invited staff to have an exhibit booth at their convention in March 2009, which will be held from March 12-14, 2009. She stated the society has extended an invitation to the Board to hold the March 2009 meeting in conjunction with their meeting.

**MOTION**

Mr. Rose made a motion the Board accept the invitation to hold the meeting on March 12, 2009. Mr. Mobley seconded the motion, which carried unanimously.

**MOTION**

Mr. Bradham made a motion the Board hold its January 21-22, 2009 meeting at the SC Pharmacy Association. Mr. Rose seconded the motion, which carried unanimously.

**M. Request Approval to be PIC in Two Places, Three Rivers Behavioral and SC Baptist Convention Disaster Relief Medical Team – Ken Copeland, R.Ph.**

On November 5, 2008 the Board received a request from Ken Copeland to be PIC in two places. Mr. Copeland is currently working with the Southern Baptist Convention, SC Disaster Relief Medical Team, which is an all volunteer medical disaster group. The team consists of physicians, nurses, certified registered nurse assistants, nurse practitioners, emergency medical technicians, and pharmacists. He is also a full time employee at Three Rivers Behavioral Center.

Ken Copeland appeared before the Board at this time and offered the following testimony.

Mr. Copeland is currently the PIC at Three Rivers Behavioral Center. As part of the Southern Baptist Convention the Southern Baptists group has disaster relief teams that go nationwide to provide disaster relief. Over time the group has comprised a completely voluntary group. There would be no conflict with his position at Three Rivers Behavioral Center. Since this a voluntary gesture he would not go should his current position not allow it.

Mrs. Bundrick noted Mr. Copeland is seeking to be PIC at a location which has not yet been permitted. Mr. Copeland stated a permit application would be submitted. He noted no medications would be stored at the location of the permit.

### **MOTION**

Mr. Mobley made a motion the Board approve Mr. Copeland's request pending inspection and approval of the permit at the facility in Florence. Mr. Rose seconded the motion, which carried unanimously.

### **Lunch**

Mr. Banks made a motion the Board recess for lunch. Mr. Bushardt seconded the motion, which carried unanimously.

The Board recessed for lunch at 12:50 p.m. and returned to public session at 2:35 p.m.

### **Public Session**

#### **7. Committee Reports**

- Pharmacy Technician Committee – David Banks, R.Ph., Al Toole, R.Ph., Dan Bushardt, R.Ph., Davis Hook, R.Ph.
  - ❖ ASHP Accreditation letter to Tri-County Technical College

This committee had no report

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

Mr. Mobley stated the committee did not meet; however, he had items which needed to be presented to the members. He further stated he and Mrs. Sanders had discussed how USP <797> addresses powder which has been opened for one year. He went on to say pharmacist should ascertain the powder was stored in a proper manner to maintain potency and to prevent degradation. He noted he and Mrs. Sanders recommend communicating this matter in the next newsletter.

### **MOTION**

Mr. Mobley made a motion the Board recommend all powders should be dated after opening, should be stored under controlled conditions which prevent degradation, and USP <797> sterile product powders discarded one year from that date. Mr. Rose seconded the motion, which carried unanimously.

Mr. Mobley stated pharmacists generally discard powders by capping the container or the powders are denatured and thrown in the trash can, which end in a landfill.

### **MOTION**

Mr. Mobley made a motion the Board recommend pharmacists use disposal companies for powders for environmental reasons. Mr. Rose seconded the motion, which carried unanimously.

- Legislative Committee – Al Toole, R.Ph., Bobby Bradham, R.Ph., Dr. Richardson, Hugh Mobley, R.Ph.

Mr. Toole stated the committee did not meet; however, he asked Mr. Cinqueonce to speak on legislative matters.

Mr. Cinqueonce stated the association's legislative committee has met and is working to advance major issues. He further stated Representative Spires has agreed to sponsor the PBM bill. He went on to say the second piece of legislations deals with immunizations and is still being drafted. He said the legislation would not only codify pharmacists' authority to administer immunizations, but would allow the pharmacist to initiate the prescription for the immunization.

- Medication Errors Committee – Dan Bushardt, R.Ph., Davis Hook, R.Ph., Dr. Richardson

This committee had no report.

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

This committee had no report.

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

This committee had no report.

- Pharmacy Technology Committee – Bobby Bradham, R.Ph., Dan Bushardt, R.Ph., David Banks, R.Ph.

The Pharmacy Technology Committee met on November 18, 2008. As a result of the meeting:

#### **MOTION**

The committee recommends the Board remove the wording ~~central fill~~ under H(1) of the central fill legislation. The sentence would now read "A Central Fill Pharmacy shall complete a pharmacy permit application provided by the Board." Since the recommendation came from committee no second was needed. The motion carried unanimously.

#### **MOTION**

The committee recommends the Board make the following change:

Under the **Determination of Need and Reasonableness of the proposed regulation based on all factors herein and expected benefits**: "This regulation will increase efficiency in the health care delivery process of prescription medication and ensure and improve the safety and welfare of the citizens of the State of South Carolina."

Since the recommendation came from committee no second was needed. The motion carried unanimously.

#### **MOTION**

The committee recommends the Board make the following change:

Under the **Effect of environment and public health**, "There will be no detrimental effects on the environment, however, public health delivery process will improve."

Since the recommendation came from committee no second was needed. The motion carried unanimously.

#### **MOTION**

The committee recommends the Board make the following change:



Under the **Detrimental effect on the environment and public health if the regulation is not implemented**, “This regulation will increase efficiency in the health care delivery process of prescription medication and ensure and improve the safety and welfare of the citizens of the State of South Carolina.”

Since the recommendation came from committee no second was needed. The motion carried unanimously.

### **MOTION**

The committee recommends the Board authorize Ms. Dantzler to proceed with the regulatory route as presented. Since the recommendation came from committee no second was needed. The motion carried unanimously.

Mr. Bradham stated the committee also discussed on-hold prescriptions. He stated an article would be placed in the newsletter concerning the ability to trace the original copy of a held prescription when a prescription has been placed and held for a number of days.

Mr. Bradham stated when there is a tamper proof prescription which has been scanned the prescription, as a result, is a blank prescription. He noted that is the idea of a tamper proof prescription so that it could not be copied. He said this would be an item the committee will continue to discuss.

Mr. Bradham stated the committee also discussed e-prescribing and the need to have the e-prescription printed for a hand copy. He further stated in May 2009, unless there are changes in federal law, physicians who are writing prescriptions for Medicare patients must have these done by e-prescribing. Beginning January 1, 2009 those physicians who are already e-prescribing will receive a bonus of that patient’s Medicare visit, which would amount to one and one-half to two percent. Those physicians who are not e-prescribing will have the money from that Medicare patient’s visit cut one percent. Whether the AMA will have this changed remains to be seen as they recently changed the mandate that prescriptions could not be faxed which was going to take effect January 1, 2009 to January 1, 2012.

❖ Workload Balance Pilot Projects, - Thomas Porter, R.Ph., Clelia Sanders, R.Ph., Joe Newton, R.Ph.

At an earlier meeting the Board approved workload balance pilot project for Wal-Mart and Walgreens. A Wal-Mart representative attending the committee meeting thought Wal-Mart would be receiving a letter from the Board stating the store had been approved and could move forward. He believes the Wal-Mart representative shared this office in Arkansas and within approximately 30 minutes of the committee Mrs. Bundrick had approximately six e-mails, phone calls and pages from the Wal-Mart home office. He went on to say Walgreens did initiate the project approximately six months ago. He stated the advantages, disadvantages, challenges, ups and downs were discussed.

The committee received a letter from an anonymous pharmacist employed with Walgreens discussing some of the problems with the pilot project. Mr. Bradham stated the company is addressing those issues.

The Board determined it would invite Walgreens to the March 12, 2008 Board meeting to update the Board on progress.

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

Dr. Richardson stated he attended the RPP meeting on Friday, November 14, 2008. He asked Mr. Sheheen to discuss the meeting with the Board.

Mr. Frank Sheheen and Mr. Rick Wilson appeared before the Board at this time and presented the Board with the quarterly report from the meeting. Mr. Wilson stated Dr. Richardson had requested data specific to the Board's use of services with RPP, which has been prepared.

Dr. Richardson asked Mr. Sheheen to present the information to the Board. Mr. Sheheen presented the Board with the paper product of the presentation and discussed the information with the Board. He offered to make the actual Powerpoint presentation at a later meeting.

Dr. Richardson stated the next RPP meeting is scheduled for February 13, 2009.

Mrs. Bundrick stated Mr. Bradham had requested staff research several items during the June 2008 Board meeting. She further stated two students presented the Board with information regarding pharmacy technician ratios and duties. She went on to say Mr. Bradham had also requested staff research drug diversion programs on a national level and how the Boards handle the disciplinary actions from the first offense to repeated offenses. She said the two students who were with staff on rotation in October researched this matter. She noted the report was contained in the members' Board meeting books and stated she would answer questions from the members.

Mr. Bradham stated he had read the report and liked the summary contained at the end of the report, which shows South Carolina was the first state to register pharmacy technicians. He went on to say it appears that approximately 30% to 40% of the states, on first offenses, have no specific guidelines as to how long a pharmacist is without his/her license. He noted he thoroughly enjoyed reading the report.

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

This committee had no report.

### **Public Comments**

There were no public comments made during the November 19, 2008 meeting.

### **Executive Session**

#### **MOTION**

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

### **Public Session**

#### **MOTION**

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

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

Request Approval of Non-Resident Wholesale Distributor and/or Manufacturer Application – Pharmacorp, Inc.

#### **MOTION**

Mr. Bushardt made a motion the Board carry over this request to allow Pharmacorp to provide information on accountability standards on alternate certification or evidence that it has policy and procedure equivalent to VAWD. Dr. Richardson seconded the motion, which carried unanimously.

Request Approval of Non-Resident Wholesale Distributor and/or Manufacturer Application –Apothecary Shop Wholesale

**MOTION**

Mr. Rose made a motion at the time Apothecary Shop Wholesale becomes VAWD certified the Board approve the application. Mr. Mobley seconded the motion, which carried unanimously.

Request Approval of Non-Resident Pharmacy – Basic Home Infusion

**MOTION**

Mr. Mobley made a motion the Board approve the application pending the pharmacy providing evidence its policies and procedures are updated to be consistent and concurrent with their practice, that cleaning and verification agents and procedures are consistent with USP <797>, that the pharmacy does sterility tests which result in validation of the products that are being compounded to coincide with the beyond use date assigned. Mr. Rose seconded the motion, which carried unanimously.

Request Approval of Reciprocity Application – Domenic Mellett

**MOTION**

Mr. Mobley made a motion the Board approve Mr. Mellett's application. Mr. Banks seconded the motion, which carried unanimously.

**MOTION**

Mr. Rose made a motion Mr. Bryant take to Mrs. Youmans that the Board should be removed from the Office of Building and Business Services, that the Board feels it should be a part of the Medically and Health Related Professions and let the Board know of her decision by the next Board meeting. Mr. Bushardt seconded the motion, which carried unanimously.

**Adjournment**

**MOTION**

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

The November 19, 2008 meeting of the SC Board of Pharmacy adjourned at 5:10 p.m.